PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LIEVOCAM 4 mg film-coated tablets

LIEVOCAM 8 mg film-coated tablets

Lornoxicam

Contains sugar:

LIEVOCAM 4 mg: contains 45 mg lactose monohydrate.

LIEVOCAM 8 mg: contains 90 mg lactose monohydrate.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LIEVOCAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What LIEVOCAM is and what it is used for

LIEVOCAM is a nonsteroidal anti-inflammatory drug (NSAID) and antirheumatic medicine. It is intended for short-term treatment of acute mild to moderate pain and symptomatic relief of pain

and inflammation in rheumatoid arthritis and osteoarthritis.

2. What you need to know before you take LIEVOCAM

Do not take LIEVOCAM if you

- Are hypersensitive (allergic) to lornoxicam or any of the other ingredients of LIEVOCAM (listed in section 6 of this leaflet).
- Are hypersensitive to other NSAIDs including acetylsalicylic acid (for instance, aspirin).
- Suffer from thrombocytopenia (low blood platelet count which increases risk of bleeding or bruising).
- Suffer from heart failure.
- Suffer from gastrointestinal bleeding, rupture and bleeding of a blood vessel in the brain, or other bleeding disorders.
- Have a history of gastrointestinal bleeding or perforation, related to previous therapy with NSAIDs.
- Suffer from an active peptic ulcer or have a history of recurrent peptic ulcer.
- Suffer from severe liver impairment.
- Suffer from severe kidney impairment.
- Are pregnant or breastfeeding.
- Are older than 65 years, weigh less than 50 kg or are undergoing acute surgery.
- Are a child under 18 years of age.

Warnings and precautions

Tell your doctor before taking LIEVOCAM if you:

- Have impaired kidney function.
- Have a history of high blood pressure and/or heart failure.
- Suffer from ulcerative colitis or Crohn’s disease.
- Have a history of bleeding tendency.
- Have a history of asthma.
- Suffer from SLE (lupus erythematosus, a rare immunological disease).

Your doctor may have to monitor you using laboratory tests on a frequent basis if you:

- Suffer from blood coagulation disorder.
- Suffer from impaired liver function.
- Are above 65 years of age.
- Will be treated with LIEVOCAM for more than 3 months.

You should inform your doctor if you are going to be treated with heparin or tacrolimus, while taking LIEVOCAM at the same time.

If you experience any unusual abdominal symptoms such as abdominal bleeding, skin reactions such as skin rash, damage to the internal lining of the nostrils, mouth, eyelids, ears, genitals or anus, or other signs of hypersensitivity, you should stop taking LIEVOCAM and contact your doctor immediately.

Medicines such as LIEVOCAM may be associated with a small increase of the risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or the duration of treatment.

You should discuss your treatment with your doctor or pharmacist if you:

- Have heart problems.
- Have previously had a stroke.
- Think that you might be at risk of developing these conditions (for example, if you have high blood pressure, diabetes or high cholesterol, or you are a smoker).

If you develop symptoms such as a fever, rash, swelling of your lymph nodes and/or swelling of your face, you may be suffering from a reaction called “drug reaction with eosinophilia and systemic symptoms” (DRESS). This reaction has been reported in people taking medicines to treat pain and inflammation called NSAIDs (nonsteroidal anti-inflammatory drugs). Inflammation of the liver and kidneys may occur, as well as abnormalities of the blood, inflammation of the heart muscle or other muscles in the body. The symptoms of this reaction are sometimes similar to having a virus infection. There often is an increase in disease-fighting white blood cells

(eosinophils) in the blood. You may initially develop fever and swelling of your lymph nodes without a rash being present. If you notice any of these signs or symptoms, contact your doctor immediately as you need to stop taking LIEVOCAM and be examined by your doctor.

Avoid using LIEVOCAM during varicella (chickenpox) infections.

Children and adolescents

LIEVOCAM is not recommended for children and adolescents below 18 years of age.

Other medicines and LIEVOCAM

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

You should avoid using LIEVOCAM if you are taking other NSAIDs such as acetylsalicylic acid (for instance, aspirin), ibuprofen and COX-2 inhibitors. LIEVOCAM may interfere with other medicines. Be particularly careful if you are taking any of the following:

- Cimetidine (used in the treatment of heartburn and peptic ulcers).
- Anticoagulants, such as warfarin, heparin or phenprocoumon (used to prevent the formation of blood clots).
- Corticosteroids (used to treat infections).
- Methotrexate (used in treatment of cancer and immunological diseases).
- Lithium (used to treat depression).
- Immunosuppressive medicines, such as ciclosporin or tacrolimus.
- Heart medicines, such as digoxin, ACE inhibitors, beta-adrenergic blockers.
- Diuretics (medicines to help your body to get rid of water and salt).
- Quinolone antibiotics (e.g. levofloxacin, ofloxacin).
- Antiplatelet medicines, such as clopidogrel (used to prevent heart attacks and strokes).
- SSRIs (selective serotonin reuptake inhibitors) (used in the treatment of depression).
- Sulphonylureas, such as glibenclamide (used in the management of diabetes).

- Inducers and inhibitors of CYP2C9 isoenzymes (such as the antibiotic rifampicin or the antifungal medicine fluconazole), as they might have an effect on the way in which your body breaks down LIEVOCAM.
- Angiotensin II receptor blockers (used to treat high blood pressure, kidney damage due to diabetes and congestive heart failure).
- Pemetrexed (used to treat some forms of lung cancer).

LIEVOCAM with food and alcohol

See section 3.

Fertility, pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LIEVOCAM.

Pregnancy:

LIEVOCAM should not be used during pregnancy. If you use certain medicines called NSAIDs (nonsteroidal anti-inflammatory drugs) from 20 weeks or later during pregnancy, it may cause a rare but serious kidney disfunction in your baby, which can lead to too little amniotic fluid surrounding your baby, and in some cases, it can cause kidney impairment in your newborn baby. Complications of prolonged periods where too little amniotic fluid surrounds your baby, are reduced range of motion of limbs (limb contractures) and delayed maturing of the lungs.

Breastfeeding:

If you are breastfeeding, treatment with LIEVOCAM is not recommended.

Fertility:

Using LIEVOCAM may impair fertility and is not recommended for women attempting to become pregnant. Women who have difficulties becoming pregnant, or who are undergoing investigation of

infertility, should consult with a doctor and consider stopping treatment with LIEVOCAM.

Driving and using machines

You should refrain from driving or operating machinery should you feel dizzy or sleepy after taking LIEVOCAM.

LIEVOCAM contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LIEVOCAM.

3. How to take LIEVOCAM

Do not share any medicines prescribed for you with any other person.
Always take LIEVOCAM exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose for adults for treatment of pain is 8 mg to 16 mg, divided in two or three doses per day. Do not take more than 16 mg a day.
The dose for patients with arthritis is 12 mg, divided in two or three doses per day. Do not take more than 16 mg a day.

LIEVOCAM is intended for oral use. Take LIEVOCAM before meals with a sufficient amount of liquid. Do not take LIEVOCAM with a meal, as food can reduce the effectiveness of LIEVOCAM.

Your doctor will tell you how long your treatment with LIEVOCAM will last. If you have the impression that the effect of LIEVOCAM is too strong or too weak, tell your doctor or pharmacist.

If you take more LIEVOCAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and your remaining tablets with you so the

doctor can see what you have taken.

In case of an overdose, you may expect the following symptoms: nausea, vomiting, symptoms associated with the central nervous system (such as dizziness or disturbances in vision).

If you forget to take LIEVOCAM

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

LIEVOCAM can have side effects.

Not all side effects reported for LIEVOCAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LIEVOCAM, please consult your health care provider for advice.

If any of the following happens, stop taking LIEVOCAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Abdominal bleeding, skin reactions such as skin rash, damage to the internal lining of the nostrils, mouth, eyelids, ears, genitals or anus.

These are all very serious side effects. If you have them, you may have had a serious reaction to LIEVOCAM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Cardiac failure, irregular heartbeat, rapid heart rate, elevated blood pressure.
- Shortness of breath, difficulty in breathing, cough, bronchospasm.
- Chest pains, or ankle swelling appears or gets worse.
- Severe or continuous stomach pain or your stools become black.
- Perforated ulcer causing vomiting of blood, gastrointestinal bleeding, black tarry stools.
- Yellowing of the skin and eyes (jaundice), these are signs of liver problems.
- Urinary problems, such as the need to wake up and urinate during the night (nocturia) or an increase in the levels of urea and creatinine in the blood.
- Fever, blistering eruption or inflammation especially on hands and feet or in the mouth area, peeling of the skin.
- Inflammation of the lining of the brain (aseptic meningitis), with symptoms such as headache, fever and a stiff neck.
- Serious infections of the skin in case of varicella (chickenpox).
- Anaemia, reduction in the blood cell count (thrombocytopenia and leukopenia), weakness.
- Tremor, migraine, visual disturbances.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Mild and passing headaches and dizziness.
- Nausea, upset stomach, abdominal pain, diarrhoea, vomiting.
- Eye discharges (conjunctivitis).

Less frequent side effects:

- Sore throat.
- Feeling blushed, hot flushes.
- Weight loss (anorexia).
- Inability to sleep, depression, confusion, nervousness, agitation.
- Feeling dizzy (vertigo), ringing in the ears (tinnitus).

- Constipation, excessive wind (flatulence), belching, dry mouth, sores and ulcers in the mouth, vomiting blood.
- Inflammation in the mouth, oesophagitis (inflammation of the gullet), gastro-oesophageal reflux, difficulty in swallowing, inflammation of the tongue.
- Stuffy nose.
- Hair loss (temporary).
- Joint pain, bone pain, muscle cramp, muscle pain.
- Feeling sleepy (somnolence), paraesthesia (tingling sensations), abnormal sense of taste.
- Bleeding, prolonged bleeding time.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LIEVOCAM.

5. How to store LIEVOCAM

- Store at or below 25 °C in a dry place. Protect from light.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LIEVOCAM contains

The active ingredient is lornoxicam.

LIEVOCAM 4 mg: Each film-coated tablet contains 4 mg lornoxicam.

LIEVOCAM 8 mg: Each film-coated tablet contains 8 mg lornoxicam.

The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate.

LIEVOCAM 4 mg contains Opadry Yellow (consisting of hypromellose, iron oxide yellow, titanium dioxide and macrogol).

LIEVOCAM 8 mg contains Instacoat Universal White (consisting of hypromellose, polyethylene glycol, talc and titanium dioxide).

What LIEVOCAM looks like and contents of the pack

LIEVOCAM 4 mg: Yellow coloured, round shaped, bevelled edge, biconvex, film-coated tablet, plain on both sides.

LIEVOCAM 8 mg: White to light yellowish, oval, biconvex, film-coated tablet, plain on both sides.

Silver aluminium foil and white opaque PVC/PVDC blister packs containing 10 tablets each.

Pack sizes: 10, 20 or 100 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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