PATIENT INFORMATION LEAFLET FOR EXXIB

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SCHEDULING STATUS: S3

EXXIB 60, 90 and 120 Film coated tablets

Etoricoxib

EXXIB 60: Contains sugar (1,68 mg lactose monohydrate per tablet).

EXXIB 90: Contains sugar (2,52 mg lactose monohydrate per tablet).

EXXIB 120: Contains sugar (3,36 mg lactose monohydrate per tablet).

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

- 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.
- EXXIB 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 EXXIB is and what it is used for

2. What you need to know before you take EXXIB

3. How to take EXXIB

4. Possible side effects

5. How to store EXXIB

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1. What EXXIB is and what it is used for

PATIENT INFORMATION LEAFLET FOR EXXIB

EXXIB is a member of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) that are used to reduce pain and inflammation. EXXIB is a selective COX-2 inhibitor.

Your doctor has prescribed EXXIB for:

- Relief of symptoms of rheumatoid arthritis
- Treatment of ankylosing spondylitis
- Treatment of gout attacks
- Short term relief of acute pain, treatment limited to a maximum period of 8 days
- Treatment of acute pain after dental surgery
- Treatment of menstrual pain.

EXXIB does not cure arthritis.

2. What you need to know before you take EXXIB

Do not take EXXIB:

- If you are allergic (hypersensitive) to etoricoxib, or any of the inactive ingredients of EXXIB (see section 6).
- If you have an active stomach ulcer or bleeding in the stomach or intestines.
- If you have a serious liver disorder.
- If you have a serious kidney disorder.
- If you have previously experienced any of the following after taking aspirin or other nonsteroidal anti-inflammatory medicines: asthma (wheezing or inability to breathe easily), nasal irritation, nasal polyps (overgrowths in the nose) or allergic symptoms such as swelling of the face, lips, tongue or throat and/or itching skin rash.
- If you have high blood pressure which has not been adequately controlled by treatment.

- If you are pregnant or breastfeeding.
- If you are under 16 years of age.
- If you have inflammatory bowel disease (characterised by inflammation of the bowel).
- If your doctor has diagnosed heart problems including heart failure (moderate or severe), chest pain (angina) or if you have had a heart attack, bypass surgery, narrow or blocked arteries of the extremities (peripheral arterial disease), or any kind of stroke (including mini-stroke or transient ischaemic attack). EXXIB may increase your risk of a heart attack and stroke and therefore it should not be taken if you have already had heart problems or a stroke.
- If you are having heart bypass surgery.
- If you are using lithium, a medicine used to treat depression.
- If you are using digoxin, a medicine used to treat various heart conditions.

Warnings and precautions

Take special care with EXXIB:

- If you have a history of stomach bleeding or ulcers (blood in your stools).
- If you are dehydrated, for example by a prolonged period of vomiting or diarrhoea.
- If you have a history of heart failure, heart attack, or any other form of heart disease.
- If you have narrow or blocked arteries of the extremities.
- If you have a history of stroke or mini-stroke.
- If you have a history of high blood pressure.
- If you have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.
- If you have a history of kidney disease.
- Dangerously low levels of potassium (hypokalaemia) and high levels of acid in the blood

(renal tubular acidosis - caused by the kidneys not removing acids from the blood into the urine as they should) have been reported when other NSAIDs medicines (such as ibuprofen) have been used for long periods of time at higher than recommended doses. Caution is advised with the use of EXXIB.

- If you have swelling due to fluid retention.
- If you have a history of liver disease.
- Serious skin reactions may occur with the treatment of EXXIB.
- If you are being treated for an infection. EXXIB can mask or hide a fever, which is a sign of infection.
- If you are elderly (over 65 years of age).
- If you are a woman trying to become pregnant.

There appears to be a higher risk of cardiovascular events with higher doses and longer duration of treatment.

Other medicines and EXXIB

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

The following medicines may cause an interaction when used in combination with EXXIB:

- Warfarin (used for the prevention of blood clots).
- Diuretics (water pills, used for the treatment of high blood pressure).
- ACE inhibitors and angiotensin receptor blockers (used to treat high blood pressure and heart failure).
- Aspirin (in low doses used as a blood thinner). EXXIB can be taken with low dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor.
- Aspirin (in high doses used to treat pain, fever and inflammation). Do not take high

doses of aspirin or other anti-inflammatory medicines while taking EXXIB.

- Ciclosporin or tacrolimus (used for suppressing the immune system).
- Lithium (used to treat depression).
- Methotrexate (used for suppressing the immune system, and often used in rheumatoid arthritis).
- Oral contraceptive pills (used to prevent unplanned pregnancies).
- Hormone replacement therapy.
- Digoxin (used for heart failure and irregular heart rhythm).
- Minoxidil (used to treat high blood pressure).
- Salbutamol (used to treat asthma).
- Ketoconazole (used for the treatment of fungal infections).
- Rifampicin (used for the treatment of tuberculosis (TB)).

EXXIB with food and drink:

EXXIB may be taken with or without food.

Pregnancy, breastfeeding and fertility

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 EXXIB.

Pregnancy

EXXIB must not be used by women who are pregnant or can become pregnant (i.e. women of childbearing potential who are not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with EXXIB you should discontinue the treatment and contact your doctor for alternative treatment.

Breastfeeding

DO NOT take EXXIB if you are breastfeeding your baby.

EXXIB may cross the placenta and be distributed into breast milk.

Fertility

NSAIDs, including EXXIB, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

EXXIB may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how EXXIB affects you.

