PACKAGE LEAFLET: INFORMATION FOR THE USER

Lexaprim 10 mg film-coated tablets
Escitalopram oxalate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT LEXAPRIM IS AND WHAT IT IS USED FOR

Lexaprim contains the active substance escitalopram. Lexaprim belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Lexaprim contains escialopram and is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

It may take a couple of weeks before you start to feel better. Continue to take Lexaprim, even if it takes some tiem before you feel any improvement in your condition.

You must talk to a doctor if you do not feel better or if you feel worse.

2. BEFORE YOU TAKE LEXAPRIM

Do not take Lexaprim

- If you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6).
- If you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- If you are born with or have had an episode of abnormal heart rhythm (Seen at ECG; an examination to evaluate how the heart is functioning).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "other medicines and Lexaprim").

Warning and Precautions

Tell your doctor or pharmacist before taking Lexaprim. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Lexaprim should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section 4 "Possible side effects").
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Lexaprim may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- If you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises.
- if you are receiving electroconvulsive treatment.
- if you have coronary heart disease.
- if you suffer or have suffered from heart problems or have recently had a heart attack.
- if you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (Being sick) or usage of diuretics (water tablets).
- if you experience a fast or irregular heart beat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Please note
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age
Lexaprim should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Lexaprim for patients

under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Lexaprim for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Lexaprim. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Lexaprim in this age group have not yet been demonstrated.

Other medicines and Lexaprim
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:

- ”Non-selective monoamine oxidase inhibitors (MAOIs)”, containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Lexaprim. After stopping Lexaprim you must allow 7 days before taking any of these medicines.
- “Reversible, selective MAO-A inhibitors”, containing moclobemide (used to treat depression).
- “Irreversible MAO-B inhibitors”, containing selegiline (used to treat Parkinson’s disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of escitalopram.
- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression.
- Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anticoagulants). These may increase bleeding-tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Lexaprim in order to verify that your dose of anticoagulant is still adequate.
- Mefloquine (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants (triclcylic antidepressants and SSRIs) due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases) clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Lexaprim may need to be adjusted.
- Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life-threatening heart rhythm disorders.

Do not take Lexaprim if you take medicines for heart rhythm problems or medicines that may affect the heart’s rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti- malarial treatment particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Lexaprim with food, drink and alcohol

Lexaprim can be taken with or without food (see section 3 “How to take Lexaprim”).

As with many medicines, combining Lexaprim with alcohol is not advisable, although Lexaprim is not expected to interact with alcohol.

Pregnancy, breast-feeding and fertility
Inform your doctor if you are pregnant or planning to become pregnant. Do not take Lexaprim if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

If you take Lexaprim during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on Lexaprim. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Lexaprim may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If used during pregnancy Lexaprim should never be stopped abruptly. It is expected that Lexaprim will be excreted into breast milk.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines
You are advised not to drive a car or operate machinery until you know how Lexaprim affects you.

3. HOW TO TAKE LEXAPRIM

Always take Lexaprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults
Depression
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Panic disorder
The starting dose of Lexaprim is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

Generalised anxiety disorder

The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Obsessive-compulsive disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly patients (above 65 years of age)
The recommended starting dose of Lexaprim is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (below 18 years of age)
Lexaprim should not normally be given to children and adolescents. For further information please see section 2 "What you need to know before you take Lexaprim".

You can take Lexaprim with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.

Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Lexaprim even if it takes some time before you feel any improvement in your condition.

Do not change the dose of your medicine without talking to your doctor first.

Continue to take Lexaprim for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you take more Lexaprim than you should
If you take more than the prescribed dose of Lexaprim, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Lexaprim box/container with you when you go to the doctor or hospital.

If you forget to take Lexaprim
Do not take a double dose to make up for forgotten doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

If you stop taking Lexaprim
Do not stop taking Lexaprim until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Lexaprim is gradually reduced over a

number of weeks.

When you stop taking Lexaprim, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Lexaprim is stopped. The risk is higher, when Lexaprim has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Lexaprim, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

If you experience any of the following symptoms you should contact your doctor or go to the hospital straight away:

Uncommon (may affect up to 1 in 100 people):

- Unusual bleeds, including gastrointestinal bleeds

Rare (may affect up to 1 in 100 people):

- Swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
- High fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

Not known (frequency cannot be estimate from the available data):

- Difficulties urinating
- Seizures (fits), see also section 2 “Warnings and precautions”
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as torsade de pointes
- Thoughts of harming or killing yourself, see also section 2 “warnings and precautions”

In addition to above the following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea)
- Headache

Common (may affect up to 1 in 10 people):

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhoea, constipation, vomiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

