

Approved Patient Information Leaflet for Medicines for Human Use:

XIBECIL

SCHEDULING STATUS: S3

XIBECIL 100 mg Capsules

XIBECIL 200 mg Capsules

Celecoxib

Contains sugar:

Each 100 mg capsule contains 27,07 mg lactose monohydrate

Each 200 mg capsule contains 54,14 mg lactose monohydrate

Read all of this leaflet carefully before you start taking XIBECIL

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

1. What XIBECIL is and what it is used for

Each capsule contains either 100 or 200 mg celecoxib.

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XIBECIL treats pain, inflammation, fever and belongs to a group of medicines called specific cyclooxygenase 2 (COX-2) inhibitors.

XIBECIL is used in the treatment of inflammation and pain in osteoarthritis and rheumatoid arthritis. XIBECIL is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, primary dysmenorrhoea and helps to relieve the signs and symptoms of progressive stiffening of the spine known as ankylosing spondylitis.

Your body makes substances called prostaglandins. Some prostaglandins cause pain and swelling, whilst others help protect the stomach lining. XIBECIL works by reducing the amount of prostaglandins which produce pain and swelling without reducing the protective prostaglandins in the stomach.

2. What you need to know before you take XIBECIL

Do not take XIBECIL:

- if you are hypersensitive (allergic) to celecoxib or any of the other ingredients of XIBECIL (listed in section 6).
- if you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections)
- if you have had nasal polyps or severe nasal congestion, or an allergic reaction such as an itchy skin rash, swelling, or wheezing after taking aspirin or another anti-inflammatory medicine, including other cyclooxygenase 2 inhibitors
- if you have a stomach or duodenal ulcer, or bleeding in the stomach
- if you have severe liver or kidney disease
- if you have severe heart failure, high blood pressure or if you have had a stroke
- if you are about to have coronary artery bypass graft surgery
- if you are pregnant or it is possible that you could become pregnant
- if you are breastfeeding

Warnings and precautions

Take special care with XIBECIL:

- if you have had an ulcer, bleeding or perforation of the gastrointestinal tract
- if you have liver or kidney disease
- if you have oedema (fluid retention)
- if you have or have had heart disease
- if you have high blood pressure
- if you suffer from diabetes
- if you have high cholesterol
- if you smoke
- if you could be dehydrated, for example by sickness or diarrhoea or the use of diuretics
- if you have an infection, as it may hide fever

Children and adolescents

XIBECIL must not be given to children under 18 years old.

Other medicines and XIBECIL

Always tell your doctor or health care professional if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are using any of the following medicines:

- Warfarin (used to prevent blood from clotting)
- ACE inhibitors (used for high blood pressure and heart failure)
- Ciclosporin and tacrolimus (used to treat various immune-mediated diseases)
- Acetylsalicylic acid (used to treat pain, fever and inflammation)
- Lithium (used to treat depression)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, do not take XIBECIL.

Driving and using machines

It is not always possible to predict to what extent XIBECIL 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 XIBECIL affects them.

Patients who experience dizziness, vertigo or somnolence while taking XIBECIL should refrain from driving or operating machinery.

XIBECIL contains lactose monohydrate

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

3. How to take XIBECIL

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

Always take XIBECIL exactly as your doctor has instructed you. Check with your doctor if you are not sure.

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

Use the lowest effective dose for the shortest possible time.

The recommended dose for osteoarthritis is 200 mg taken as a single dose or as two divided doses.

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The recommended dose for rheumatoid arthritis is 100 mg or 200 mg twice per day.

The recommended dose for pain following dental surgery is 100 mg or 200 mg twice per day.

The recommended dose for pain following an operation is 200 mg once daily.

The recommended dose for musculoskeletal pain is 200 mg twice daily.

The recommended dose for primary dysmenorrhoea is 400 mg initially, followed by an additional 200 mg on the first day if needed. On subsequent days, the recommended dose is 200 mg twice daily.

The recommended dose for ankylosing spondylitis is 200 mg daily, taken as a single dose or as 100 mg twice per day.

If you have liver problems, or you are over 65 years of age and weigh less than 50 kg, do not take more than 100 mg once daily for osteoarthritis and 200 mg per day for rheumatoid arthritis.

Method of administration

You can take XIBECIL with or without meals.