EXXIB contains lactose monohydrate

EXXIB contains lactose monohydrate (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking EXXIB.

3. How to take EXXIB

Do not share medicines prescribed for you with any other person. Always take EXXIB exactly as your doctor or pharmacist has told you. Do not take more than the recommended dose for your condition. Your doctor will tell you how long your treatment with EXXIB will last. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of EXXIB is too weak or too strong, talk to your doctor or pharmacist.

The usual dose is:

Rheumatoid arthritis:

The recommended dose is 90 mg once daily.

Ankylosing Spondylitis:

The recommended dose is 90 mg once daily.

Short term relief of acute pain:

The recommended dose is 90 mg or 120 mg once daily, limited to a maximum of 8 days treatment.

Acute gouty arthritis:

The recommended dose is 120 mg once a day, which should only be used for the acute symptomatic period, limited to a maximum of 8 days treatment.

For the treatment of menstrual pain:

The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after dental surgery:

The recommended dose is 90 mg once daily.

If you take more EXXIB 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.

If you forget to take EXXIB

If you have missed your dose by only a few hours, take the missed dose as soon as you

remember. If it is almost time for your next dose, skip the missed dose and take your EXXIB at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

EXXIB can have side effects.

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

If any of the following happens, stop taking EXXIB 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.

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

- Severe pain and swelling/inflammation following a dental extraction, “Dry socket”
- Inflammation of the gastrointestinal tract, respiratory tract infection, urinary tract infection (bladder infection).
- Difficulty breathing.
- Stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels.

- Changes in the way your heart betas, for example, if you notice it beating faster, slower, or irregular, disease of the heart with shortness of breath and swelling of the feet or legs due to fluid build-up, non-specific ECG changes, heart attack feeling of tightness, pressure or heaviness in the chest (angina).
- Inflammation of the pancreas (pancreatitis), stomach ulcers including perforation and bleeding in the digestive tract.
- Yellowing of the skin and/or eyes, also called jaundice, inflammation of the liver (hepatitis), liver failure.
- Rare skin conditions with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Kidney problems including poor function of the kidneys, kidney failure, kidney disorder/inflammation (interstitial nephritis), passing too much protein in the urine (nephrotic syndrome), inability of the kidneys to remove acids from the blood into the urine (renal tubular acidosis).

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:

- Swelling of the legs and/or feet due to fluid retention (oedema).
- Dizziness, headache.
- High blood pressure.
- Stomach pain, flatulence, heartburn, diarrhoea, abdominal discomfort, nausea.
- Increase in liver enzymes (ALT and AST).
- Discolouration of the skin.
- Unusual tiredness or weakness, flu-like symptoms.

Less frequent side effects:

- Blood disorder (low level of red blood cells, an abnormally low amount of platelets).
- Increased or decreased appetite, weight gain.
- Anxiety, depression, mental impairment.
- Sleeping problems, numbness or tingling sensation, a decreased ability for physical sensation.
- Eye inflammation or infection.
- Ringing sound in the ears, spinning sensation (vertigo).
- Hot flushes, very high blood pressure that became worse.
- Coughing, shortness of breath, nose bleeds.
- Stomach swelling, reflux, changes in bowel movement pattern, constipation, dry mouth, small intestine ulcers, irritable bowel syndrome, inflammation of the oesophagus, mouth ulcers, vomiting, inflammation of the stomach.
- Swelling of the face, skin rash or itchy skin, redness of the skin.
- Muscle cramp/spasm, muscle pain/stiffness.
- Presence of protein in the urine.
- Chest pain.
- Changes in blood tests (increased blood urea, increased creatine phosphokinase, decreased haematocrit, decreased haemoglobin, increased potassium levels, increased serum creatinine, increased uric acid, decreased blood sodium.

Frequency unknown:

- Decreased level of platelets.
- Confusion, hallucinations (seeing or hearing things that do not exist), restlessness.
- Drowsiness, taste alteration.
- Blurred vision.

- Swelling of the arms, hands and legs (peripheral oedema).
- Pinkish, itchy swellings on the skin, also called hives, lesions on the skin.
- Low levels of potassium in the blood (hypokalaemia).

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 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 EXXIB.

5. How to store EXXIB

- Store at or below 30 °C.
- Protect from moisture.
- Do not remove blister strips from outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label or 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 EXXIB contains

The active substance is etoricoxib.

EXXIB 60: Each film coated tablet contains 60 mg etoricoxib.

EXXIB 90: Each film coated tablet contains 90 mg etoricoxib.

EXXIB 120: Each film coated tablet contains 120 mg etoricoxib

The other ingredients are anhydrous calcium phosphate dibasic, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose.

EXXIB 60 and EXXIB 120 contains Opadry Green consisting of FD&C Blue # 2/indigo carmine aluminium lake, hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide and triacetin.

EXXIB 90 contains Opadry White consisting of hypromellose, lactose monohydrate, titanium dioxide and triacetin.

What EXXIB looks like and contents of the pack

EXXIB 60: Green, round, biconvex, film coated tablets debossed with '444' on one side and 'L' on the other side.

EXXIB 90: White to off-white, round, biconvex, film coated tablets debossed with '445' on one side and 'L' on the other side.

EXXIB 120: Pale-green, round, biconvex, film coated tablets debossed with '446' on one side and 'L' on the other side.

Silver aluminium/CFB foil blister strips, or silver aluminium foil and transparent PVC/PVDC or PVC/PE/PVDC film blister strips. Each blister strip contains 8 or 10 tablets.

Pack size: 8 or 30 tablets packed into a cardboard box.

Holder of certificate of registration

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