Uncommon (may affect up to 1 in 100 people):

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

Rare (may affect up to 1 in 100 people):

- Aggression, depersonalisation, hallucination
- Slow heart beat

Not known (frequency cannot be estimate from the available data):

- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Abnormal liver function test (increased amounts of liver enzymes in the blood)
- Movement disorders (involuntary movements of the muscles)
- Painful erections (priapism)
- Signs of increased bleeding e.g. from skin and mucous membrans (ecchymosis)
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in women that are not nursing
- Mania
- An increased risk of bone fractures has been observed in patients taking this type of medicines.
- Alternation of the heart rhythm (called "prolongation of QT interval", seen on ECG, measuring electrical activity of the heart).

In addition, a number of side effects are known to occur with drugs that work in a similar way to escitalopram (the active ingredient of Lexaprim).
These are:

- Motor restlessness (akathisia)
- Loss of appetite

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEXAPRIM

Do not store above 30º C.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lexaprim contains
The active substance is escitalopram. Each tablet contains 10 mg of escitalopram (as escitalopram oxalate).
The other ingredients are:
- Tablet core: colloidal anhydrous silica, lactose monohydrate, povidone, microcrystalline cellulose, croscarmellose sodium, talc and magnesium stearate.
- Coating: hypromellose, titanium dioxide and Macrogol 400.

What Lexaprim looks like and contents of the pack

The tablets are cylindrical, white, biconvex, scored and engraved with code ES1.
Lexaprim is supplied in packs containing 28 tablets (in 7 tablets blister-packs)

Marketing Authorisation Holder and Manufacturer
LABORATORIOS CINFA, S.A.
Olaz-Chipi, 10. Polígono Industrial Areta.
31620 Huarte-Pamplona (Navarra), Spain.

This leaflet was approved in 12/2016

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lexaprim 15 mg film-coated tablets
Escitalopram oxalate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT LEXAPRIM IS AND WHAT IT IS USED FOR

Lexaprim contains the active substance escitalopram. Lexaprim belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Lexaprim contains escialopram and is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

It may take a couple of weeks before you start to feel better. Continue to take Lexaprim, even if it takes some tiem before you feel any improvement in your condition.

You must talk to a doctor if you do not feel better or if you feel worse.

2. BEFORE YOU TAKE LEXAPRIM

Do not take Lexaprim

- if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6).
- If you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- If you are born with or have had an episode of abnormal heart rhythm (Seen at ECG; an examination to evaluate how the heart is functioning).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "other medicines and Lexaprim").

Warning and Precautions

Tell your doctor or pharmacist before taking Lexaprim. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Lexaprim should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section 4 "Possible side effects").
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Lexaprim may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- If you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises.
- if you are receiving electroconvulsive treatment.
- If you have coronary heart disease.
- If you suffer or have suffered from heart problems or have recently had a heart attack.
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (Being sick) or usage of diuretics (water tablets).
- If you experience a fast or irregular heart beat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Please note
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age
Lexaprim should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts,

suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Lexaprim for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Lexaprim for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Lexaprim. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Lexaprim in this age group have not yet been demonstrated.

Other medicines and Lexaprim
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Lexaprim. After stopping Lexaprim you must allow 7 days before taking any of these medicines.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
- "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of escitalopram.
- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression.
- Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anticoagulants). These may increase bleeding-tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Lexaprim in order to verify that your dose of anticoagulant is still adequate.
- Mefloquine (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants (triclcylic antidepressants and SSRIs) due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases) clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Lexaprim may need to be adjusted.
- Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life-threatening heart rhythm disorders.

Do not take Lexaprim if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti- malarial treatment particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Lexaprim with food, drink and alcohol
Lexaprim can be taken with or without food (see section 3 "How to take Lexaprim").

As with many medicines, combining Lexaprim with alcohol is not advisable, although Lexaprim is not expected to interact with alcohol.

Pregnancy, breast-feeding and fertility
Inform your doctor if you are pregnant or planning to become pregnant. Do not take Lexaprim if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

If you take Lexaprim during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on Lexaprim. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Lexaprim may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If used during pregnancy Lexaprim should never be stopped abruptly. It is expected that Lexaprim

will be excreted into breast milk.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines
You are advised not to drive a car or operate machinery until you know how Lexaprim affects you.

3. HOW TO TAKE LEXAPRIM

Always take Lexaprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults
Depression
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Panic disorder
The starting dose of Lexaprim is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day,

depending on how you respond to the medicine.

Generalised anxiety disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Obsessive-compulsive disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly patients (above 65 years of age)
The recommended starting dose of Lexaprim is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (below 18 years of age)
Lexaprim should not normally be given to children and adolescents. For further information please see section 2 "What you need to know before you take Lexaprim".