Duration of administration

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

As the cardiovascular risks of XIBECIL may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used.

If you take more XIBECIL than you should

In the event of overdosage, consult your doctor. If not available, contact the nearest hospital or poison centre.

If you forget to take XIBECIL

If you forget to take a dose, leave that dose out completely. Take your next dose at the right time and continue as before. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

XIBECIL can have side effects.

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

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

- If you have cardiac symptoms such as shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm
- If you experience dizziness and headache
- If you have an allergic reaction such as skin rash or itching, swelling of the face, wheezing or difficulty breathing
- If you have blistering or peeling of the skin

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- If you have any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements, or vomiting blood

These are very serious side effects. If you have them, you may have had a serious reaction to XIBECIL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Sleeping problems, dizziness
- Fluid build-up in the body, swollen ankles and legs
- Bronchitis, coughing, blocked nose, swollen sinuses, sore throat, chest infection
- Stomach ache, diarrhoea, vomiting indigestion, wind
- Skin rash
- Urinary infections

Less frequent side effects:

- Raised blood pressure, palpitations (awareness of your heartbeat), feeling short of breath, coughing
- Vomiting
- Allergic skin reaction, loss of hair
- Anaemia, bruising of the skin
- Anxiety, depression, tiredness, blurred vision, tinnitus (ringing in the ears)
- Fluid build-up in the tissues
- Feeling confused
- Congestive heart failure
- Ulcers in the digestive system, blood in bowel movements
- Effects on the skin such as bruising

The following side effects have been reported in post-marketing surveillance:

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- Sudden, life threatening severe allergic reaction
- Hallucinations
- Inflammation of the blood vessels
- Bleeding in the digestive system
- Hepatitis (inflamed liver)
- Kidney failure or kidney disease
- Effects on the skin such as flushing, swelling, blistering and peeling or increased sensitivity to light
- Heart failure, blood clotting and stroke
- Absence of sense of smell and infection of the brain membranes
- Menstrual disorders

If you notice any side effects not mentioned in this leaflet, please inform your Health care provider.

Reporting of side effects

If you get side effects, talk to your Health care provider. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of XIBECIL.

5. How to store XIBECIL

Store all medicines out of reach of children.

Store at or below 25°C.

Store in original packaging.

There are no special storage instructions for XIBECIL.

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

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What XIBECIL contains

The active substance is celecoxib.

XIBECIL 100 mg: Each capsule contains 100 mg celecoxib.

XIBECIL 200 mg: Each capsule contains 200 mg celecoxib.

Contains sugar (lactose monohydrate).

Each 100 mg capsule contains 27,07 mg of lactose monohydrate.

Each 200 mg capsule contains 54,14 mg of lactose monohydrate.

The other ingredients are:

For Capsule core: Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Povidone (K-30) and Sodium Lauryl Sulfate.

For Empty capsule shell: Gelatin, Purified water and Titanium dioxide (E171).

For Printing Ink (BLUE TEK SB 6018): Shellac (E904), Dehydrated Alcohol (E1510), Isopropyl Alcohol, Butyl Alcohol, Propylene Glycol (E1520), Strong Ammonia Solution (E527), FD & C Blue # 2 Aluminium Lake (Indigo Carmine) (E132) for 100 mg capsules and Yellow Iron Oxide NF (E132) for 200 mg capsules.

What XIBECIL looks like and contents of the pack

XIBECIL 100 mg are Size “2” hard gelatin capsule opaque white with blue band reverse printed “100” in white on body and “CEL” in white on cap filled with white to off-white colored granular powder.

XIBECIL 200 mg are Size “2” hard gelatin opaque white with yellow band reverse printed “200” in white on body and “CEL” in white on cap filled with white to off-white colored granular powder.

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XIBECIL are packed in - Alu foil blister strips or transparent PVC/PE/PVDC - Alu blister strips, each containing 10 capsules. The capsules are placed in an outer cardboard carton. The carton may contain 10, 30 or 60 capsules.

XIBECIL capsules are packed in HDPE jars –100 capsules are packed in a HDPE container with HDPE Cap along with silica gel bag and sealed Aluminium tagger. Each jar is packed in carton along with a PIL.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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XIBECIL 200: 55/3.1/0616.614

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Professional Information for this medicine is available on the following URL:

<https://Austell.Co.Za/Product-Info/>

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