

Applicant: Ruby Pharmaceuticals (Pty) Ltd

Proprietary Name: LEXIB 100 / 200

API & Dosage Form & Strength(s): Celecoxib / capsules / 100 - 200 mg

Date: 16 May 2023

Ver:vf

1.3.2 PATIENT INFORMATION LEAFLET



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LEXIB 100 mg

LEXIB 200 mg

Celecoxib 100 mg & 200mg capsules

Contains sugar

LEXIB 100: Lactose monohydrate 20,225 mg / capsule

LEXIB 200: Lactose monohydrate 40,45 mg / capsule

Read all of this leaflet carefully before you start taking **LEXIB**

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

1. What **LEXIB** is and what it is used for

LEXIB is used in adults for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, primary dysmenorrhoea and mild to moderate post-operative pain.



LEXIB belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAID), and specifically a sub-group known as (COX-2) inhibitors. Your body makes prostaglandins that may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. **LEXIB** acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

You should expect your medicine to start working within hours of taking the first dose, but you may not experience a full effect for several days.

2. What you need to know before you take LEXIB

Do not take LEXIB if you:

- if you are allergic to celecoxib or any of the other ingredients of **LEXIB** (listed in section 6)
- if you have had an allergic reaction to a group of medicines called “sulfonamides” (e.g. some antibiotics used to treat infections)
- if you currently have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines
- if as a result of taking acetylsalicylic acid or any other anti-inflammatory and pain relieving medicine (NSAID) you have had asthma, nose polyps, severe nose congestion, or an allergic reaction such as an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing
- if you are pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor
- if you are breast-feeding
- if you have severe liver disease
- if you have severe kidney disease
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease
- if you have heart failure, established ischaemic heart disease, or cerebrovascular disease, e.g. you have been diagnosed with a heart attack, stroke, or transient ischaemic attack



(temporary reduction of blood flow to the brain; also known as “mini-stroke”), angina, or blockages of blood vessels to the heart or brain

- if you have or have had problems with your blood circulation (peripheral arterial disease) or if you have had surgery on the arteries of your legs

Warnings and precautions

Talk to your doctor before taking **LEXIB**.

if you have previously had an ulcer or bleeding in your stomach or intestines. (Do not take Celecoxib if you currently have an ulcer or bleeding in your stomach or intestine)

- if you are taking acetylsalicylic acid (even at low dose for heart protective purposes)
- if you use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban)
- if you use medicines called corticosteroids (e.g. prednisone)
- if you are using Celecoxib at the same time as other non-acetylsalicylic NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided
- if you smoke, have diabetes, raised blood pressure or raised cholesterol
- if your heart, liver or kidneys are not working well your doctor may want to keep a regular check on you
- if you have fluid retention (such as swollen ankles and feet)
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (used to treat excess fluid in the body)
- if you have had a serious allergic reaction or a serious skin reaction to any medicines
- if you feel ill due to an infection or think you have an infection, as Celecoxib may mask a fever or other signs of infection and inflammation
- if you are over 65 years of age your doctor will want to monitor you regularly
- the consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems



As with other NSAIDs (e.g. ibuprofen or diclofenac) this medicine may lead to an increase in blood pressure, and so your doctor may ask to monitor your blood pressure on a regular basis. Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.

Celecoxib may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant (see section on Pregnancy and breast-feeding).

Other medicines and LEXIB

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

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

- Dextromethorphan (used to treat coughs)
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure)
- Fluconazole and rifampicin (used to treat fungal and bacterial infections)
- Warfarin or other warfarin like medicines ("blood-thinning" agents that reduce blood clotting) including newer medicines like apixaban
- Lithium (used to treat some types of depression)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat
- Neuroleptics (used to treat some mental disorders)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)



- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants)
Celecoxib can be taken with low dose acetylsalicylic acid (75 mg or less daily).

Ask your doctor for advice before taking both medicines together.

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 **LEXIB**.

Pregnancy

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

Breast-feeding

LEXIB must not be used during breast-feeding.

Fertility

NSAIDs, including **LEXIB**, 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

You should be aware of how you react to **LEXIB** before you drive or operate machinery. If you feel dizzy or drowsy after taking **LEXIB**, do not drive or operate machinery until these effects wear off.

LEXIB contains lactose:

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



3. How to take LEXIB

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you think or feel that the effect of **LEXIB** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you what dose you should take. As the risk of side effects associated with heart problems may increase with dose and duration of use, it is important that you use the lowest dose that controls your pain and you should not take **LEXIB** for longer than necessary to control symptoms.

LEXIB is for oral use. The capsules can be taken at any time of the day, with or without food. However, try to take each dose of **LEXIB** at the same time each day.

The recommended dose is:

For osteoarthritis the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 200 mg capsule once a day; or
- one 100 mg capsule twice a day.

For rheumatoid arthritis the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 100 mg capsule twice a day.

