

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 medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms of illness are the same as yours.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflets please tell your doctor or pharmacist.

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1.What Exxara is and what it is used for

- Exxara is a non-steroidal anti-inflammatory drug and antirheumatic drug (NSAID) of the oxicam class. It is intended for short term treatment of acute mild to moderate pain.
- **Exxara is indicated for adults 18 years of age and older.**

2. Before you take Exxara

Do not take Exxara

- If you are allergic to lornoxicam or any of the other ingredients of this medicine (listed in section 6);
- If you are taking other NSAIDs such as acetylsalicylic acid (for instance, aspirin); ibuprofen and COX-2 inhibitors;
- If you are hypersensitive to other NSAIDs including acetylsalicylic acid (for instance, aspirin);
- If you suffer from thrombocytopenia (low blood platelet count which increases risk of bleeding or bruising);
- If you suffer from severe heart failure;
- If you suffer from gastrointestinal bleeding, rupture and bleeding of a blood vessel in the brain, or other bleeding disorders;
- If you have a history of gastrointestinal bleeding or perforation, related to previous therapy with NSAIDs;
- If you suffer from an active peptic ulcer or have a history of recurrent peptic ulcer;
- If you suffer from severe liver impairment;
- If you suffer from severe kidney impairment;
- If you are in the last three months of your pregnancy.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Exxara. This is particularly important:
- If you have impaired kidney function;
- If you have a history of high blood pressure and/or heart failure;
- 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,
- Or you will be treated with Exxara for more than 3 months.

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

- 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 Exxara and contact your doctor immediately.

- Medicines such as Exxara 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,
- 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 Exxara during varicella (chickenpox) infections.**

Other medicines and Exxara

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

- Do not take Exxara if you are taking other NSAIDs such as **acetylsalicylic acid** (for instance, aspirin), **ibuprofen** and **COX-2 inhibitors**. Ask your doctor or pharmacist if you are uncertain.
Exxara 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 heparin or phenprocoumon - used to prevent the formation of blood clots;
- Corticosteroids;
- Methotrexate - used in treatment of cancer and immunological diseases;
- Lithium;
- Immunosuppressive agents, such as ciclosporin or tacrolimus;
- Heart medicines, such as digoxin, ACE-inhibitors, beta-adrenergic blockers;
- Diuretics;

- Quinolone antibiotics;
- Anti-platelet agents - medicines used to prevent heart attacks and strokes;
- SSRI (Selective Serotonin Reuptake Inhibitors) – used in the treatment of depression;
- Sulphonylureas, for instance 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 Exxara;
- Angiotensin II receptor blocker - used to treat high blood pressure, kidney damage due to diabetes and congestive heart failure;
- Pemetrexed - used to treat some forms of lung cancer.

Exxara with food and drink

- Exxara film-coated tablets are intended for oral use. Take this medicine before meals with a sufficient amount of liquid.
- Taking this medicine with food is not recommended because this may reduce its effectiveness.

Pregnancy, breast-feeding and fertility

- 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.
- Fertility*
- **Using Exxara 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 Exxara.
- Pregnancy*
- During the first 6 months of pregnancy treatment with Exxara is not recommended, unless explicitly advised by your doctor.
- You must not take Exxara during the last three months of your pregnancy.

Breast-feeding

- If you are breast-feeding treatment with Exxara is not recommended, unless explicitly advised by your doctor.

Driving and using machines

- Exxara has negligible or no influence on the ability to drive or use machinery.

3.How to take Exxara

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose for adults is 8-16 mg divided in doses of 8 mg: 8 mg taken twice a day or 16 mg taken once a day.
- On the first day you take Exxara the dose can be 16 mg followed by 8 mg 12 hours later. After the first day do not take more than 16 mg a day.
- Exxara tablets must be swallowed with sufficient amounts of liquid. **Do not take Exxara with a meal, as food can reduce the effectiveness of Exxara.**
- Exxara is not recommended for children and adolescents below 18 years old, due to lack of data on safety and efficacy.

If you take more Exxara than you should

- Please contact your doctor or the pharmacist if you have taken more Exxara than prescribed.
- In case of an overdose, you may expect the following symptoms: nausea, vomiting, symptoms associated with central nervous system (such as dizziness or disturbances in vision).

