

Package leaflet: information for the user

meloxicam cinfa 7.5 mg tablets meloxicam

Read all of this leaflet carefully before you start taking this medicine.

- 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 signs of illness are the same as yours.
- If you feel that any side effect that you suffer is serious, or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

What is in this leaflet:

1. What meloxicam cinfa is and what it is used for.
2. Before you take meloxicam cinfa.
3. How to take meloxicam cinfa
4. Possible side effects
5. How to store meloxicam cinfa.
6. Contents of the pack and other information

1. What meloxicam cinfa is and what it is used for

Meloxicam cinfa belongs to the group of medicines called nonsteroidal antiinflammatory drugs (NSAIDs).

Meloxicam cinfa is indicated in the short duration treatment of osteoarthritis and in the long term symptomatic treatment of certain inflammatory rheumatic diseases (rheumatoid arthritis and ankylosing spondylitis).

2. Before you take meloxicam cinfa

Do not take meloxicam cinfa:

- If you are allergic (hypersensitive) to meloxicam or to any of the other ingredients of meloxicam cinfa.
- If you are allergic (hypersensitive) to other substances with similar action, such as other nonsteroidal antiinflammatory drugs (NSAIDs) or acetylsalicylic acid (aspirin).
- If you have a history of asthma, nasal polyps (nasal obstruction caused by swelling within the nose) or urticaria (sudden swelling of the face and neck, or skin rash) after the administration of acetylsalicylic acid or other NSAIDs.
- If you are in the last trimester of pregnancy.
- If you have a history of stomach or intestinal perforation or bleeding related to previous treatment with NSAIDs.
- If you suffer active stomach or intestinal ulcer or bleeding, or have a history of repeated stomach or intestinal bleeding or ulcer.
- If you suffer from serious liver disease.
- If you suffer from non-dialysed serious kidney disease.
- If you suffer bleeding or have a history of any kind of cerebrovascular haemorrhage (bleeding of the brain).
- If you have a severe heart failure.

Please contact your doctor if you are not sure about any of the above situations.

Take special care with meloxicam cinfa:

Medicines like meloxicam cinfa can be associated with a slight increase in the risk of suffering heart attack ("myocardial infarctions") or stroke ("cerebral infarction"). Any potential risk is greater at high doses and during prolonged treatments. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, a history of stroke, or if you think you might be at risk of suffering these conditions (e.g., you have high blood pressure, suffer diabetes, have increased cholesterol, or are a smoker), comment the treatment with your doctor or pharmacist.

Since treatment adjustment will be necessary, it is important to ask the doctor for advice before taking meloxicam cinfa in cases of:

- Problems with the kidneys, liver or heart disease (hypertension and/or heart failure), or fluid retention (please also see the section "How to take meloxicam cinfa").
- A history of digestive disease (e.g., stomach or intestinal ulcer in the past).
- Concomitant treatment with medicines that increase the risk of stomach or intestinal ulcer or bleeding, e.g. oral corticosteroids, certain antidepressants (selective serotonin reuptake inhibitors [SSRIs]), agents that prevent blood clotting such as acetylsalicylic acid (aspirin) or anticoagulants like warfarin. In these cases, talk to your doctor before taking meloxicam cinfa (see the section "Other medicines and meloxicam cinfa").
- Intolerance of certain sugars.

Meloxicam cinfa, like any other nonsteroidal antiinflammatory drug, can mask the symptoms of underlying infectious disease (e.g., fever). Therefore, consult your doctor if you observe signs of infection, or if the symptoms worsen.

Meloxicam cinfa may alter fertility in women. You therefore should not take this medicine if you are planning to become pregnant, if you have problems becoming pregnant, or if you are undergoing fertility tests.

In elderly patients there is a greater risk of adverse effects, particularly gastrointestinal bleeding, ulcers or perforations. Heart, liver and kidney function must be closely monitored. The doses are to be lowered.

Meloxicam cinfa must not be given to children under 15 years of age.

Skin rashes that may prove life-threatening for the patient (Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported when using meloxicam cinfa. These rashes initially appear as red spots or circular blotches, often with a blister in their centre.