For ankylosing spondylitis the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 200 mg capsule once a day; or
- one 100 mg capsule twice a 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.

Kidney or liver problems: make sure your doctor knows if you have liver or kidney problems as you may need a lower dose.

The elderly, especially those with a weight less than 50 kg: if you are over 65 years of age and especially if you weigh less than 50 kg, your doctor may want to monitor you more closely.

You should not take more than 400 mg per day.

Use in children

Celecoxib is for adults only; it is not for use in children.

If you take more LEXIB than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to take **LEXIB**

If you forget to take a capsule, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

LEXIB can cause side effects.

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

If any of the following happen, stop taking **LEXIB** and tell your doctor immediately or go to the casualty department at your nearest hospital.



If you have:

- an allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
- heart problems such as pain in the chest • severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or blood-stained stools, or vomiting blood
- a skin reaction such as rash, blistering or peeling of the skin
- liver failure (symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow))

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- High blood pressure, including worsening of existing high blood pressure
- Heart attack
- Fluid build-up with swollen ankles, legs and/or hands
- Urinary infections
- Bronchitis
- Chest infection
- Shortness of breath, sinusitis (sinus inflammation, sinus infection, blocked or painful sinuses), blocked or runny nose, sore throat, coughs, colds,
- Flu-like symptoms
- Dizziness, headache
- Vomiting, stomach-ache, diarrhoea, indigestion, wind
- Rash, itching
- Muscle stiffness
- Difficulty swallowing
- Difficulty sleeping
- Nausea (feeling sick)
- Joint stiffness or painful joints
- Worsening of existing allergies
- Accidental injury



Less frequent side effects:

- Anaemia (changes in red blood cells that can cause fatigue and breathlessness).
- Low levels of platelets in the blood.
- Hypersensitivity.
- Swelling in the face, lips, tongue or throat, difficulty swallowing, breathing problems, nettle rash. These could be symptoms of a serious allergic reaction such as angioedema.
- Anxiety.
- Feeling confused.
- Sleepiness or drowsiness.
- Blurred vision.
- Ringing in the ears.
- Irregular heartbeat.
- Palpitations (awareness of your heartbeat).
- Fast heart rate.
- Heart failure.
- Flushing.
- Ulcers in your oesophagus, stomach and small intestine.
- Inflammation of the pancreas.
- Ruptured intestine.
- Increased liver enzymes.
- Hair loss.
- Bruising of the skin.
- Face swelling.
- Hallucination.
- Bleeding in the brain.
- Loss of taste.
- Impaired sense of smell.
- Meningitis (inflammation of the membrane around the brain and spinal cord).
- Stroke.
- Inflammation of the eye.
- Heart attack.
- Blood clot inside a blood vessel of the heart.



- Inflammation of the blood vessels.
- Blood clot in the lungs.
- Inflammation of the lungs.
- Inflammation of the liver.
- Liver failure.
- Liver disease.
- Jaundice (yellowing of the skin and eyes).
- Increased sensitivity to light.
- Serious skin conditions such as Stevens-Johnson syndrome, exfoliative dermatitis and toxic epidermal necrolysis (can cause rash, blistering or peeling of the skin) and acute generalized exanthematous pustulosis (symptoms include the skin becoming red with swollen areas covered in numerous small pustules).
- A serious hypersensitivity reaction called DRESS, including skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs.
- Kidney failure.
- Inflammation of the kidneys and other kidney problems (such as nephrotic syndrome and minimal change disease, which may be accompanied by symptoms such as water retention, foamy urine, fatigue and loss of appetite).
- Low levels of sodium in the blood (a condition known as hyponatraemia).
- Menstrual disturbances.

Frequency unknown:

- Decrease in fertility in females, which is usually reversible on discontinuation of the medicine.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 **LEXIB**

5. How to store LEXIB

Store all medicines out of reach of children.

Store at or below 25° C

Store the capsules in the original blisters and keep the blisters in the outer carton until required for use.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Ask your pharmacist how to dispose of medicines you no longer use.

6. Contents of the pack and other information

What **LEXIB** contains

- The active substance is celecoxib
- The other ingredients are:
- Capsules content: croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone, sodium lauryl sulphate
- Capsule shells: gelatin, sodium lauryl sulphate, titanium dioxide
- Printing ink: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, ammonia solution concentrated, black iron oxide, potassium hydroxide

What **LEXIB** looks like and contents of the pack

LEXIB 100 mg: Size '3', White to White opaque hard gelatin capsules, imprinted with 'CEL' on cap & '100 mg' on body in black ink, filled with white to off-white slug to granular powder.



LEXIB 200 mg: Size '2', White to White opaque hard gelatin capsules, imprinted with 'CEL' on cap & '200 mg' on body in black ink, filled with white to off-white slug to granular powder.

LEXIB 100 and 200 mg is available in blister packs of PVC/PE laminate and Aluminium lid foil in outer cartons in packs of 28, 30, 56, 60, 100.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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4091

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