If you forget to take Exxara

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

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

4.Possible side effects

- Like all medicines, this medicine can cause side effects, although not everybody gets them.
- Medicines such as Exxara may be associated with a small increase in the risk of **heart attack or stroke**.
- 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 Exxara and contact your doctor immediately.
- If you get any of the following side effects, **stop taking this medicine and tell your doctor immediately**, or **contact the emergency department** at your nearest hospital:
 - Shortness of breath, chest pains, or ankle swelling appear or get worse;
 - Severe or continuous stomach pain or your stools become black;
 - Yellowing of the skin and eyes (jaundice) – these are signs of liver problems;
 - An allergic reaction - which can include skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing;
 - Fever, blistering eruption or inflammation especially on hands and feet or in the mouth area (Stevens-Johnson syndrome);
 - Exceptionally, serious infections of the skin in case of varicella (chickenpox). Undesirable effects associated with using Exxara are given below.

Common side effects (may affect up to 1 in 10 people)

- Mild and passing headache and dizziness,
- Nausea, abdominal pain, upset stomach, diarrhea and vomiting.

Uncommon side effects (may affect up to 1 in 100 people)

- Weight loss (anorexia), inability to sleep, depression;
- Eye discharges (conjunctivitis);
- Feeling dizzy, ringing in the ears (tinnitus);
- Cardiac failure, irregular heartbeat, heart rate, feeling blushed;
- Constipation, excessive wind (flatulence), belching, dry mouth, gastritis, peptic ulcer, upper abdominal pain, duodenal ulcer, mouth ulcers;
- Increase in liver function tests (as seen from blood tests) and feeling unwell (malaise);
- Rash, itching, increased sweating, redness of the skin (erythema), angioedema (swelling of the deeper layers of skin, usually of the face), hives (urticaria), oedema, stuffy nose as a result of an allergy (rhinitis);
- Hair loss;
- Arthralgia (pain in the joints).

Rare side effects (may affect up to 1 in 1,000 people)

- Sore throat;
- Anaemia, reduction in the blood cell count (thrombocytopenia and leukopenia), weakness;

- Hypersensitivity, anaphylactoid reaction and anaphylaxis (organism reaction characterized usually by face swelling, flushing, difficulties breathing and lightheadedness);
- Confusion, nervousness, agitation, feeling sleepy (somnolence), paraesthesia (tingling sensations), abnormal sense of taste, tremor, migraine, visual disturbances;
- Elevated blood pressure, hot flush;
- Bleeding, haematoma (bruising), prolonged bleeding time;
- Difficulty in breathing (dyspnoea), cough, bronchospasm;
- Perforated ulcer, vomiting of blood, gastrointestinal bleeding, black tarry stools;
- Inflammation in the mouth, oesophagitis (inflammation of the gullet), gastro-oesophageal reflux, difficulty in swallowing, aphthous stomatitis (ulcers), inflammation of the tongue,
- Abnormal liver function;
- Skin problems, such as eczema, rash;
- Bone pain, muscle cramp, muscle pain;
- 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.

Very rare side effects (may affect up to 1 in 10,000 people)

- liver damage, hepatitis (inflammation of the liver), jaundice, cholestasis (interrupted flow of bile from the liver);
- Bruising, oedema, severe skin disorder (Stevens-Johnson syndrome, Toxic epidermal necrolysis);
- Aseptic meningitis;
- NSAID class effects: neutropenia, agranulocytosis, aplastic anaemia, hemolytic anaemia, kidney toxicity.

To report any side effect(s):

- Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

• Other GCC States:

Please contact the relevant competent authority.

5.How to store Exxara

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

- Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the carton or on the blister 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 to protect the environment.

6.Further information

a) What Exxara contains

- The active substance is lornoxicam
- One film-coated tablet contains 8 mg lornoxicam
- The other ingredients are:

Core: Lactose monohydrate, Microcrystalline cellulose PH-101, Microcrystalline cellulose PH-102, Povidone K30, Croscarmellose sodium, Magnesium stearate.
Film: Macrogol, Titanium dioxide (E171), Talc, Hypromellose.

b) What Exxara looks like and contents of the pack

- Exxara 8 mg is white, oval, biconvex film coated tablet.
- Exxara is distributed in pack sizes of 20 film-coated tablets.

c) Marketing Authorisation Holder and Manufacturer:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)
P.O.Box 4180 Riyadh 11491, Kingdom of Saudi Arabia
2nd Industrial City, Riyadh, Kingdom of Saudi Arabia
Tel: +966 (11) 2653948 -2653427
Fax: +966 (11) 2654723

For further information about this medicinal product, or to report a suspected adverse drug event please contact the Marketing authorization Holder.
E-mail: pharmacovigilance@avalon.com.sa
Call: +966 (11) 4635247, Ext: 3328

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d) Shelf life: 24 months

THIS IS A MEDICAMENT
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. -The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the period of treatment prescribed for you. - Do not repeat the same prescription without consulting your doctor. -Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists

