

**PATIENT INFORMATION LEAFLET**  
**EXTRIB RANGE**

**SCHEDULING STATUS:**

**S3**

**PROPRIETARY NAME AND DOSAGE FORM:**

**EXTRIB 30 mg** film coated tablets

**EXTRIB 60 mg** film coated tablets

**EXTRIB 90 mg** film coated tablets

**EXTRIB 120 mg** film coated tablets

**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 or your pharmacist.
- **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.

**1. WHAT EXTRIB CONTAINS:**

The active substance 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.

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

The following colourants are also included; Opadry II Green (30 mg, 60 mg and 120 mg tablets), Opadry II White (90 mg tablets only).

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

**2. WHAT EXTRIB IS USED FOR:**

- To reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout.
- To relieve short term pain, including cramp-like pain or discomfort before or during a menstrual period, and pain associated with dental surgery.

**3. BEFORE YOU TAKE EXTRIB:**

**Do not take EXTRIB:**

- if you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of **EXTRIB** (see **What EXTRIB contains**).
- 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.

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- 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 and breastfeeding**).
- 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)

**Take special care with EXTRIB if:**

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

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- 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.

#### **Pregnancy and breastfeeding:**

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

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **EXTRIB**.

Women attempting conceive should not use **EXTRIB**.

#### **Driving and using machinery:**

**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.

#### **Important information about some of the ingredients of EXTRIB:**

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

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

#### **Taking other medicines with EXTRIB:**

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

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The following medicines may interact with **EXTRIB**:

- 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, 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)

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#### 4. HOW TO TAKE EXTRIB:

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

Always take **EXTRIB** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

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

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.

**Osteoarthritis:** The usual dose is 30 mg once daily.

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

**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.

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**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.

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:**

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 a dose of 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 a forgotten dose.

**5. POSSIBLE SIDE EFFECTS:**

**EXTRIB** can have side effects.

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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 taking **EXTRIB**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking **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:

- 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

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- 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, appetite increase or decrease, weight gain
- dizziness, headache
- abdominal pain, wind (excessive gas), heartburn, diarrhoea, indigestion/stomach discomfort, feeling sick or being sick (vomiting)
- constipation, inflammation of the stomach lining that can become serious and may lead to bleeding,
- weakness and extreme tiredness, flu-like symptoms

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) as per blood test results
- gastroenteritis (a stomach infection which may give you repeated diarrhoea or stomach pain)
- anxiety, depression, decrease in mental sharpness
- problems sleeping, numbness or tingling, taste alteration

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- eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning when standing still)
- flushing
- cough, breathlessness, nosebleeds
- 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).
- bruising, swelling of the face, skin rash or itchy skin, redness of the skin,
- pressure or heaviness in the chest (angina pectoris)

Side effects of unknown frequency:

- confusion, seeing or hearing things that are not there (hallucinations), restlessness, nervousness
- sensitivity of skin to light
- shock, fever, aseptic meningitis (similar to a mild cold or flu)
- sleepiness
- blurred vision or problems seeing
- low number of platelets, which may cause bleeding and bruising. May require a blood transfusion. Bleeding may be serious or life threatening.

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

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**6. STORING AND DISPOSING OF EXTRIB:**

Store all medicines out of reach of children.

Store at or below 25°C.

Keep blisters in the 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).