Other signs that may appear include sores in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

Those skin rashes that may threaten the patient's life are often accompanied by flu-like symptoms. The rash may progress to form widespread blisters or flaking of the skin.

The highest risk of the appearance of serious skin reactions is during the first few weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis when using meloxicam cinfa, you should not use meloxicam cinfa again at any time.

If you develop a rash or any of these skin symptoms you should stop taking meloxicam cinfa, visit your doctor immediately and tell him/her that you are taking this medicine.

Other medicines and meloxicam cinfa:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Always tell your doctor or pharmacist if you are taking any of the following medicines before using meloxicam cinfa:

- Acetylsalicylic acid (aspirin) or other nonsteroidal antiinflammatory drugs.
- Corticosteroids.
- Oral anticoagulants such as warfarin, heparin for injection, antiplatelet drugs or other thrombolytic agents.
- Lithium.
- Methotrexate.
- Angiotensin-converting enzyme inhibitors (ACEIs), diuretics, beta-blockers and angiotensin II receptor antagonists (medicines used to treat heart problems).
- Selective serotonin reuptake inhibitors (antidepressants).
- Cyclosporine.
- Cholestyramine.

Concomitant treatment with antiinflammatory drugs, corticosteroids, agents that prevent blood clotting (e.g., warfarin or heparin, antiplatelet drugs) or that break up blood clots (thrombolytic agents), and certain antidepressants (selective serotonin reuptake inhibitors) can increase the risk of gastroduodenal ulcers, bleeding and damage to the intestinal and gastric mucosa. The concomitant use of meloxicam cinfa with such medicines is therefore not recommended.

Women should inform their doctor when using an intrauterine device (IUD), since the efficacy of this contraceptive method may decrease with the concomitant use of NSAIDs.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before using any medicine.

Pregnancy:

It is advisable not to take meloxicam during pregnancy.

Meloxicam is absolutely contraindicated in the first three months of pregnancy.

Lactation:

Nonsteroidal antiinflammatory drugs are excreted in breast milk. Meloxicam cinfa should therefore not be taken while breastfeeding.

Driving and using machines:

Meloxicam cinfa can affect the ability to drive and use machines, as it can cause adverse effects such as drowsiness or vertigo and blurred vision. If you notice these effects, do not use machines or drive until the symptoms disappear. Ask your doctor for advice.

Important information about some of the ingredients of meloxicam cinfa:

This medicine contains lactose. If your doctor has indicated that you suffer intolerance to certain sugars, ask him or her before taking this medicine.

3. How to take meloxicam cinfa

Always take meloxicam cinfa exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will inform you of the duration of treatment with meloxicam cinfa.

Adults and children over 15 years of age:

The usual dose is:

- For the treatment of osteoarthritis: one tablet a day. The dose may be increased to two tablets a day after consulting the doctor.
- For the treatment of rheumatoid arthritis and ankylosing spondylitis: two tablets a day.

DO NOT EXCEED THE DAILY DOSE OF 15 mg/day (two tablets).

Elderly people and patients with reduced kidney and liver function:

In elderly people the recommended dose for the long-term treatment of rheumatoid arthritis and ankylosing spondylitis is one tablet a day.

Patients with an increased risk of adverse reactions should also start treatment with one tablet a day.

In patients with severe renal failure subjected to dialysis, the maximum meloxicam cinfa dose is one tablet a day.

If you have the impression that the effect of meloxicam cinfa is too strong or too weak, tell your doctor or pharmacist.

Method of administration:

Meloxicam cinfa is intended for oral administration only. The daily dose should be swallowed as a single dose with water or some other liquid, in the course of a meal.

If you take more meloxicam cinfa than you should:

If you have taken more meloxicam cinfa than you should, consult your doctor or pharmacist immediately, specifying the medicine and quantity taken. It is recommended to take the package and the leaflet of the medicine to the healthcare provider.

The symptoms of overdose are normally limited to lethargy, drowsiness, nausea, vomiting and stomach ache. These symptoms are generally reversible. A large overdose can cause serious adverse reactions, however. If you have exceeded the prescribed dose, seek medical advice immediately.

