

## Package leaflet: Information for the user

### **bucomax lozenges with lidocaine mint flavour**

lidocaine hydrochloride / amylmetacresol / 2,4-dichlorobenzyl alcohol

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **What is in this leaflet:**

1. What **bucomax with lidocaine** is and what it is used for
2. What you need to know before you take **bucomax with lidocaine**.
3. How to take **bucomax with lidocaine**.
4. Possible side effects.
5. How to store **bucomax with lidocaine**.
6. Contents of the pack and other information.

#### **1. What bucomax with lidocaine is and what it is used for**

**bucomax with lidocaine** is a combination of amylmetacresol, 2,4-dichlorobenzyl alcohol, 2 antiseptics, and lidocaine hydrochloride, a local anaesthetic for the throat.

It is indicated for local symptomatic relief of minor infections of the mouth and throat, presenting with pain and without fever for adults and adolescents over 12 years of age.

#### **2. What you need to know before you take bucomax with lidocaine**

##### **Do not take bucomax with lidocaine:**

- If you are allergic (hypersensitivity) to lidocaine hydrochloride, amylmetacresol, 2,4-dichlorobenzyl alcohol or any of the other ingredients of **bucomax with lidocaine** (listed in section 6).
- Children under 6 years of age must not take this medicine.

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking bucomax lozenges:

- If you have asthma.
- If you do not feel better after 2 days of treatment or you have a fever, headache, nausea or vomiting, you must consult your doctor.
- The anaesthesia caused by this medicine in the throat area may enhance aspiration (coughing during meals or a choking sensation) while eating. This medicine must not be used before meals or before drinking.
- The prolonged use of this medicine for more than 5 days is not recommended as it may affect the natural microbial balance in the throat.

- Keep to the specified dosage: If taken in large amounts or repeatedly, this medicine passes into the blood stream and can act on the heart and nervous system, which could result in seizures.
- Ill or weak elderly people should talk to a doctor before taking this medicine, as they are more sensitive to possible adverse reactions.

### **Children and adolescents**

Children aged 6 to 11 years should not take this medicine.

Children under 6 years of age: Must not take this medicine; it is contraindicated.

### **Other medicines and bucomax with lidocaine**

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

In particular, if you are taking any of the following medicines, it may be necessary to modify the dose of some of them:

- Beta-blockers (to treat diseases of the heart or arteries) and medicines such as cimetidine (to treat stomach ulcers).
- Other amide-type local anaesthetics.
- Medicines indicated for heart arrhythmias such as mexiletine or procainamide.
- Medicines such as fluvoxamine (to treat depression).
- Antibiotics such as erythromycin and itraconazole.

Although they are not expected to interact with each other, you must not take any other oropharyngeal antiseptics if you are taking **bucomax with lidocaine**.

### **bucomax with lidocaine lozenges with food, drink and alcohol**

This medicine must not be used before meals or before drinking.

Alcoholic drinks must not be consumed during treatment with this medicine.

### **Pregnancy and breast-feeding:**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy:

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

It is advisable not to use this medicine during pregnancy.

#### Breast-feeding:

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

### **Driving and using machines:**

Observe your response to the medicine. This medicine is not expected to cause drowsiness or reduce the ability to react, but should this be the case, do not drive and handle dangerous machinery.

### **Important information about some of the ingredients of bucomax with lidocaine**

This medicine contains isomalt (E-953) and maltitol (E-965). If your doctor has told you that you are intolerant to certain sugars, ask him or her before taking this medicine.

It may have a mild laxative effect because each lozenge contains 1830 mg of isomalt and 633 mg of maltitol.

Calories: 2.3 kcal/g maltitol/isomalt.

### **3. How to take bucomax with lidocaine**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- Adults and adolescents over 12 years of age: dissolve 1 lozenge slowly in the mouth every 2 or 3 hours, up to a maximum of 8 lozenges in 24 hours.

#### **Use in children and adolescents**

This medicine is contraindicated in children under 6 years of age.

#### **If you take more bucomax with lidocaine than you should**

It may cause increased or abnormal heart rate, increased blood pressure, sedation, altered breathing during sleep, loss of consciousness, cardiovascular collapse, insomnia, hallucinations, tremor and epileptic seizures (symptoms of depression or stimulation of the central nervous system). Drowsiness can be a symptom of overdose. It may cause agitation in children.

In case of overdose or accidental ingestion of large amounts, blurred vision, ringing in the ears and dizziness may occur. Go to a medical centre immediately or call the Toxicology Information Service (tel. +34 91 562 04 20), specifying the medicine and the amount taken.

The prolonged use of this medicinal product for more than 5 days is not recommended as it may affect the natural microbial balance in the throat.

Use of large doses and for long periods of time can cause seizures in children under 6 years of age.

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

### **4. Possible side effects.**

Like all medicines, **bucmax with lidocaine** can cause side effects, although not everybody gets them.

While the combination of active substances in this medicine has been used, the following side effects have been reported, although their frequency has not been clearly established:

Occasionally, skin lesions, hives, oedema or anaphylactic reactions can occur, with swelling of the mouth and throat. If you notice these or any other side effect not listed in this leaflet, tell your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### **5. How to store bucomax with lidocaine**

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

No special storage conditions are required.

**Shelf life**

Do not use **bucomax with lidocaine** after the expiry date which is 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. Contents of the pack and other information****What bucomax lozenges with lidocaine mint flavour contains:**

Each lozenge contains the following active substances:

Lidocaine hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2,4-dichlorobenzyl alcohol	1.20 mg

The other ingredients (excipients) are: mint essential oil, anise essential oil, levomenthol, indigo carmine colouring (E-132), quinoline yellow (E-104), sodium saccharin (E-954), tartaric acid (E-334), isomalt (E-953) and maltitol (E-965).

**What the product looks like and contents of the pack:**

**bucomax with lidocaine** are cylindrical, biconvex, green, mint-flavoured lozenges. Each pack contains 8 or 24 lozenges.

**Marketing authorisation holder and manufacturer:**

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

**This leaflet was last approved in: December 2012**

*Detailed and up-to-date information on this medicine is available on the website of the Spanish Agency for Medicines and Medical Devices (AEMPS) <http://www.aemps.gob.es/>*

## Package leaflet: Information for the user

### **bucomax lozenges with lidocaine orange flavour**

lidocaine hydrochloride / amylmetacresol / 2,4-dichlorobenzyl alcohol

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **What is in this leaflet:**

1. What **bucomax with lidocaine** is and what it is used for
2. What you need to know before you take **bucomax with lidocaine**.
3. How to take **bucomax with lidocaine**.
4. Possible side effects.
5. How to store **bucomax with lidocaine**.
6. Contents of the pack and other information.

#### **1. What bucomax with lidocaine is and what it is used for**

**bucomax with lidocaine** is a combination of amylmetacresol, 2,4-dichlorobenzyl alcohol, 2 antiseptics, and lidocaine hydrochloride, a local anaesthetic for the throat.

It is indicated for local symptomatic relief of minor infections of the mouth and throat, presenting with pain and without fever for adults and adolescents over 12 years of age.

#### **2. What you need to know before you take bucomax with lidocaine**

##### **Do not take bucomax with lidocaine:**

- If you are allergic (hypersensitivity) to lidocaine hydrochloride, amylmetacresol, 2,4-dichlorobenzyl alcohol or any of the other ingredients of **bucomax with lidocaine** (listed in section 6).
- Children under 6 years of age must not take this medicine.

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking bucomax lozenges:

- If you have asthma.
- If you do not feel better after 2 days of treatment or you have a fever, headache, nausea or vomiting, you must consult your doctor.
- The anaesthesia caused by this medicine in the throat area may enhance aspiration (coughing during meals or a choking sensation) while eating. This medicine must not be used before meals or before drinking.
- The prolonged use of this medicine for more than 5 days is not recommended as it may affect the natural microbial balance in the throat.

- Keep to the specified dosage: If taken in large amounts or repeatedly, this medicine passes into the blood stream and can act on the heart and nervous system, which could result in seizures.
- Ill or weak elderly people should talk to a doctor before taking this medicine, as they are more sensitive to possible adverse reactions.

### **Children and adolescents**

Children aged 6 to 11 years should not take this medicine.

Children under 6 years of age: Must not take this medicine; it is contraindicated.

### **Other medicines and bucomax with lidocaine**

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

In particular, if you are taking any of the following medicines, it may be necessary to modify the dose of some of them:

- Beta-blockers (to treat diseases of the heart or arteries) and medicines such as cimetidine (to treat stomach ulcers).
- Other amide-type local anaesthetics.
- Medicines indicated for heart arrhythmias such as mexiletine or procainamide.
- Medicines such as fluvoxamine (to treat depression).
- Antibiotics such as erythromycin and itraconazole.

Although they are not expected to interact with each other, you must not take any other oropharyngeal antiseptics if you are taking **bucomax with lidocaine**.

### **bucomax with lidocaine lozenges with food, drink and alcohol**

This medicine must not be used before meals or before drinking.

Alcoholic drinks must not be consumed during treatment with this medicine.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

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

It is advisable not to use this medicine during pregnancy.

#### Breast-feeding

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

### **Driving and using machines**

Observe your response to the medicine. This medicine is not expected to cause drowsiness or reduce the ability to react, but should this be the case, do not drive and handle dangerous machinery.

### **Important information about some of the ingredients of bucomax with lidocaine**

This medicine contains isomalt (E-953) and maltitol (E-965). If your doctor has told you that you are intolerant to certain sugars, ask him or her before taking this medicine.

It may have a mild laxative effect because each lozenge contains 1830 mg of isomalt and 633 mg of maltitol.

Calories: 2.3 kcal/g maltitol/isomalt.

### **3. How to take bucomax with lidocaine**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- Adults and adolescents over 12 years of age: dissolve 1 lozenge slowly in the mouth every 2 or 3 hours, up to a maximum of 8 lozenges in 24 hours.

#### **Use in children and adolescents**

This medicine is contraindicated in children under 6 years of age.

#### **If you take more bucomax with lidocaine than you should**

It may cause increased or abnormal heart rate, increased blood pressure, sedation, altered breathing during sleep, loss of consciousness, cardiovascular collapse, insomnia, hallucinations, tremor and epileptic seizures (symptoms of depression or stimulation of the central nervous system). Drowsiness can be a symptom of overdose. It may cause agitation in children.

In case of overdose or accidental ingestion of large amounts, blurred vision, ringing in the ears and dizziness may occur. Go to a medical centre immediately or call the Toxicology Information Service (tel. +34 91 562 04 20), specifying the medicine and the amount taken.

The prolonged use of this medicinal product for more than 5 days is not recommended as it may affect the natural microbial balance in the throat.

Use of large doses and for long periods of time can cause seizures in children under 6 years of age.

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

### **4. Possible side effects.**

Like all medicines, **bucamax with lidocaine** can cause side effects, although not everybody gets them.

While the combination of active substances in this medicine has been used, the following side effects have been reported, although their frequency has not been clearly established:

Occasionally, skin lesions, hives, oedema or anaphylactic reactions can occur, with swelling of the mouth and throat. If you notice these or any other side effect not listed in this leaflet, tell your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### **5. How to store bucomax with lidocaine**

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

No special storage conditions are required.

**Shelf life**

Do not use **bucamax with lidocaine** after the expiry date which is 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. Contents of the pack and other information**

**What bucomax lozenges with lidocaine orange flavour contains:**

Each lozenge contains the following active substances:

Lidocaine hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2,4-dichlorobenzyl alcohol	1.20 mg

The other ingredients (excipients) are: levomenthol, sodium saccharin (E-954), isomalt (E-953), maltitol (E-965), sunset yellow colouring (E-110), cochineal red colouring (E-124), citric acid monohydrate (E-330) and orange flavour.

**What the product looks like and contents of the pack**

**bucamax with lidocaine** are cylindrical, biconvex, orange-coloured, orange-flavoured lozenges. Each pack contains 8 or 24 lozenges.

**Marketing authorisation holder and manufacturer:**

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

**This leaflet was last approved in: December 2012**

*Detailed and up-to-date information on this medicine is available on the website of the Spanish Agency for Medicines and Medical Devices (AEMPS) <http://www.aemps.gob.es/>*

## Package leaflet: Information for the user

### **bucomax lozenges with lidocaine honey and lemon flavour** lidocaine hydrochloride / amylmetacresol / 2,4-dichlorobenzyl alcohol

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **What is in this leaflet:**

1. What **bucomax with lidocaine** is and what it is used for
2. What you need to know before you take **bucomax with lidocaine**.
3. How to take **bucomax with lidocaine**.
4. Possible side effects.
5. How to store **bucomax with lidocaine**.
6. Contents of the pack and other information.

#### **1. What bucomax with lidocaine is and what it is used for**

**bucomax with lidocaine** is a combination of amylmetacresol, 2,4-dichlorobenzyl alcohol, 2 antiseptics, and lidocaine hydrochloride, a local anaesthetic for the throat.

It is indicated for local symptomatic relief of minor infections of the mouth and throat, presenting with pain and without fever for adults and adolescents over 12 years of age.

#### **2. What you need to know before you take bucomax with lidocaine**

##### **Do not take bucomax with lidocaine:**

- If you are allergic (hypersensitivity) to lidocaine hydrochloride, amylmetacresol, 2,4-dichlorobenzyl alcohol or any of the other ingredients of **bucomax with lidocaine** (listed in section 6).
- Children under 6 years of age must not take this medicine.

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking bucomax lozenges:

- If you have asthma.
- If you do not feel better after 2 days of treatment or you have a fever, headache, nausea or vomiting, you must consult your doctor.
- The anaesthesia caused by this medicine in the throat area may enhance aspiration (coughing during meals or a choking sensation) while eating. This medicine must not be used before meals or before drinking.
- The prolonged use of this medicine for more than 5 days is not recommended as it may affect the natural microbial balance in the throat.

- Keep to the specified dosage: If taken in large amounts or repeatedly, this medicine passes into the blood stream and can act on the heart and nervous system, which could result in seizures.
- Ill or weak elderly people should talk to a doctor before taking this medicine, as they are more sensitive to possible adverse reactions.

### **Children and adolescents**

Children aged 6 to 11 years should not take this medicine.

Children under 6 years of age: Must not take this medicine; it is contraindicated.

### **Other medicines and bucomax with lidocaine**

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

In particular, if you are taking any of the following medicines, it may be necessary to modify the dose of some of them:

- Beta-blockers (to treat diseases of the heart or arteries) and medicines such as cimetidine (to treat stomach ulcers).
- Other amide-type local anaesthetics.
- Medicines indicated for heart arrhythmias such as mexiletine or procainamide.
- Medicines such as fluvoxamine (to treat depression).
- Antibiotics such as erythromycin and itraconazole.

Although they are not expected to interact with each other, you must not take any other oropharyngeal antiseptics if you are taking **bucomax with lidocaine**.

### **bucomax with lidocaine lozenges with food, drink and alcohol**

This medicine must not be used before meals or before drinking.

Alcoholic drinks must not be consumed during treatment with this medicine.

### **Pregnancy and breast-feeding:**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy:

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

It is advisable not to use this medicine during pregnancy.

#### Breast-feeding:

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

### **Driving and using machines:**

Observe your response to the medicine. This medicine is not expected to cause drowsiness or reduce the ability to react, but should this be the case, do not drive and handle dangerous machinery.

### **Important information about some of the ingredients of bucomax with lidocaine**

This medicine contains isomalt (E-953) and maltitol (E-965). If your doctor has told you that you are intolerant to certain sugars, ask him or her before taking this medicine.

It may have a mild laxative effect because each lozenge contains 1830 mg of isomalt and 633 mg of maltitol.

Calories: 2.3 kcal/g maltitol/isomalt.

### **3. How to take bucomax with lidocaine**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- Adults and adolescents over 12 years of age: dissolve 1 lozenge slowly in the mouth every 2 or 3 hours, up to a maximum of 8 lozenges in 24 hours.

#### **Use in children and adolescents**

This medicine is contraindicated in children under 6 years of age.

#### **If you take more bucomax with lidocaine than you should**

It may cause increased or abnormal heart rate, increased blood pressure, sedation, altered breathing during sleep, loss of consciousness, cardiovascular collapse, insomnia, hallucinations, tremor and epileptic seizures (symptoms of depression or stimulation of the central nervous system). Drowsiness can be a symptom of overdose. It may cause agitation in children.

In case of overdose or accidental ingestion of large amounts, blurred vision, ringing in the ears and dizziness may occur. Go to a medical centre immediately or call the Toxicology Information Service (tel. +34 91 562 04 20), specifying the medicine and the amount taken.

The prolonged use of this medicinal product for more than 5 days is not recommended as it may affect the natural microbial balance in the throat.

Use of large doses and for long periods of time can cause seizures in children under 6 years of age.

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

### **4. Possible side effects.**

Like all medicines, **bucomax with lidocaine** can cause side effects, although not everybody gets them.

While the combination of active substances in this medicine has been used, the following side effects have been reported, although their frequency has not been clearly established:

Occasionally, skin lesions, hives, oedema or anaphylactic reactions can occur, with swelling of the mouth and throat. If you notice these or any other side effect not listed in this leaflet, tell your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### **5. How to store bucomax with lidocaine**

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

No special storage conditions are required.

**Shelf life**

Do not use **bucomax with lidocaine** after the expiry date which is 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. Contents of the pack and other information****What bucomax lozenges with lidocaine honey and lemon flavour contains:**

Each lozenge contains the following active substances:

Lidocaine hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2,4-dichlorobenzyl alcohol	1.20 mg

The other ingredients (excipients) are: mint essential oil, quinoline yellow (E-104), sodium saccharin (E-954), tartaric acid (E-334), isomalt (E-953), maltitol (E-965), sunset yellow colouring (E-110), lemon essence and honey flavour.

**What the product looks like and contents of the pack:**

**bucomax with lidocaine** are cylindrical, biconvex, yellow, honey and lemon-flavoured lozenges. Each pack contains 8 or 24 lozenges.

**Marketing authorisation holder and manufacturer:**

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

**This leaflet was last approved in: December 2012**

*Detailed and up-to-date information on this medicine is available on the website of the Spanish Agency for Medicines and Medical Devices (AEMPS) <http://www.aemps.gob.es/>*