You can take Lexaprim with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.

Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Lexaprim even if it takes some time before you feel any improvement in your condition.

Do not change the dose of your medicine without talking to your doctor first.

Continue to take Lexaprim for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you take more Lexaprim than you should
If you take more than the prescribed dose of Lexaprim, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Lexaprim box/container with you when you go to the doctor or hospital.

If you forget to take Lexaprim
Do not take a double dose to make up for forgotten doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

If you stop taking Lexaprim

Do not stop taking Lexaprim until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Lexaprim is gradually reduced over a number of weeks.

When you stop taking Lexaprim, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Lexaprim is stopped. The risk is higher, when Lexaprim has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Lexaprim, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

If you experience any of the following symptoms you should contact your doctor or go to the hospital straight away:

Uncommon (may affect up to 1 in 100 people):

- Unusual bleeds, including gastrointestinal bleeds

Rare (may affect up to 1 in 100 people):

- Swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
- High fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

Not known (frequency cannot be estimate from the available data):

- Difficulties urinating
- Seizures (fits), see also section 2 “Warnings and precautions”
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as torsade de pointes
- Thoughts of harming or killing yourself, see also section 2 “warnings and precautions”

In addition to above the following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea)
- Headache

Common (may affect up to 1 in 10 people):

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhoea, constipation, vomiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

Uncommon (may affect up to 1 in 100 people):

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

Rare (may affect up to 1 in 100 people):

- Aggression, depersonalisation, hallucination
- Slow heart beat

Not known (frequency cannot be estimate from the available data):

- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Abnormal liver function test (increased amounts of liver enzymes in the blood)
- Movement disorders (involuntary movements of the muscles)
- Painful erections (priapism)
- Signs of increased bleeding e.g. from skin and mucous membrans (ecchymosis)
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in women that are not nursing
- Mania
- An increased risk of bone fractures has been observed in patients taking this type of medicines.
- Alternation of the heart rhythm (called "prolongation of QT interval", seen on ECG, measuring electrical activity of the heart).

In addition, a number of side effects are known to occur with drugs that work in a similar way to escitalopram (the active ingredient of Lexaprim).
These are:

- Motor restlessness (akathisia)

- Loss of appetite

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEXAPRIM

Do not store above 30º C.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lexaprim contains

The active substance is escitalopram. Each tablet contains 15 mg of escitalopram (as escitalopram oxalate).
The other ingredients are:
- Tablet core: colloidal anhydrous silica, lactose monohydrate, povidone, microcrystalline cellulose, croscarmellose sodium, talc and magnesium stearate.
- Coating: hypromellose, titanium dioxide and Macrogol 400.

What Lexaprim looks like and contents of the pack

The tablets are cylindrical, white, biconvex, scored and engraved with code ES2.
Lexaprim is supplied in packs containing 28 tablets (in 7 tablets blister-packs).

Marketing Authorisation Holder and Manufacturer

LABORATORIOS CINFA, S.A.
Olaz-Chipi, 10. Polígono Industrial Areta.
31620 Huarte-Pamplona (Navarra), Spain.

This leaflet was approved in 12/2016

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lexaprim 20 mg film-coated tablets
Escitalopram oxalate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT LEXAPRIM IS AND WHAT IT IS USED FOR

Lexaprim contains the active substance escitalopram. Lexaprim belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Lexaprim contains escialopram and is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

It may take a couple of weeks before you start to feel better. Continue to take Lexaprim, even if it takes some tiem before you feel any improvement in your condition.

You must talk to a doctor if you do not feel better or if you feel worse.

2. BEFORE YOU TAKE LEXAPRIM

Do not take Lexaprim

- if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6).
- If you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- If you are born with or have had an episode of abnormal heart rhythm (Seen at ECG; an examination to evaluate how the heart is functioning).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "other medicines and Lexaprim").

Warning and Precautions

Tell your doctor or pharmacist before taking Lexaprim. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Lexaprim should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section 4 "Possible side effects").
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Lexaprim may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- If you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises.
- if you are receiving electroconvulsive treatment.
- If you have coronary heart disease.
- If you suffer or have suffered from heart problems or have recently had a heart attack.
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (Being sick) or usage of diuretics (water tablets).
- If you experience a fast or irregular heart beat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Please note
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age
Lexaprim should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts,

suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Lexaprim for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Lexaprim for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Lexaprim. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Lexaprim in this age group have not yet been demonstrated.

Other medicines and Lexaprim
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Lexaprim. After stopping Lexaprim you must allow 7 days before taking any of these medicines.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
- "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of escitalopram.
- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression.
- Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anticoagulants). These may increase bleeding-tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Lexaprim in order to verify that your dose of anticoagulant is still adequate.
- Mefloquine (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants (triclcylic antidepressants and SSRIs) due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases) clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Lexaprim may need to be adjusted.
- Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life-threatening heart rhythm disorders.

Do not take Lexaprim if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti- malarial treatment particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Lexaprim with food, drink and alcohol
Lexaprim can be taken with or without food (see section 3 "How to take Lexaprim").

As with many medicines, combining Lexaprim with alcohol is not advisable, although Lexaprim is not expected to interact with alcohol.

Pregnancy, breast-feeding and fertility
Inform your doctor if you are pregnant or planning to become pregnant. Do not take Lexaprim if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

If you take Lexaprim during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on Lexaprim. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Lexaprim may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If used during pregnancy Lexaprim should never be stopped abruptly. It is expected that Lexaprim

will be excreted into breast milk.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines
You are advised not to drive a car or operate machinery until you know how Lexaprim affects you.

3. HOW TO TAKE LEXAPRIM

Always take Lexaprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults
Depression
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Panic disorder
The starting dose of Lexaprim is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. Your doctor can

either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

Generalised anxiety disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Obsessive-compulsive disorder
The normally recommended dose of Lexaprim is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly patients (above 65 years of age)
The recommended starting dose of Lexaprim is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (below 18 years of age)
Lexaprim should not normally be given to children and adolescents. For further information please see section 2 "What you need to know before you take Lexaprim".

You can take Lexaprim with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.

Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Lexaprim even if it takes some time before you feel any improvement in your condition.

Do not change the dose of your medicine without talking to your doctor first.

Continue to take Lexaprim for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you take more Lexaprim than you should
If you take more than the prescribed dose of Lexaprim, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Lexaprim box/container with you when you go to the doctor or hospital.

If you forget to take Lexaprim
Do not take a double dose to make up for forgotten doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

If you stop taking Lexaprim

Do not stop taking Lexaprim until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Lexaprim is gradually reduced over a number of weeks.

When you stop taking Lexaprim, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Lexaprim is stopped. The risk is higher, when Lexaprim has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Lexaprim, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

If you experience any of the following symptoms you should contact your doctor or go to the hospital straight away:

Uncommon (may affect up to 1 in 100 people):

- Unusual bleeds, including gastrointestinal bleeds

Rare (may affect up to 1 in 100 people):

- Swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
- High fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.
-
- Not known (frequency cannot be estimate from the available data):
- Difficulties urinating
- Seizures (fits), see also section 2 “Warnings and precautions”
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as torsade de pointes
- Thoughts of harming or killing yourself, see also section 2 “warnings and precautions”

In addition to above the following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea)
- Headache

Common (may affect up to 1 in 10 people):

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhoea, constipation, vomiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

Uncommon (may affect up to 1 in 100 people):

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

Rare (may affect up to 1 in 100 people):

- Aggression, depersonalisation, hallucination
- Slow heart beat

Not known (frequency cannot be estimate from the available data):

- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Abnormal liver function test (increased amounts of liver enzymes in the blood)
- Movement disorders (involuntary movements of the muscles)
- Painful erections (priapism)
- Signs of increased bleeding e.g. from skin and mucous membrans (ecchymosis)
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in women that are not nursing
- Mania
- An increased risk of bone fractures has been observed in patients taking this type of medicines.
- Alternation of the heart rhythm (called "prolongation of QT interval", seen on ECG, measuring electrical activity of the heart).

In addition, a number of side effects are known to occur with drugs that work in a similar way to escitalopram (the active ingredient of Lexaprim).
These are:

- Motor restlessness (akathisia)

- Loss of appetite

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEXAPRIM

Do not store above 30º C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lexaprim contains

The active substance is escitalopram. Each tablet contains 20 mg of escitalopram (as escitalopram oxalate).

The other ingredients are:

- Tablet core: colloidal anhydrous silica, lactose monohydrate, povidone, microcrystalline cellulose, croscarmellose sodium, talc and magnesium stearate.
- Coating: hypromellose, titanium dioxide and Macrogol 400.

What Lexaprim looks like and contents of the pack

The tablets are cylindrical, white, biconvex, scored and engraved with code ES3.

Lexaprim is supplied in packs containing 28 tablets (in 7 tablets blister-packs).

Marketing Authorisation Holder and Manufacturer

LABORATORIOS CINFA, S.A.

Olaz-Chipi, 10. Polígono Industrial Areta.

31620 Huarte-Pamplona (Navarra), Spain.

This leaflet was approved in 12/2016

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists