1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LORNBLOC 4 mg film-coated tablets

Lornoxicam

Contains sugar: 90 mg lactose monohydrate

LORNBLOC 8 mg film-coated tablets

Lornoxicam

Contains sugar: 90 mg lactose monohydrate

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LORNBLOC 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 LORNBLOC is and what it is used for
2. What you need to know before you take/use LORNBLOC.
3. How to take LORNBLOC.
4. Possible side effects
5. How to store LORNBLOC
6. Contents of the pack and other information

1. What LORNBLOC is and what it is used for

LORNBLOC is a non-steroidal anti-inflammatory drug (NSAID) and antirheumatic medicine of the oxicam class. It is intended for short term treatment of mild to moderate pain associated with inflammation outside the joints as well as symptoms of rheumatoid arthritis and osteoarthritis such as pain and inflammation of joints.

2. What you need to know before you take/use LORNBLOC

Do not take LORNBLOC

- If you are hypersensitive (allergic) to lornoxicam or any of the other ingredients of LORNBLOC (listed in section 6).
- If you are taking other nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin or e.g. diclofenac, ibuprofen and COX-2 inhibitors (e.g. celecoxib).
- If you have had pervious hypersensitivity reactions such as pain, tightness, and a feeling of constriction in the chest and back (bronchospasm), include runny nose congestion and sneezing (rhinitis), swelling and welts on the surface of the skin (angioedema) or itchy, raised, red or skin-coloured welts on the skin's surface (urticaria) when using non-steroidal anti-inflammatory medicines, including acetylsalicylic acid a medicine that treats fever and relieves mild to moderate pain.
- If you suffer from thrombocytopenia (low blood platelet count which increases risk of bleeding or bruising).
- If you have heart problems.
- If you suffer from digestive tract bleeding and/or bleeding of a blood vessel in the brain (cerebrovascular bleeding), or other bleeding disorders.
- If you have a medical history of gastrointestinal bleeding or perforation, related to previous therapy with NSAIDs.

- If you suffer from an active stomach ulcer or have a history of recurrent digestive tract ulcers.
- If you have liver problems.
- If you have kidney problems.
- If you are older than 65 years and weight less than 50 kg.
- If you have or need to undergo a surgical procedure.
- If you are pregnant or breastfeeding your baby.
- If you are under the age of 18 year.

Warnings and precautions

Special care should be taken with LORNBLOC:

- If you experience any unusual abdominal symptoms such as abdominal bleeding, skin reactions such as skin rash especially if this presents with fever and swelling of the glands and/or face, damage to the internal lining of the nostrils, mouth, eyelids, ears, genitals or anus, or other signs of hypersensitivity, you should stop taking LORNBLOC and contact your doctor immediately.
- If you have kidney problems.
- If you have a history of high blood pressure and have heart problems.
- If you suffer from ulcerative colitis or Crohn's disease.
- If you have a history of bleeding tendency.
- If you have a history of asthma.
- If you suffer from SLE (lupus erythematosus, a rare immunological disease).
- Your doctor may have to monitor you by laboratory tests on a frequent basis if
    - you suffer from blood coagulation disorder,
    - you suffer from impaired liver function,
    - you are elderly (65 years and above),
    - or you will be treated with LORNBLOC for more than 3 months.

- If you have an inherited disorder which causes a build-up of certain chemicals in your body (porphyria).
- Medicines such as LORNBLOC may be associated with an increase in the risk of having a 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,
- you had previously a stroke,
- or you 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).

- Avoid using LORNBLOC during varicella (chickenpox) infections.
- Use with caution if concomitant use is required with the following medicines:

  -Other NSAIDs (used to treat inflammatory conditions).

  -Heparin (used to prevent blood clotting).

  -Tacrolimus (used in patients who had organ transplants).

Other medicines and LORNBLOC

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

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

- Cimetidine, used in the treatment of heartburn and peptic ulcers, as concomitant use may result in higher concentrations of lornoxicam as contained in LORNBLOC.

- Anticoagulants, such as heparin (e.g. warfarin) used to prevent the formation of blood clots, as you may experience prolonged bleeding.
- Corticosteroids, other non-steroidal anti-inflammatory medicines and aspirin , used to reduce inflammation, as this may lead to an increased risk of developing holes and sores in the lining of your digestive tract.
- Methotrexate, used in treatment of cancer and immunological diseases, as this may lead to an increased concentration of methotrexate which may lead to toxicity.
- Immunosuppressive medicines, such as ciclosporin or tacrolimus, as this may lead to an increased risk of kidney toxicity.
- Heart medicines such as digoxin, ACE inhibitors (e.g. perindopril), Angiotensin II receptor blockers (e.g. telmisartan), beta-adrenergic blockers (e.g. atenolol), water tablets (e.g. furosemide) and amiodarone, as there may be a decreased effect of these heart medicines.
- Lithium, used for mood disorders, as this may lead to lithium toxicity.
- Medicines used to treat tuberculosis (TB) such as rifampicin.
- Sulphonylureas, used in the management of diabetes, as this may lead to a decrease in the blood sugar lowering effect of sulfonylureas.
- Antimicrobial medicines and antifungal medicines such as miconazole.
- Other non-steroidal anti-inflammatory medicines such as diclofenac, ibuprofen and aspirin.

- SSRI (Selective Serotonin Reuptake Inhibitors), used in the treatment of depression, as you may experience prolonged bleeding.
- Tranylcypromine, used in the treatment of depression.

- Quinolone antibiotics which treat respiratory tract infections, skin infections and urinary tract infections such as ciprofloxacin and/or moxifloxacin, and phenytoin (used to treat epilepsy), as this may lead to an increase in the risk to develop seizures (convulsions).
- Pemetrexed, used in the treatment of e.g. lung cancer.

Pregnancy, breastfeeding and fertility

You should not take LORNBLOC if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking LORNBLOC.

Driving and using machines

It is not always possible to predict to what extent LORNBLOC may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LORNBLOC affects you.

Since adverse reactions such as dizziness or sleepiness have been reported in patients receiving LORNBLOC, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that LORNBLOC does not adversely affect your ability to do so (see Possible side effects).

LORNBLOC contains lactose monohydrate

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

3. How to take LORNBLOC

Do not share medicines prescribed for you with any other person.

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

LORNBLOC must be swallowed with sufficient amounts of liquid. Do not take LORNBLOC with a meal, as food can reduce the effectiveness of LORNBLOC.

The dosage will depend on the condition being treated. The usual dosage of LORNBLOC is 8 mg to 16 mg per day given in 2 to 3 divided doses. The total daily dose should not exceed 16 mg.

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

Paediatric population

LORNBLOC is not recommended for children and adolescents below 18 years old.

If you take more LORNBLOC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs of an overdose can include: nausea and vomiting, dizziness, disorders with your co-ordination, balance and speech (ataxia), coma and cramps, liver and kidney damage, coagulation disorders (the body's ability to control clotting of the blood).

If you forget to take LORNBLOC

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

4. Possible side effects

LORNBLOC can have side effects.

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

If any of the following happens, stop taking LORNBLOC 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 with fever, swelling of your glands and face,
- rash or itching (urticaria),
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).
- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to LORNBLOC.

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:

- Increased temperature, stiff neck, nausea and vomiting as these may be symptoms of aseptic meningitis (inflammation of the linings of the brain).

- Irregular heartbeat (palpitations) or increased heartbeat (tachycardia).
- Heart problems which can cause shortness of breath, increase in blood pressure (hypertension) or ankle swelling (cardiac failure).
- Difficulty in breathing; shortness of breath (dyspnoea).
- Blood in your stool as this may be due to bleeding in your digestive tract.
- Abnormal laboratory results which indicate e.g. low blood platelets, red blood cells or white blood cells and/or increased liver enzymes.
- Constriction of air passages which causes difficulty breathing, coughing, wheezing and chest tightness (bronchospasm and symptoms of irritation in the airway).
- Hepatotoxicity resulting in e.g. liver failure (hepatic failure), inflammation of the liver (hepatitis), yellow pigmentation of skin and eyes; yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice) and Failure of normal amounts of bile to reach the intestine resulting in obstructive jaundice (cholestasis).
- Swelling in your feet and ankles, increased urination, muscle cramps as these may be symptoms of kidney failure.

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:

- Headache and dizziness;
- nausea, stomach pain, indigestion (dyspepsia), diarrhoea, vomiting.

Less frequent side effects:

- Lack/loss of appetite (anorexia) or weight changes;
- inability to sleep (insomnia), feeling abnormally sad or down (depression), confusion, nervousness, agitation;

- sleepiness (somnolence); abnormal taste (dysgeusia), an unintentional muscle movement involving to-and-fro movements (oscillations) of one or more parts of the body (tremor), migraine;
- inflammation of conjunctiva/membrane of the eye (conjunctivitis); visual disturbances;
- light-headedness and loss of balance (vertigo);
  ringing in the ears (tinnitus);
- reddening of the face and/or neck (flushing); bleeding (haemorrhage); collection of blood outside the blood vessels, usually in liquid form within the tissue (haematoma);
- runny nose; cough;
- difficulty passing stools (constipation);
- excess amount of air/gas in the stomach (flatulence);
- burping (eructation), dry mouth;
- inflammation of the stomach (gastritis);
- sores in the mouth,
- inflammation of the tongue (glossitis);
- difficulty in swallowing (dysphagia);
- joint pains (arthralgia), bone pain, muscle spasms/ pain (myalgia);
- increased need to urinate at night (nocturia);
- problems with bladder control, frequency of urination, as well as the volume and composition of urine (micturition).

Side effects with an unknown frequency

- cramps in legs,
- changes in appetite,
- increased sweating.

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, pharmacist or nurse. You can also report side effects to

SAHPRA: via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of LORNBLOC.

5. How to store LORNBLOC

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LORNBLOC contains

The active substance is 4 mg or 8 mg lornoxicam.

The other ingredients are croscarmellose sodium, hypromellose (E464), lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, povidone, titanium dioxide (E171).

Contains sugar: Lactose monohydrate 90 mg

What LORNBLOC looks like and contents of the pack

LORNBLOC 4 mg is a white to yellowish, oblong film-coated tablet, debossed with "E04" on one side and plain on the other side.

LORNBLOC 8 mg is a white to yellowish, oblong film-coated tablet, debossed with "E05" on one side and plain on the other side.

Clear polyvinylchloride/polyethylene/polyvinylidene chloride/aluminium blisters with 10 tablets per blister strip. 2 or 10 blister strips are packed into a carton in pack sizes of 20 or 100 tablets.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

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Registration number

LORNBLOC 4 mg: 48/3.1/0735

LORNBLOC 8 mg: 48/3.1/0736

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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