If you forget to take meloxicam cinfa:

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, meloxicam cinfa can cause side effects, although not everybody gets them.

Medicines like meloxicam cinfa can be associated with a slight increase in the risk of suffering heart attack ("myocardial infarctions") or stroke ("cerebral infarction").

Tell your doctor immediately if you notice any gastrointestinal side effect when you start the treatment (e.g., stomach ache, heartburn) or if you have previously had any side effects due to long-term treatment with NSAIDs, especially if you are an elderly person.

Stop taking meloxicam cinfa immediately if you notice the appearance of a skin rash or any mucosal lesions (e.g., the surface within the oral cavity), or any signs of allergy.

The following list includes all the side effects described during treatment with meloxicam, including those observed in people taking doses higher than those recommended, or in the context of long term treatment. The frequency categories are defined as follows:

- Common: less than 1 in every 10 patients, but more than 1 in every 100 patients treated (1-10%).
- Uncommon: less than 1 in every 100 patients, but more than 1 in every 1000 patients treated (0.1-1%).
- Rare: less than 1 in every 1000 patients, but more than 1 in every 10,000 patients treated (0.01-0.1%).
- Very rare: less than 1 in every 10,000 patients.

Common side effects:

Anaemia (lowering of the concentration of the red blood pigment haemoglobin), stunning sensation, headache, upper abdominal discomfort, nausea and vomiting, stomach ache, constipation, flatulence, diarrhoea, itching, skin rash, oedema (fluid accumulation in the tissues) - including lower leg oedema.

Uncommon side effects:

Lowered platelet and white blood cell counts, vertigo, tinnitus (buzzing sounds in the ears), drowsiness, palpitations, increased blood pressure, hot flushes, wheals (urticaria), sodium and water accumulation or retention in the body, elevated blood potassium levels (hyperpotassaemia), transient alterations in liver function parameters (e.g., transaminase or bilirubin elevation), altered kidney function tests (e.g., increased blood urea or creatinine), gastrointestinal bleeding, stomach or intestinal ulcer, oesophagitis, stomatitis, belching.

Rare side effects:

Serious and sudden allergic reactions, mood alterations, insomnia, nightmares, confusion, disorientation, vision alterations including blurred vision, conjunctivitis (inflammation of the conjunctiva), gastrointestinal perforation, gastritis, colitis, asthma attacks in patients with allergy to aspirin or other NSAIDs, hepatitis (inflammation of the liver), inflammation of the skin and/or mucous membranes (angioedema), blister reactions such as erythema multiforme, photosensitivity (skin reactions resulting from exposure to light), acute renal failure in patients with risk factors.

There have been isolated reports of a total loss of white blood cells (agranulocytosis). Furthermore, during treatment with other NSAIDs, there have been isolated reports of side effects in the form of kidney inflammation (interstitial nephritis) and certain kidney disorders (acute tubular necrosis, nephrotic syndrome, papillary necrosis) - though such problems have not been observed with meloxicam.

Very rare side effects:

Skin rashes that may threaten the patient's life (Stevens-Johnson syndrome, toxic epidermal necrolysis; see section 2) may also appear.

If you feel that any side effect that you suffer is serious, or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

Side effects of unknown frequency:

Pancreatitis (inflammation of the pancreas).

5. How to store meloxicam cinfa

Keep this medicine out of the sight and reach of children. Do not store at a temperature above 25°C.

Do not use meloxicam cinfa after the expiry date stated on the pack 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 medicines you no longer use. These measures will help protect the environment.

6. Other information**What meloxicam cinfa contains:**

The active drug substance is meloxicam. Each tablet contains 7.5 mg of meloxicam.

The other ingredients are: sodium citrate, microcrystalline cellulose (E-460), lactose monohydrate, povidone, colloidal anhydrous silica, magnesium stearate, potato sodium carboxymethyl starch (type A).

Contents of the pack:

Each package contains 20 tablets.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.

C/ Olaz-Chipi, 10 - Polígono Industrial Areta

31620 Huarte - Pamplona (Navarre)-Spain

Distributor

Reich Pharm Limited

Unit 3001, 30/F, Citicorp Centre,

18 Whitfield Road,

Hong Kong

Tel.: 2470 1927

Fax.: 2470 3448

HK Reg. No. HK-57809

This leaflet was approved in October 2012

Package leaflet: information for the user

meloxicam cinfa 15 mg tablets

meloxicam

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- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience side effects, consult your doctor or pharmacist, even if these side effects do not appear in this leaflet.

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1. What meloxicam cinfa is and what it is used for

Meloxicam cinfa belongs to the group of medicines called nonsteroidal antiinflammatory drugs (NSAIDs).

Meloxicam cinfa is indicated in the short duration treatment of osteoarthritis and in the long term symptomatic treatment of certain inflammatory rheumatic diseases (rheumatoid arthritis and ankylosing spondylitis).

2. Before you take meloxicam cinfa

Do not take meloxicam cinfa:

- If you are allergic (hypersensitive) to meloxicam or to any of the other ingredients of meloxicam cinfa.
- If you are allergic (hypersensitive) to other substances with similar action, such as other nonsteroidal antiinflammatory drugs (NSAIDs) or acetylsalicylic acid (aspirin).
- If you have a history of asthma, nasal polyps (nasal obstruction caused by swelling within the nose) or urticaria (sudden swelling of the face and neck, or skin rash) after the administration of acetylsalicylic acid or other NSAIDs.
- If you are in the last trimester of pregnancy.
- If you have a history of stomach or intestinal perforation or bleeding related to previous treatment with NSAIDs.
- If you suffer active stomach or intestinal ulcer or bleeding, or have a history of repeated stomach or intestinal bleeding or ulcer.
- If you suffer from serious liver disease.
- If you suffer from non-dialysed serious kidney disease.
- If you suffer bleeding or have a history of cerebrovascular haemorrhage (bleeding of the brain).
- If you have a severe heart failure.

Please contact your doctor if you are not sure about any of the above situations.

Take special care with meloxicam cinfa:

Medicines like meloxicam cinfa can be associated with a slight increase in the risk of suffering heart attack (“myocardial infarctions”) or stroke (“cerebral infarction”). Any potential risk is greater at high doses and during prolonged treatments. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, a history of stroke, or if you think you might be at risk of suffering these conditions (e.g., you have high blood pressure, suffer diabetes, have increased cholesterol, or are a smoker), comment the treatment with your doctor or pharmacist.

Since treatment adjustment will be necessary, it is important to ask the doctor for advice before taking meloxicam cinfa in cases of:

- Problems with the kidneys, liver or heart disease (hypertension and/or heart failure), or fluid retention (please also see the section "How to take meloxicam cinfa").
- A history of digestive disease (e.g., stomach or intestinal ulcer in the past).
- Concomitant treatment with medicines that increase the risk of stomach or intestinal ulcer or bleeding, e.g. oral corticosteroids, certain antidepressants (selective serotonin reuptake inhibitors [SSRIs]), agents that prevent blood clotting such as acetylsalicylic acid (aspirin) or anticoagulants like warfarin. In these cases, talk to your doctor before taking meloxicam cinfa (see the section "Other medicines and meloxicam cinfa").
- Intolerance of certain sugars.

Meloxicam cinfa, like any other nonsteroidal antiinflammatory drug, can mask the symptoms of underlying infectious disease (e.g., fever). Therefore, consult your doctor if you observe signs of infection, or if the symptoms worsen.

Meloxicam cinfa may alter fertility in women. You therefore should not take this medicine if you are planning to become pregnant, if you have problems becoming pregnant, or if you are undergoing fertility tests.

In elderly patients there is a greater risk of adverse effects, particularly gastrointestinal bleeding, ulcers or perforations. Heart, liver and kidney function must be closely monitored. The doses are to be lowered.

Meloxicam cinfa must not be given to children under 15 years of age.

Skin rashes that may prove life-threatening for the patient (Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported when using meloxicam cinfa. These rashes initially appear as red spots or circular blotches, often with a blister in their centre.

Other signs that may appear include sores in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

Those skin rashes that may threaten the patient's life are often accompanied by flu-like symptoms. The rash may progress to form widespread blisters or flaking of the skin.

The highest risk of the appearance of serious skin reactions is during the first few weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis when using meloxicam cinfa, you should not use meloxicam cinfa again at any time.

If you develop a rash or any of these skin symptoms you should stop taking meloxicam cinfa, visit your doctor immediately and tell him/her that you are taking this medicine.

Other medicines and meloxicam cinfa:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Always tell your doctor or pharmacist if you are taking any of the following medicines before using meloxicam cinfa:

- Acetylsalicylic acid (aspirin) or other nonsteroidal antiinflammatory drugs.
- Corticosteroids.
- Oral anticoagulants such as warfarin, heparin for injection, antiplatelet drugs or other thrombolytic agents.
- Lithium.
- Methotrexate.
- Angiotensin-converting enzyme inhibitors (ACEIs), diuretics, beta-blockers and angiotensin II receptor antagonists (medicines used to treat heart problems).
- Selective serotonin reuptake inhibitors (antidepressants).
- Cyclosporine.
- Cholestyramine.

Concomitant treatment with antiinflammatory drugs, corticosteroids, agents that prevent blood clotting (e.g., warfarin or heparin, antiplatelet drugs) or that break up blood clots (thrombolytic agents), and certain antidepressants (selective serotonin reuptake inhibitors) can increase the risk of gastroduodenal ulcers, bleeding and damage to the intestinal and gastric mucosa. The concomitant use of meloxicam cinfa with such medicines is therefore not recommended.

Women should inform their doctor when using an intrauterine device (IUD), since the efficacy of this contraceptive method may decrease with the concomitant use of NSAIDs.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before using any medicine.

Pregnancy:

It is advisable not to take meloxicam during pregnancy.

Meloxicam is absolutely contraindicated in the first three months of pregnancy.

Lactation:

Nonsteroidal antiinflammatory drugs are excreted in breast milk. Meloxicam cinfa should therefore not be taken while breastfeeding.

Driving and using machines:

Meloxicam cinfa can affect the ability to drive and use machines, as it can cause adverse effects such as drowsiness or vertigo and blurred vision. If you notice these effects, do not use machines or drive until the symptoms disappear. Ask your doctor for advice.

Important information about some of the ingredients of meloxicam cinfa:

This medicine contains lactose. If your doctor has indicated that you suffer intolerance to certain sugars, ask him or her before taking this medicine.

3. How to take meloxicam cinfa

Always take meloxicam cinfa exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will inform you of the duration of treatment with meloxicam cinfa.

Adults and children over 15 years of age:

The usual dose is:

- For the treatment of osteoarthritis: half a tablet a day. The dose may be increased to one tablet a day a day after consulting the doctor.
- For the treatment of rheumatoid arthritis and ankylosing spondylitis: one tablet a day.

DO NOT EXCEED THE DAILY DOSE OF 15 mg/day (one tablet).

Elderly people and patients with reduced kidney and liver function:

In elderly people the recommended dose for the long-term treatment of rheumatoid arthritis and ankylosing spondylitis is half a tablet a day.

Patients with an increased risk of adverse reactions should also start treatment with half a tablet a day.

In patients with severe renal failure subjected to dialysis, the maximum meloxicam cinfa dose is half a tablet a day.

If you have the impression that the effect of meloxicam cinfa is too strong or too weak, tell your doctor or pharmacist.

Method of administration:

Meloxicam cinfa is intended for oral administration only. The daily dose should be swallowed as a single dose with water or some other liquid, in the course of a meal.

If you take more meloxicam cinfa that you should:

If you have taken more meloxicam cinfa than you should, consult your doctor or pharmacist immediately, specifying the medicine and quantity taken. It is recommended to take the package and the leaflet of the medicine to the healthcare provider.

The symptoms of overdose are normally limited to lethargy, drowsiness, nausea, vomiting and stomach ache. These symptoms are generally reversible. A large overdose can cause serious adverse reactions, however. If you have exceeded the prescribed dose, seek medical advice immediately.

If you forget to take meloxicam cinfa:

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, meloxicam cinfa can cause side effects, although not everybody gets them.

