

PATIENT INFORMATION LEAFLET (APPROVED)

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SCHEDULING STATUS

S3

EXTRIB 30 mg film coated tablets

EXTRIB 60 mg film coated tablets

EXTRIB 90 mg film coated tablets

EXTRIB 120 mg film coated tablets

Etoricoxib

EXTRIB 30 mg contains sugar (lactose monohydrate, 2,52 mg per tablet)

EXTRIB 60 mg contains sugar (lactose monohydrate, 5,04 mg per tablet)

EXTRIB 90 mg contains sugar (lactose monohydrate, 7,56 mg per tablet)

EXTRIB 120 mg contains sugar (lactose monohydrate, 10,08 mg per tablet).

Read all of this leaflet carefully before you start taking EXTRIB

- 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.
- EXTRIB 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

PATIENT INFORMATION LEAFLET (APPROVED)

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

1. What EXTRIB is and what it is used for

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

EXTRIB is used:

- to reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and acute attacks of gout
- to relieve short term pain, including cramp-like pain or discomfort before or during a menstrual period, and moderate to severe acute post-operative pain associated with dental surgery
- short term relief of acute pain, treatment limited to a maximum period of 8 days.

2. What you need to know before you take EXTRIB

Do not take EXTRIB:

- if you are hypersensitive (allergic) to etoricoxib, or to any of the ingredients of EXTRIB (see section 6)

PATIENT INFORMATION LEAFLET (APPROVED)

- if you have a stomach ulcer or previously had a stomach ulcer or have bleeding in your stomach or intestines
- if you have a serious liver disease
- if you have a serious kidney disease
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors
- if you have high blood pressure which has not been controlled by treatment
- if you have inflammatory bowel disease, such as Crohn's disease, ulcerative colitis or colitis
- if you have heart problems
- if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility)
- if you are under 16 years of age
- if you are using digoxin (a medicine for heart failure and irregular heart rhythm)
- if you are using lithium (a medicine used to treat some types of depression).

Warnings and precautions

Take special care with EXTRIB if:

- you have a history of liver or kidney disease
- you are dehydrated, for example by a prolonged bout of vomiting or diarrhoea
- you have a history of heart failure, or any other form of heart disease
- you have swelling due to fluid retention

PATIENT INFORMATION LEAFLET (APPROVED)

- you have a history of stroke or mini-stroke
- you have a history of high blood pressure or allergies
- you have high cholesterol, diabetes, or you are a smoker. These can increase your risk of heart disease
- you are elderly (i.e., over 65 years of age)
- you have a history of stomach bleeding or ulcers
- you are being treated for an infection. EXTRIB may mask or hide a fever, which is a sign of infection
- you are a woman trying to become pregnant.

There may be a higher risk of cardiovascular events such as heart attack and strokes with higher doses and longer duration of EXTRIB treatment.

If you are taking EXTRIB for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

EXTRIB can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue it without consulting your doctor because EXTRIB cannot substitute for aspirin for this purpose. Aspirin increases the risk of gastrointestinal events.

Serious skin reactions, which may be fatal, may occur. Signs and symptoms may include fever, rash, peeling of the skin, and/or blisters and sores.

PATIENT INFORMATION LEAFLET (APPROVED)

EXTRIB can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time, to make sure that it is safe to continue treatment.

It is important that you use the lowest dose that controls your pain, and you should not take EXTRIB for longer than necessary.

