Package leaflet: information for the user

meloxicam cinfa 7.5 mg tablets

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 medicinal product 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 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 meloxicam cinfa is and what it is used for

Meloxicam cinfa contains the active ingredient meloxicam. Meloxicam cinfa belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) used to reduce inflammation and pain in joints and muscles.

Meloxicam is indicated for adults and children aged 16 years and over. Meloxicam is used for the:
- Short-term treatment of arthrosis (osteoarthrosis) attacks
- Long-term treatment of
  - Rheumatoid arthritis
  - Ankylosing spondylitis

2. What you need to know before you take meloxicam cinfa

Do not take meloxicam cinfa:
- If you are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- In the last three months of pregnancy
- Children and adolescents under 16 years of age
- If you have had any of the following disorders after taking acetylsalicylic acid (aspirin) or other NSAIDs:
  - wheezing, tightness in the chest, shortness of breath (asthma)
  - blocked nose due to inflammation of the internal part of the nose (nasal polyps)
  - Skin rashes, urticaria
  - Sudden inflammation of the skin or mucous membranes, such as inflammation around the eyes, face, lips, mouth or throat, possibly hindering respiration (angioedema)
- If after previous therapy with NSAIDs you presented:
  - Bleeding in the stomach or intestines
  - Perforations in the stomach or intestines
- Ulcers or bleeding in the stomach or intestines
- If you have recently or ever had stomach or peptic ulcers or bleeding (ulcers or bleeder that have occurred at least twice)
- Severe deterioration of liver function

- Severe non-dialysed renal failure
- Recent bleeding in the brain (cerebrovascular haemorrhage)
- Any type of bleeding disorders
- Severe heart failure
- Intolerance to some sugars as this medicine contains lactose (see also “meloxicam cinfa contains lactose”).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking meloxicam cinfa.

Warnings

Medicines like meloxicam 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 take more than the recommended dose. Do not take meloxicam for longer than prescribed (see section 3 “How to take meloxicam cinfa”).

If you have heart problems, a history of stroke, or if you think you might be at risk of suffering these conditions, talk to your doctor or pharmacist about the treatment.

For example if you:
- Have high blood pressure (hypertension)
- Have high levels of sugar in the blood (diabetes mellitus)
- Have high levels of LDL cholesterol in the blood (hypercholesterolaemia)
- Smoke

Immediately stop treatment with meloxicam as soon as you notice bleeding (that causes black stools) or ulcers in your digestive system (causing abdominal pain).

Skin rashes that may prove life-threatening for the patient (Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported when using meloxicam. 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 or 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, you should not use meloxicam again at any time.

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

Meloxicam is not suitable if you need immediate relief from acute pain.

Meloxicam can mask the symptoms of an infection (e.g. fever). If you believe you may have an infection, you must see a doctor.

Precautions for use

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

- Having suffered inflammation of the throat (oesophagitis), inflammation of the stomach (gastritis) or a history of any other disease of the digestive system, e.g. Crohn's disease, ulcerative colitis
- High blood pressure (arterial hypertension)
- Elderly patients
- Disease of the heart, liver or kidneys
- High levels of sugar in the blood (diabetes mellitus)
- Low blood volume (hypovolaemia) that can occur if you have suffered blood significant loss or serious burns, surgery or low intake of liquids
- Intolerance to any sugars diagnosed by your doctor, as this medicine contains lactose
- Higher levels of potassium in blood previously diagnosed by your doctor. Your doctor will have to monitor your evolution during the treatment.

Other medicines and meloxicam cinfa

Meloxicam may affect or be affected by other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Specifically, inform your doctor or pharmacist if you are taking/have taken or used any of the following medicines:
- Other NSAIDs
- Potassium salts (used to prevent or treat low levels of potassium in the blood)
- Tacrolimus (used after organ transplants)
- Trimethoprim (used to treat urinary tract infections)
- Medicines that prevent blood coagulation
- Medicines that dissolve blood clots (thrombolytics)
- Medicines for treating diseases of the heart and kidneys
- Corticosteroids (e.g. used in cases of inflammation or allergic reactions)
- Cyclosporine (used after organ transplants or for severe skin diseases, rheumatoid arthritis or nephrotic syndrome)
- Deferasirox (used to treat chronic iron caused excess by frequent blood transfusions)
- Any diuretic medicine (“tablets for urination”). Your doctor may monitor your kidney function if you are taking diuretics.
- Medicines for treating high blood pressure (e.g. Beta-blockers)
- Lithium (used to treat behavioural disorders).
- Selective serotonin reuptake inhibitors (SSRI) (used for treating depression).
- Methotrexate (used to treat tumours or severe uncontrolled disease of the skin and active rheumatoid arthritis)
- Pemetrexed (used to treat cancer)
- Cholestyramine (used to lower blood cholesterol levels)
- Oral antidiabetics (sulphonylureas, nateglinide) (used for treating diabetes. Your doctor must carefully monitor your blood sugar level for hypoglycaemia.)

Pregnancy, breast-feeding and fertility

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

Pregnancy

During the first and second trimester of pregnancy, your doctor will only prescribe this medicine for you if it is clearly necessary, due to the potential risk of miscarriage or malformation. In this case, the dose should be kept as low as possible and the duration of the treatment must be as short as possible.

During the 3 last months of pregnancy, this medicine is contraindicated: NEVER take this medicine because it can have severe or even fatal consequences for your baby, especially the heart, lungs and/or kidneys, even with one single administration.

If you have taken this medicine while pregnant, talk to your doctor/midwife immediately so appropriate monitoring can be considered.

Breast-feeding

It is advisable not to take this medicine during breast-feeding.

Fertility

This medicine may make it more difficult to become pregnant. You must tell your doctor if you intend to become pregnant or if you are having difficulty becoming pregnant.

Driving and using machines

This medicine can cause vision disturbances including blurred vision, dizziness, drowsiness, vertigo or other central nervous system disorders. If you notice these effects, do not drive or use machines.

Meloxicam cinfa contains lactose

This medicine contains lactose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

Meloxicam cinfa contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per tablet; it is essentially “sodium-free”.

3. How to take meloxicam cinfa

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

The recommended dose is:

Arthrosis episodes:
7.5 mg of meloxicam (one tablet) once a day. This can be increased to 15 mg of meloxicam (two tablets) once a day.

Rheumatoid arthritis:
15 mg of meloxicam (two tablets) once a day. This can be reduced to 7.5 mg of meloxicam (one tablet) once a day.

Ankylosing spondylitis:
15 mg of meloxicam (two tablets) once a day. This can be reduced to 7.5 mg of meloxicam (one tablet) once a day.

Do not exceed the maximum recommended dose of 15 mg a day.

If any of the situations described under the heading "**Warnings and precautions**" affects you, your doctor may limit your dose to 7.5 mg (one tablet) once a day.

Elderley patients.
If you are an elderly patient, the recommended dose in the long-term treatment of rheumatoid arthritis and ankylosing spondylitis is 7.5 mg (one tablet) once a day.

Patients with an increased risk of adverse reactions
If you are a patient with an increased risk of adverse reactions, your doctor will start the treatment at a dose of 7.5 mg (one tablet) per day.

Patients with kidney problems
If you are a patient on dialysis with severe kidney problems, your dose must not exceed 7.5 mg (one tablet) per day. No dose adjustment is required in patients with mild to moderate kidney problems.

Patients with liver problems
No dose adjustment is required in patients with mild to moderate liver problems.

Use in children and adolescents

This medicine should not be given to children or adolescents under 16 years of age.

If your think the effects of meloxicam are too strong or too weak, or if you do not see an improvement after several days, tell your doctor or pharmacist.

Method of administration

Oral.

Swallow the tablets with water or other drinks during meals. The tablet can be divided into equal doses.

If you take more meloxicam cinfa than you should

If you have taken too many tablets or you suspect an overdose, contact your doctor or go to the nearest hospital immediately.

The symptoms associated with acute overdose of NSAIDs are generally limited to:
- Lack of energy (lethargy)
- Drowsiness
- Nausea and vomiting
- Pain in the stomach area (epigastric pain).

These symptoms generally improve when you stop taking meloxicam. Bleeding may occur in the stomach or intestines (gastrointestinal bleeding).