Medicines like meloxicam cinfa can be associated with a slight increase in the risk of suffering heart attack ("myocardial infarctions") or stroke ("cerebral infarction").

Tell your doctor immediately if you notice any gastrointestinal side effect when you start the treatment (e.g., stomach ache, heartburn) or if you have previously had any side effects due to long-term treatment with NSAIDs, especially if you are an elderly person.

Stop taking meloxicam cinfa immediately if you notice the appearance of a skin rash or any mucosal lesions (e.g., the surface within the oral cavity), or any signs of allergy.

The following list includes all the side effects described during treatment with meloxicam, including those observed in people taking doses higher than those recommended, or in the context of long term treatment. The frequency categories are defined as follows:

- Common: less than 1 in every 10 patients, but more than 1 in every 100 patients treated (1-10%).
- Uncommon: less than 1 in every 100 patients, but more than 1 in every 1000 patients treated (0.1-1%).
- Rare: less than 1 in every 1000 patients, but more than 1 in every 10,000 patients treated (0.01-0.1%).
- Very rare: less than 1 in every 10,000 patients.

Common side effects:

Anaemia (lowering of the concentration of the red blood pigment haemoglobin), stunning sensation, headache, upper abdominal discomfort, nausea and vomiting, stomach ache, constipation, flatulence, diarrhoea, itching, skin rash, oedema (fluid accumulation in the tissues) - including lower leg oedema.

Uncommon side effects:

Lowered platelet and white blood cell counts, vertigo, tinnitus (buzzing sounds in the ears), drowsiness, palpitations, increased blood pressure, hot flushes, wheals (urticaria), sodium and water accumulation or retention in the body, elevated blood potassium levels (hyperpotassaemia), transient alterations in liver function parameters (e.g., transaminase or bilirubin elevation), altered kidney function tests (e.g., increased blood urea or creatinine), gastrointestinal bleeding, stomach or intestinal ulcer, oesophagitis, stomatitis, belching.

Rare side effects:

Serious and sudden allergic reactions, mood alterations, insomnia, nightmares, confusion, disorientation, vision alterations including blurred vision, conjunctivitis (inflammation of the conjunctiva), gastrointestinal perforation, gastritis, colitis, asthma attacks in patients with allergy to aspirin or other NSAIDs, hepatitis (inflammation of the liver), serious skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis / Lyell syndrome), inflammation of the skin and/or mucous membranes (angioedema), blister reactions such as erythema multiforme, photosensitivity (skin reactions resulting from exposure to light), acute renal failure in patients with risk factors.

There have been isolated reports of a total loss of white blood cells (agranulocytosis). Furthermore, during treatment with other NSAIDs, there have been isolated reports of side effects in the form of kidney inflammation (interstitial nephritis) and certain kidney disorders (acute tubular necrosis, nephrotic syndrome, papillary necrosis) - though such problems have not been observed with meloxicam.

Very rare side effects:

Skin rashes that may threaten the patient's life (Stevens-Johnson syndrome, toxic epidermal necrolysis; see section 2) may also appear.

If you feel that any side effect that you suffer is serious, or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

Side effects of unknown frequency:

Pancreatitis (inflammation of the pancreas).

5. How to store meloxicam cinfa

Keep out of the sight and reach of children. Do not store at a temperature above 25°C.

Do not use meloxicam cinfa after the expiry date stated on the pack 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 medicines you no longer use. These measures will help protect the environment.

6. Other information**What meloxicam cinfa contains:**

The active drug substance is meloxicam. Each tablet contains 15 mg of meloxicam.

The other ingredients are: sodium citrate, microcrystalline cellulose (E-460), lactose monohydrate, povidone, colloidal anhydrous silica, magnesium stearate, potato sodium carboxymethyl starch (type A).

Contents of the pack:

Each package contains 20 tablets.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.

C/ Olaz-Chipi, 10 - Polígono Industrial Areta

31620 Huarte - Pamplona (Navarre)-Spain

Distributor

Reich Pharm Limited

Unit 3001, 30/F, Citicorp Centre,

18 Whitfield Road,

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Fax: 2470 3448

Hk Reg. No. HK-57808

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