Other medicines and EXTRIB

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

- ciclosporin or tacrolimus (for suppressing the immune system)
- medicines that prevent blood clots (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (for suppressing the immune system, and often used in rheumatoid arthritis)
- diuretics (water tablets) e.g., furosemide
- ACE inhibitors and angiotensin receptor blockers (used to help control high blood pressure and heart failure)
- lithium (used to treat some types of depression)
- digoxin (a medicine for heart failure and irregular heart rhythm)
- corticosteroids (used to treat arthritis)
- aspirin and other anti-inflammatory medicines: the risk of stomach ulcers is greater if you take EXTRIB with any of these medicines. EXTRIB can be taken with low-dose aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke,

PATIENT INFORMATION LEAFLET (APPROVED)

you should not stop taking aspirin until you talk to your doctor. Do not take high dose aspirin or other anti-inflammatory medicines while taking EXTRIB

- birth control pills
- hormone replacement therapy
- salbutamol (a medicine for asthma)
- minoxidil (to treat high blood pressure)

EXTRIB with food and drink

EXTRIB may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using EXTRIB.

EXTRIB should not be taken if you are pregnant or breastfeeding your baby.

Women attempting conceive should not use EXTRIB.

Driving and using machines

EXTRIB may cause you to feel dizzy or sleepy. If you experience these side effects when taking EXTRIB do not drive, use any tools or operate machines.

PATIENT INFORMATION LEAFLET (APPROVED)

It is not always possible to predict to what extent EXTRIB may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EXTRIB affects them.

EXTRIB contains lactose

EXTRIB contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take EXTRIB.

EXTRIB contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take EXTRIB

Do not share medicines prescribed for you with any other person. Always use EXTRIB exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

It is important that you do not take more than the recommended dose for your condition or take EXTRIB for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

EXTRIB should be taken by mouth once a day and can be taken with or without food.

Adults:

Osteoarthritis: The usual dose is 30 mg once daily.

Rheumatoid arthritis: The usual dose is 90 mg once daily.

PATIENT INFORMATION LEAFLET (APPROVED)

Ankylosing spondylitis: The usual dose is 90 mg once daily.

Short term relief of acute pain: The usual dose is 90 or 120 mg once daily, limited to a maximum of 8 days treatment.

Gout: The usual dose is 120 mg once daily, limited to a maximum of 8 days treatment.

Pain before or during menstrual period: The usual dose is 120 mg once daily.

Post-operative dental surgery pain: The usual dose is 90 mg once daily.

People with liver problems:

- If you have mild liver disease, you should not take more than 60 mg once daily.
- If you have moderate liver disease, you should not take more than 60 mg every other day.

Children:

EXTRIB should not be taken by children or adolescents under 16 years of age.

Your doctor will tell you how long your treatment with EXTRIB will last.

If you have the impression that the effect of EXTRIB is too strong or too weak, tell your doctor or pharmacist.

If you take more EXTRIB than you should

PATIENT INFORMATION LEAFLET (APPROVED)

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 EXTRIB

If you forget to take a dose of EXTRIB, take the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

EXTRIB can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to EXTRIB. 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:

PATIENT INFORMATION LEAFLET (APPROVED)

- fast or irregular heartbeat
- heart problems such as a feeling of tightness, pressure or pain in the chest (heart attack), severe increase in blood pressure which could make you sweat or flushed
- stroke (muscle weakness in the face, arm or leg - usually just on one side)
- serious liver problems: yellowing of your skin and eyeballs (jaundice), pain in your upper right abdomen, abdominal swelling or generally feeling unwell
- serious kidney problems: decreased urine output, swelling of the legs, ankles or feet, nausea or extreme tiredness, seizures or coma in severe cases
- wheezing or shortness of breath
- very serious skin reactions with reddening, blistering, severe inflammation and skin loss.

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:

- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention
- dizziness, headache
- abdominal pain, wind (excessive gas), heartburn, diarrhoea, indigestion/stomach discomfort, nausea
- bruising
- weakness and extreme tiredness, flu-like symptoms
- changes in blood tests related to your liver.

