PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

CELEBREX® 100 capsules

CELEBREX® 200 capsules

Celecoxib

Contains sugar (lactose monohydrate)

Each 100 mg capsule contains 149,7 mg lactose monohydrate.

Each 200 mg capsule contains 49,8 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking CELEBREX

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

1. What CELEBREX is and what it is used for

CELEBREX treats pain, inflammation and fever and belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and specifically a sub-group called cyclooxygenase 2 (COX-2)

inhibitors.

CELEBREX is used in the treatment of inflammation and pain in osteoarthritis and rheumatoid arthritis. CELEBREX 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. CELEBREX works by reducing the number of prostaglandins which produce pain and swelling without reducing the protective prostaglandins in the stomach.

2. What you need to know before you take CELEBREX

Do not take CELEBREX:

- If you are hypersensitive (allergic) to celecoxib or any of the other ingredients of CELEBREX (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 severe liver or kidney disease.
- If you have asthma, 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 heart disease or if you have had a stroke.
- If you have problems with your blood circulation (peripheral arterial disease), a condition in which a build-up of fatty deposits in the arteries restricts blood supply to leg muscles.
- If you are about to have coronary artery bypass graft surgery.
- If you are pregnant.
- If it is possible that you could become pregnant during ongoing treatment, you should discuss methods of contraception with your doctor.

Warnings and precautions

Take special care with CELEBREX.

Some people will need special care from their doctors when they are taking CELEBREX. Make sure that your doctor knows before you start taking CELEBREX:

- If you have high blood pressure.
- If you suffer from diabetes.
- If you smoke.
- If you have high cholesterol.
- If you currently have or have had an ulcer, bleeding or perforation of the gastrointestinal tract.
- If you have had a serious allergic reaction or a serious skin reaction to any medicines.
- If you develop symptoms of a serious hypersensitivity reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), including skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs; stop taking CELEBREX immediately if these symptoms occur.
- If you have oedema (fluid retention).
- If you have liver or kidney disease.
- If you could be dehydrated, for example by sickness or diarrhoea or the use of diuretics.
- If you have an infection, as CELEBREX may hide a fever or other signs of infection.

Other medicines and CELEBREX

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

Before you start taking CELEBREX, make sure your doctor knows if you are taking:

- Other anti-inflammatory medicines.
- Aspirin.
- Corticosteroids.
- Diuretics (used to treat fluid retention).
- Warfarin or warfarin-type anticoagulants, apixaban, dabigatran or rivaroxaban (used to prevent blood from clotting).
- Rifampicin (used to treat bacterial infections).
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression).
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders).
- Anti-hypertensive medicines including ACE inhibitors, angiotensin II receptor antagonists and beta-blockers (e.g. metoprolol) (used for high blood pressure and heart failure).

- Ciclosporin (used for immune system suppression e.g. after transplants).
- Fluconazole (used to treat fungal infections).
- Dextromethorphan (used to treat coughs).
- Lithium (used to treat depression).

CELEBREX with alcohol

The consumption of alcohol and CELEBREX may increase the risk of gastrointestinal problems.

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 health care provider for advice before taking this medicine.

CELEBREX may make it more difficult to become pregnant. You should tell your doctor if you are having problems becoming pregnant.

CELEBREX 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 CELEBREX, you should discontinue the treatment and contact your doctor for alternative treatment.

CELEBREX must not be used during breastfeeding.

Driving and using machines

If you feel dizzy or tired after taking CELEBREX, do not drive or use machinery until you are feeling normal again.

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

CELEBREX contains lactose

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

3. How to take CELEBREX

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

Always take CELEBREX exactly as your doctor has told you. Check with your doctor or pharmacist if you

are not sure.

Use the lowest effective dose for the shortest possible time.

Take the capsules with a sufficient quantity of liquid e.g. one glass of water.

CELEBREX may be taken with or without food.

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

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 per day for osteoarthritis and 200 mg per day for rheumatoid arthritis.

If you have liver problems, your doctor will introduce CELEBREX at the lowest recommended dose for pain post dental surgery.

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

If you take more CELEBREX than you should

In the event of overdosage or if you accidentally take too many capsules, consult your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CELEBREX

If you miss a dose, either take it as soon as you remember or wait until the next scheduled dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CELEBREX can have side effects.

Not all side effects reported for CELEBREX are included in this leaflet. Should your general health worsen

or if you experience any untoward effects while taking CELEBREX, please consult your health care provider for advice.

CELEBREX may cause the following reactions. If any of the following happens, stop taking CELEBREX 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, swelling of the face, wheezing or difficulty breathing.
- If you have blistering or peeling of the skin.
- If you have any sign of bleeding in the stomach or intestines, such as passing black or blood-stained bowel movements, or vomiting blood.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Bronchitis.
- Sore throat.
- Blocked or runny nose, sneezing and post-nasal drip (rhinitis).
- Sinus inflammation, sinus infection, blocked or painful sinuses (sinusitis).
- Chest infection.
- Urinary tract infection.
- Worsening of existing allergies.
- Difficulty sleeping.
- Muscle stiffness.
- High blood pressure, including worsening of existing high blood pressure.
- Cough.
- Vomiting.
- Stomach-ache.
- Diarrhoea.

- Indigestion.
- Wind.
- Tooth disorder.
- Skin rash.
- Itching.
- Fluid build-up with swelling of ankles, legs and/or hands.
- Flu-like symptoms.
- 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.

Other side effects:

- 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 generalised 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.
- Decreased fertility in females.

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 SAHPRA via the "**6.04 Adverse Drug Reactions 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 CELEBREX.

5. How to store CELEBREX

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package.

Keep the blister strip in the outer carton.

Protect from light/moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister and 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 CELEBREX contains

- The active substance is celecoxib. Each capsule contains either 100 or 200 mg celecoxib.
- The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone and sodium lauryl sulphate. The capsules shells contain gelatine and titanium dioxide. The printing ink contains butyl alcohol (E1013200), dehydrated alcohol (E1034800), FD&C Blue #2 Aluminium Lake

(E132) (100 mg), isopropyl alcohol, propylene glycol, shellac, strong ammonia solution and yellow ferric oxide (E172) (200 mg).

What CELEBREX looks like and contents of the pack

CELEBREX 100: Hard gelatine capsule (containing white to off-white granulation). White, opaque body with blue ink band containing in white '100'; white, opaque cap with blue ink band containing in white '7767'. Each blue ink band nearly, but not completely circumscribes the capsule.

CELEBREX 200: Hard gelatine capsule (containing white to off-white granulation). White, opaque body with gold ink band containing in white '200'; white, opaque cap with gold ink band containing in white '7767'. Each gold ink band nearly, but not completely circumscribes the capsule.

CELEBREX is supplied in blister strips, each containing 10 or 15 capsules. The capsules are placed in an outer cardboard carton. The carton may contain 10, 15, 30 or 60 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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