Severe intoxication can cause serious adverse reactions (see section 4):
- High blood pressure (arterial hypertension)
- Acute kidney (renal) failure
- Altered liver function (hepatic insufficiency)
- Respiratory arrest or reduction (respiratory depression)
- Loss of consciousness (coma)
- Fits (seizures)
- Collapse of blood circulation (cardiovascular collapse)
- Cardiac arrest
- Immediate allergic reactions (hypersensitivity), including:

- fainting
- Shortness of breath
- Skin reactions

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount taken.

If you forget to take meloxicam cinfa:

Do not take a double dose to make up for a forgotten dose. Simply take your next dose at the right time.

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

4. Possible side effects

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

Stop taking meloxicam and immediately consult your doctors or the nearest hospital if you notice:

Any allergic reaction (hypersensitivity) that may occur in the form of:
- Skin reactions, such as itching (pruritus), formation of blisters on the skin or scaling, which may be skin rashes that can threaten the patient's life (Stevens-Johnson syndrome and toxic epidermal necrolysis), lesions in the soft tissues (lesions in mucous membranes) or erythema multiforme (see section 2).
  Erythema multiforme is a serious allergic reaction of the skin that causes marks, red wheals or purple areas with blisters. It can also affect the mouth, eyes and other moist areas of the body.
- Inflammation of the skin or mucous membranes such as inflammation around the eyes, face and lips, mouth or throat, possibly hindering breathing, swollen ankles/legs (oedema of the lower limbs)
- Shortness of breath or asthma attacks
- Inflammation of the liver (hepatitis). This can cause symptoms such as:
- Yellowing of the skin or the eyes (jaundice)
- Abdominal pain
- Loss of appetite

Any adverse effects of the digestive tract, especially:
- Bleeding (causing black stools)
- Ulcers of the digestive tract (causing abdominal pain)

Bleeding of the digestive tract (gastrointestinal haemorrhage), formation of ulcers or holes in the digestive system (perforation) may sometimes be severe and potentially fatal, especially in elderly patients.

If you have previously suffered any symptom of the digestive tract due to prolonged use of NSAIDs, request medical advice immediately, especially if you are elderly. Your doctor can monitor your evolution while you are in treatment.

If you suffer altered vision, do not drive or use machines.

General adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs)

The use of some non-steroidal anti-inflammatory drugs (NSAIDs) can be linked to a slight increase in the risk of blocked arteries (arterial thrombotic event), e.g. heart attack (myocardial infarction) or stroke (apoplexy), particularly at higher doses and in long-term treatment.

Cases have been reported of fluid retention (oedema), high blood pressure (hypertension) and heart failure (cardiac failure) linked to treatment with NSAIDs.

The adverse reactions observed most commonly affect the digestive tract (gastrointestinal adverse events):
- ulcers of the stomach and upper part of the small intestine (peptic/gastroduodenal ulcers)
- holes in the intestinal wall (perforation) or bleeding of the digestive tract (sometimes fatal, especially in elderly patients).

After the administration of NSAIDs the following adverse reactions have been reported:
- Nausea and vomiting
- Liquid stools (diarrhoea)
- Flatulence
- constipation
- Indigestion (dyspepsia)
- abdominal pain
- Black stools due to bleeding in the digestive tract (melena)
- Vomiting blood (haematemesis)
- Inflammation of the mouth with ulcers (ulcerative stomatitis)
- Worsening of the inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease).

Less frequently, inflammation of the stomach (gastritis) has been observed.

Adverse effects of meloxicam active substance of this medicine

Very common: may affect more than 1 in 10 patients
- gastrointestinal adverse effects such as indigestion (dyspepsia), nausea and vomiting, abdominal pain, constipation, flatulence, liquid stools (diarrhoea)

Common: may affect up to 1 in 10 patients
- headache

Uncommon: may affect up to 1 in 100 patients
- Dizziness (sensation of lightheadedness)
- Sensation of dizziness or spinning (vertigo)
- Drowsiness
- Anaemia (reduction in the amount of the pigmentation of the red cells called haemoglobin)
- Increased blood pressure (hypertension)
- Hot flushes (temporary reddening of the face and neck)
- Water and sodium retention
- Increased potassium levels (hyperkalaemia). This can cause symptoms such as:
- Altered heartbeat (arrhythmias)
    - Palpitations (when you notice your heartbeat more than usual)
    - Muscle weakness
    - Belching
- Inflammation of the stomach (gastritis)
- Bleeding of the digestive tract
- Inflammation of the mouth (stomatitis)
- Immediate allergic reactions (hypersensitivity)
    - Itching (pruritus)
- Skin reactions
- Inflammation caused by fluid retention (oedema), including swollen ankles/legs (oedema of the lower limbs)
- Sudden inflammation of the skin or mucous membranes, such as inflammation around the eyes, face, lips, mouth or throat, possibly hindering respiration (angioedema)

- Transient alterations of liver function values (e.g. increased levels of liver enzymes such as transaminase or an increase in the biliary pigmentation, bilirubin). Your doctor can detect them with a simple blood test.
- Altered laboratory test results for kidney function (e.g. increased creatinine or urea).

Rare: may affect up to 1 in 1,000 patients
- Mood swings
- nightmares
- Abnormal blood count, including:
    - Abnormal differential blood count
    - Decrease in the number of white blood cells (neutropenia)
    - Reduced platelet count (thrombocytopenia)

These adverse effects can increase the risk of infection and cause symptoms such as bruising or nosebleeds.
- Ringing in the ears (tinnitus)
- Noticing your heartbeat (palpitations)
- Ulcers of the stomach and upper part of the small intestine (peptic/gastroduodenal ulcers)
- Throat inflammation (oesophagitis)
- The start of asthma attacks (observed in people allergic to acetylsalicylic acid (aspirin) or other NSAIDs)
- Severe formation of blisters on the skin or scaling (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- Urticaria
- Altered vision including:
    - blurred vision
    - Conjunctivitis (inflammation of the eye or eyelid)
- Inflammation of the large intestine (colitis)

Very rare: may affect up to 1 in 10,000 patients
- Vesicular skin reactions (formation of blisters) and reddening (erythema multiforme). Erythema multiforme is a serious allergic reaction of the skin that causes marks, red wheals or purple areas with blisters. It can also affect the mouth, eyes and other moist areas of the body.
- Inflammation of the liver (hepatitis). This can cause symptoms such as:
    - Yellowing of the skin or the eyes (jaundice)
    - Abdominal pain
    - Loss of appetite
- Acute renal insufficiency (kidney failure) specifically in patients with risk factors such as heart disease, diabetes or kidneys disease
- A hole in the intestinal wall (perforation).

Not known: frequency cannot be estimated from the available data
- confusion
- disorientation
- Breathlessness and skin reactions (anaphylactic/anaphylactoid reactions) due to exposure to sunlight (photosensitivity reactions)
- Heart failure has been described (cardiac insufficiency) linked to treatment with NSAIDs
- Complete loss of certain types of white cells (agranulocytosis), especially in patients taking meloxicam in conjunction with other medicinal products that can inhibit, depress or potentially destroy a component of the bone marrow (myelotoxic medicinal products). This can cause:
- Sudden fever
- Sore throat
- Infection
- Inflammation of the pancreas (pancreatitis)
- Infertility in women, delayed ovulation.

Adverse effects caused by other non-steroidal anti-inflammatory drugs (NSAIDs) that still have not been observed after taking meloxicam

Changes in the structure of the kidneys that causes acute kidney failure:
- Very rare cases of kidney inflammation (interstitial nephritis)
- Death of some kidney cells (acute tubular necrosis or papillae necrosis)
- Proteins in the urine (nephrotic syndrome with proteinuria).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 meloxicam cinfa

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

Do not store at a temperature above 25ºC.

Do not use this medicine after the expiry date which is stated on the container 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 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, carboxymethyl starch (type A) (of potato).

What the product looks like and contents of the pack

Cylindrical, biconvex, scored yellow tablets marked with the code "M7" on one side.

It is supplied in PVC-PVDC/Aluminium blisters. Each pack contains 20 tablets.

Marketing authorisation holder and manufacturer:
Laboratorios Cinfa, S.A.
C/ Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte (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 last revised in: June 2021

Package leaflet: information for the user

meloxicam cinfa 15 mg tablets

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- This medicinal product 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 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 meloxicam cinfa is and what it is used for

Meloxicam cinfa contains the active ingredient meloxicam. Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) used to reduce inflammation and pain in joints and muscles.

Meloxicam is indicated for adults and children aged 16 years and over. Meloxicam is used for the:
- Short-term treatment of arthrosis (osteoarthrosis) attacks
- Long-term treatment of
  - Rheumatoid arthritis
  - Ankylosing spondylitis

2. What you need to know before you take meloxicam cinfa

Do not take meloxicam cinfa
- If you are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- In the last three months of pregnancy
- Children and adolescents under 16 years of age
- If you have had any of the following disorders after taking acetylsalicylic acid (aspirin) or other NSAIDs:
  - wheezing, tightness in the chest, shortness of breath (asthma)
  - blocked nose due to inflammation of the internal part of the nose (nasal polyps)
  - Skin rashes, urticaria
  - Sudden inflammation of the skin or mucous membranes, such as inflammation around the eyes, face, lips, mouth or throat, possibly hindering respiration (angioedema)
- If after previous therapy with NSAIDs you presented:
  - Bleeding in the stomach or intestines
  - Perforations in the stomach or intestines
- Ulcers or bleeding in the stomach or intestines
- If you have recently or ever had stomach or peptic ulcers or bleeding (ulcers or bleeder that have occurred at least twice)
- Severe deterioration of liver function

- Severe non-dialysed renal failure
- Recent bleeding in the brain (cerebrovascular haemorrhage)
- Any type of bleeding disorders
- Severe heart failure
- Intolerance to some sugars as this medicine contains lactose (see also “meloxicam cinfa contains lactose”).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking meloxicam cinfa.

Warnings

Medicines like meloxicam 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 take more than the recommended dose. Do not take meloxicam for longer than prescribed (see section 3 “How to take meloxicam cinfa”).

If you have heart problems, a history of stroke, or if you think you might be at risk of suffering these conditions, talk to your doctor or pharmacist about the treatment.

For example if you:
- Have high blood pressure (hypertension)
- Have high levels of sugar in the blood (diabetes mellitus)
- Have high levels of LDL cholesterol in the blood (hypercholesterolaemia)
- Smoke

Immediately stop treatment with meloxicam as soon as you notice bleeding (that causes black stools) or ulcers in your digestive system (causing abdominal pain).

Skin rashes that may prove life-threatening for the patient (Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported when using meloxicam. 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 or 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, you should not use meloxicam again at any time.

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

Meloxicam is not suitable if you need immediate relief from acute pain.

Meloxicam can mask the symptoms of an infection (e.g. fever). If you believe you may have an infection, you must see a doctor.

Precautions for use

Since treatment adjustment will be necessary, it is important to ask the doctor for advice before taking meloxicam cinfa in cases of:
- Having suffered inflammation of the throat (oesophagitis), inflammation of the stomach (gastritis) or a history of any other disease of the digestive system, e.g. Crohn's disease, ulcerative colitis
- High blood pressure (arterial hypertension)
- Elderly patients
- Disease of the heart, liver or kidneys
- High levels of sugar in the blood (diabetes mellitus)
- Low blood volume (hypovolaemia) that can occur if you have suffered blood significant loss or serious burns, surgery or low intake of liquids
- Intolerance to any sugars diagnosed by your doctor, as this medicine contains lactose
- Higher levels of potassium in blood previously diagnosed by your doctor. Your doctor will have to monitor your evolution during the treatment.

Other medicines and meloxicam cinfa

Meloxicam may affect or be affected by other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Specifically, inform your doctor or pharmacist if you are taking/have taken or used any of the following medicines:
- Other NSAIDs
- Potassium salts (used to prevent or treat low levels of potassium in the blood)
- Tacrolimus (used after organ transplants)
- Trimethoprim (used to treat urinary tract infections)
- Medicines that prevent blood coagulation
- Medicines that dissolve blood clots (thrombolytics)
- Medicines for treating diseases of the heart and kidneys
- Corticosteroids (e.g. used in cases of inflammation or allergic reactions)
- Cyclosporine (used after organ transplants or for severe skin diseases, rheumatoid arthritis or nephrotic syndrome)
- Deferasirox (used to treat chronic iron caused excess by frequent blood transfusions)
- Any diuretic medicine (“tablets for urination”). Your doctor may monitor your kidney function if you are taking diuretics.
- Medicines for treating high blood pressure (e.g. Beta-blockers)
- Lithium (used to treat behavioural disorders).
- Selective serotonin reuptake inhibitors (SSRI) (used for treating depression).
- Methotrexate (used to treat tumours or severe uncontrolled disease of the skin and active rheumatoid arthritis)
- Pemetrexed (used to treat cancer)
- Cholestyramine (used to lower blood cholesterol levels)
- Oral antidiabetics (sulphonylureas, nateglinide) (used for treating diabetes. Your doctor must carefully monitor your blood sugar level for hypoglycaemia.)

Pregnancy, breast-feeding and fertility

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

Pregnancy

During the first and second trimester of pregnancy, your doctor will only prescribe this medicine for you if it is clearly necessary, due to the potential risk of miscarriage or malformation. In this case, the dose should be kept as low as possible and the duration of the treatment must be as short as possible.

During the 3 last months of pregnancy, this medicine is contraindicated: NEVER take this medicine because it can have severe or even fatal consequences for your baby, especially the heart, lungs and/or kidneys, even with one single administration.

If you have taken this medicine while pregnant, talk to your doctor/midwife immediately so appropriate monitoring can be considered.

Breast-feeding

It is advisable not to take this medicine during breast-feeding.

Fertility

This medicine may make it more difficult to become pregnant. You must tell your doctor if you intend to become pregnant or if you are having difficulty becoming pregnant.

Driving and using machines

This medicine can cause vision disturbances including blurred vision, dizziness, drowsiness, vertigo or other central nervous system disorders. If you notice these effects, do not drive or use machines.

Meloxicam cinfa contains lactose

This medicine contains lactose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

Meloxicam cinfa contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per tablet; it is essentially "sodium-free".

3. How to take meloxicam cinfa

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

The recommended dose is:

Arthrosis episodes:
7.5 mg of meloxicam (half a tablet) once a day. This can be increased to 15 mg of meloxicam (one tablet) once a day.

Rheumatoid arthritis:
15 mg of meloxicam (one tablet) once a day. This can be reduced to 7.5 mg of meloxicam (half a tablet) once a day.

Ankylosing spondylitis:
15 mg of meloxicam (one tablet) once a day. This can be reduced to 7.5 mg of meloxicam (half a tablet) once a day.

Do not exceed the maximum recommended dose of 15 mg a day.

If any of the situations described under the heading "**Warnings and precautions**" affects you, your doctor may limit your dose to 7.5 mg (half a tablet) once a day.

Elderly patients.
If you are an elderly patient, the recommended dose in the long-term treatment of rheumatoid arthritis and ankylosing spondylitis is 7.5 mg (half a tablet) once a day.

Patients with an increased risk of adverse reactions
If you are a patient with an increased risk of adverse reactions, your doctor will start the treatment at a dose of 7.5 mg (half a tablet) once a day.

Patients with kidney problems
If you are If you are a patient on dialysis with severe kidney problems, your dose must not exceed 7.5 mg (half a tablet) once a day. No dose adjustment is required in patients with mild to moderate kidney problems.

Patients with liver problems
No dose adjustment is required in patients with mild to moderate liver problems.

Use in children and adolescents
This medicine should not be given to children or adolescents under 16 years of age.

If your think the effects of meloxicam are too strong or too weak, or if you do not see an improvement after several days, tell your doctor or pharmacist.

Method of administration

Oral.

Swallow the tablets with water or other drinks during meals.

The tablet can be divided into equal doses.

If you take more meloxicam cinfa than you should

If you have taken too many tablets or you suspect an overdose, contact your doctor or go to the nearest hospital immediately.

The symptoms associated with acute overdose of NSAIDs are generally limited to**:**
- Lack of energy (lethargy)
- Drowsiness
- Nausea and vomiting
- Pain in the stomach area (epigastric pain).

These symptoms generally improve when you stop taking meloxicam. Bleeding may occur in the stomach or intestines (gastrointestinal bleeding).

Severe intoxication can cause serious adverse reactions (see section 4):
- High blood pressure (arterial hypertension)
- Acute kidney (renal) failure
- Altered liver function (hepatic insufficiency)
- Respiratory arrest or reduction (respiratory depression)
- Loss of consciousness (coma)
- Fits (seizures)
- Collapse of blood circulation (cardiovascular collapse)
- Cardiac arrest
- Immediate allergic reactions (hypersensitivity), including:
    - fainting
    - Shortness of breath
    - Skin reactions

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount taken.

If you forget to take meloxicam cinfa:

Do not take a double dose to make up for a forgotten dose. Simply take your next dose at the right time.

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

4. Possible side effects

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

Stop taking meloxicam and immediately consult your doctors or the nearest hospital if you notice:

Any allergic reaction (hypersensitivity) that may occur in the form of:
- Skin reactions, such as itching (pruritus), formation of blisters on the skin or scaling, which may be skin rashes that can threaten the patient's life (Stevens-Johnson syndrome and toxic epidermal necrolysis), lesions in the soft tissues (lesions in mucous membranes) or erythema multiforme (see section 2).
- Erythema multiforme is a serious allergic reaction of the skin that causes marks, red wheals or purple areas with blisters. It can also affect the mouth, eyes and other moist areas of the body.
- Inflammation of the skin or mucous membranes such as inflammation around the eyes, face and lips, mouth or throat, possibly hindering breathing, swollen ankles/legs (oedema of the lower limbs)
- Shortness of breath or asthma attacks
- Inflammation of the liver (hepatitis). This can cause symptoms such as:
    - Yellowing of the skin or the eyes (jaundice)
    - Abdominal pain
    - Loss of appetite

Any adverse effects of the digestive system, especially:
- Bleeding (causing black stools)
- Ulcers in the digestive system (causing abdominal pain).

Bleeding of the digestive system (gastrointestinal haemorrhage), formation of ulcers or holes in the digestive system (perforation) may sometimes be severe and potentially fatal, especially in elderly patients.

If you have previously suffered any symptom of the digestive system due to prolonged use of NSAIDs, request medical advice immediately, especially if you are elderly. Your doctor can monitor your evolution while you are in treatment.

If you suffer altered vision, do not drive or use machines.

General adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs)

The use of some non-steroidal anti-inflammatory drugs (NSAIDs) can be linked to a slight increase in the risk of blocked arteries (arterial thrombotic event), e.g. heart attack (myocardial infarction) or stroke (apoplexy), particularly at higher doses and in long-term treatment.

Cases have been reported of fluid retention (oedema), high blood pressure (hypertension) and heart failure (cardiac failure) linked to treatment with NSAIDs.

The adverse reactions observed most commonly affect the digestive system (gastrointestinal adverse events):
- ulcers of the stomach and upper part of the small intestine (peptic/gastroduodenal ulcers)
- holes in the intestinal wall (perforation) or bleeding of the digestive tract (sometimes fatal, especially in elderly patients).

After the administration of NSAIDs the following adverse reactions have been reported:
- Nausea and vomiting
- Liquid stools (diarrhoea)
- Flatulence
- constipation
- Indigestion (dyspepsia)
- abdominal pain
- Black stools due to bleeding in the digestive tract (melena)
- Vomiting blood (haematemesis)
- Inflammation of the mouth with ulcers (ulcerative stomatitis)
- Worsening of the inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease).

Less frequently, inflammation of the stomach (gastritis) has been observed.

Adverse effects of meloxicam, the active substance of this medicine

Very common: may affect more than 1 in 10 patients
- gastrointestinal adverse reactions such as indigestion (dyspepsia), nausea and vomiting, abdominal pain, constipation, flatulence, liquid stools (diarrhoea)

Common: may affect up to 1 in 10 patients
- headache

Uncommon: may affect up to 1 in 100 patients
- Dizziness (sensation of lightheadedness)
- Sensation of dizziness or spinning (vertigo)
- Drowsiness
- Anaemia (reduction in the amount of the pigmentation of the red cells called haemoglobin)
- Increased blood pressure (hypertension)
- Hot flushes (temporary reddening of the face and neck)
- Water and sodium retention
- Increased potassium levels (hyperkalaemia). This can cause symptoms such as:
  - Altered heartbeat (arrhythmias)
  - Palpitations (when you notice your heartbeat more than usual)
  - Muscle weakness
- Belching
- Inflammation of the stomach (gastritis)
- Bleeding of the digestive system
- Inflammation of the mouth (stomatitis)
- Immediate allergic reactions (hypersensitivity)
- Itching (pruritus)
- Skin reactions
- Inflammation caused by fluid retention (oedema), including swollen ankles/legs (oedema of the lower limbs)
- Sudden inflammation of the skin or mucous membranes, such as inflammation around the eyes, face, lips, mouth or throat, possibly hindering respiration (angioedema)
- Transient alterations of liver function values (e.g. increased levels of liver enzymes such as transaminase or an increase in the biliary pigmentation, bilirubin). Your doctor can detect them with a simple blood test.

- Altered laboratory test results for kidney function (e.g. increased creatinine or urea).

Rare: may affect up to 1 in 1,000 patients
- Mood swings
- nightmares
- Abnormal blood count, including:
    - Abnormal differential blood count
    - Decrease in the number of white blood cells (neutropenia)
    - Reduced platelet count (thrombocytopenia)

  These adverse effects can increase the risk of infection and cause symptoms such as bruising or nosebleeds.
- Ringing in the ears (tinnitus)
- Noticing your heartbeat (palpitations)
- Ulcers of the stomach and upper part of the small intestine (peptic/gastroduodenal ulcers)
- Throat inflammation (oesophagitis)
- The start of asthma attacks (observed in people allergic to acetylsalicylic acid (aspirin) or other NSAIDs)
- Severe formation of blisters on the skin or scaling (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- Urticaria
- Altered vision including:
    - blurred vision
    - Conjunctivitis (inflammation of the eye or eyelid)
- Inflammation of the large intestine (colitis)

Very rare: may affect up to 1 in 10,000 patients
- Vesicular skin reactions (formation of blisters) and reddening (erythema multiforme).
- Erythema multiforme is a serious allergic reaction of the skin that causes marks, red wheals or purple areas with blisters. It can also affect the mouth, eyes and other moist areas of the body.
- Inflammation of the liver (hepatitis). This can cause symptoms such as:
    - Yellowing of the skin or the eyes (jaundice)
    - Abdominal pain
    - Loss of appetite
- Acute renal insufficiency (kidney failure) specifically in patients with risk factors such as heart disease, diabetes or kidneys disease
- A hole in the intestinal wall (perforation).

Not known: frequency cannot be estimated from the available data
- confusion
- disorientation
- Breathlessness and skin reactions (anaphylactic/anaphylactoid reactions) due to exposure to sunlight (photosensitivity reactions)
- Heart failure has been described (cardiac insufficiency) linked to treatment with NSAIDs
- Complete loss of certain types of white cells (agranulocytosis), especially in patients taking meloxicam in conjunction with other medicinal products that can inhibit, depress or potentially destroy a component of the bone marrow (myelotoxic medicinal products). This can cause:
    - Sudden fever
    - Sore throat
    - Infection
    - Inflammation of the pancreas (pancreatitis)
    - Infertility in women, delayed ovulation

Adverse effects caused by other non-steroidal anti-inflammatory drugs (NSAIDs) that still have not been observed after taking meloxicam

Changes in the structure of the kidneys that causes acute kidney failure:
- Very rare cases of kidney inflammation (interstitial nephritis)

- Death of some kidney cells (acute tubular necrosis or papillae necrosis)
- Proteins in the urine (nephrotic syndrome with proteinuria).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 meloxicam cinfa

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

Do not store at a temperature above 25ºC.

Do not use this medicine after the expiry date which is stated on the container 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 containers and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and 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, carboxymethyl starch (type A) (of potato).

What the product looks like and contents of the pack

Cylindrical, biconvex, scored yellow tablets marked with the code "M1" on one side.

It is supplied in PVC-PVDC/Aluminium. Each pack contains 20 tablets.

Marketing authorisation holder and manufacturer:
Laboratorios Cinfa, S.A.
C/ Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte (Navarre)-Spain

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