PATIENT INFORMATION LEAFLET (APPROVED)

Less frequent side effects:

- infections of the mouth, nose, throat, cystitis or bladder infection (you may find it painful to urinate or see blood in your urine)
- low red blood cell count (anaemia), decreased white blood cells, as per blood test results
- appetite increase or decrease, weight gain
- anxiety, depression, decrease in mental sharpness
- eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning when standing still)
- pressure or heaviness in the chest (angina pectoris)
- flushing
- cough, breathlessness, nosebleeds
- constipation, inflammation of the stomach lining that can become serious and may lead to bleeding, feeling sick or being sick (vomiting)
- stomach or bowel bloating, changes in your bowel habits, dry mouth, stomach ulcer, irritable bowel syndrome (stomach cramps, discomfort or bloating), a burning sensation due to stomach acid in the upper abdomen, lower chest or throat, mouth ulcers
- problems with your pancreas (you may experience upper abdominal pain that radiates into the back, which may be aggravated by eating foods high in fat, swollen and tender abdomen, nausea, vomiting, fever and increased heart rate)
- muscle cramp/spasm, muscle pain/stiffness
- high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, serious kidney problems
- chest pain
- decreased haematocrit, decreased, haemoglobin, decreased blood cells which, help

PATIENT INFORMATION LEAFLET (APPROVED)

blood to clot, increased serum creatinine, increased uric acid, decrease in raised potassium levels in the blood, low blood levels of sodium.

The following side effects have been reported but the frequency for them to occur is not known:

- low number of platelets, which may cause bleeding and bruising. May require a blood transfusion. Bleeding may be serious or life threatening
- confusion, seeing or hearing things that are not there (hallucinations), restlessness, nervousness
- sleepiness
- blurred vision or problems seeing
- severe increase in blood pressure (hypertensive crisis), general swelling
- dark tarry stool with or without visible blood, vomiting blood, chronic, inflammatory bowel disease that causes inflammation in the digestive tract, Crohn's disease (a lifelong condition where parts of the digestive system become inflamed)
- bruising, swelling of the face, skin rash or itchy skin, redness of the skin.

EXTRIB can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis), especially when taken at higher than recommended doses or for a prolonged period.

It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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

PATIENT INFORMATION LEAFLET (APPROVED)

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 online service for adverse drug reaction reporting by following the link:

<https://www.sahpra.org.za/Publications/Index/8>.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

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

5. How to store EXTRIB

Store all medicines out of reach of children.

Store at or below 25 °C

Keep blisters in carton until required for use.

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

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 EXTRIB contains

The active ingredient is etoricoxib.

EXTRIB 30 mg: Each film coated tablet contains 30 mg etoricoxib.

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

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

EXTRIB 120 mg: Each film coated tablet contains 120 mg etoricoxib.

PATIENT INFORMATION LEAFLET (APPROVED)

The other ingredients are:

Tablet cores:

Calcium hydrogen phosphate anhydrous, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate and microcrystalline cellulose.

Film coating:

Opadry II Green (30 mg, 60 mg and 120 mg tablets)

HPMC 2910/Hypromellose 15 cP, lactose monohydrate, titanium dioxide, triacetin, FD & C Blue # 2/Indigo Carmine aluminium lake (3% - 5%), iron oxide yellow

Opadry II White (90 mg tablets only)

HPMC 2910/Hypromellose 15 cP, lactose monohydrate, titanium dioxide, triacetin.

What EXTRIB looks like and contents of the pack

EXTRIB 30 mg: Blue-green, apple-shaped, biconvex film coated tablets engraved '30' on one face and other face plain.

EXTRIB 60 mg: Dark-green, apple-shaped, biconvex film coated tablets engraved '60' on one face and other face plain.

EXTRIB 90 mg: White, apple-shaped, biconvex film coated tablets engraved '90' on one face and other face plain.

EXTRIB 120 mg: Pale-green, apple-shaped, biconvex film coated tablets engraved '120' on one face and other face plain.

EXTRIB tablets are available in silver aluminium blister strips, packed inside an outer carton.

Each pack contains 7, 10, 28 or 30 tablets consisting of either 7 or 10, tablets per blister.

PATIENT INFORMATION LEAFLET (APPROVED)

Holder of Certificate of Registration

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EXTRIB 120 mg: A50/3.1/0237