PROPOSED PATIENT INFORMATION LEAFLET FOR CELEXII

PATIENT I LEAFLET

SCHEDULING STATUS: S3

CELEXII 100, hard gelatine capsules

CELEXII 200, hard gelatine capsules

Celecoxib

CELEXII 100 contains sugar (lactose, 20,83 mg).

CELEXII 200 contains sugar (lactose, 41,65 mg).

Read all of this leaflet carefully before you start taking CELEXII.

- 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.
- CELEXII 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 CELEXII is and what it is used for

2. What you need to know before you take CELEXII

3. How to take CELEXII

4. Possible side effects

5. How to store CELEXII

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1. What CELEXII is and what it is used for

PROPOSED PATIENT INFORMATION LEAFLET FOR CELEXII

CELEXII belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), and specifically a sub-group known as cyclooxygenase-2 (COX-2) inhibitors.

Your body makes substances called prostaglandins. Some prostaglandins may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. CELEXII acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

CELEXII is used in adults for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis (progressive stiffening of the spine).

CELEXII is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, primary dysmenorrhoea (painful menstrual periods).

2. What you need to know before you take CELEXII

Do not take CELEXII:

- If you are hypersensitive (allergic) to celecoxib or any of the ingredients of CELEXII (See section 6 **"What this product contains"**).
- If you have had an allergic reaction to a group of medicines called "sulphonamides" (medicines that prevent the growth of bacteria).
- If you have severe liver disease.
- If you have severe kidney disease.
- If you have had allergic reactions such as asthma, nose polyps, severe nasal congestion, or an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing from aspirin or other NSAIDs (anti-inflammatory and pain-relieving medicines, such as diclofenac, ibuprofen).
- If you have established ischaemic heart disease, or cerebrovascular disease, e.g., you

have been diagnosed with a heart attack, stroke, or blockages of blood vessels to the heart or brain.

- If you are about to have coronary artery bypass graft surgery.
- If you currently have an ulcer in your stomach or intestines, or if you are bleeding in your stomach or intestines (you may notice that you have black sticky stools or bloody diarrhoea).
- If you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease.
- if you are pregnant or it is possible that you could become pregnant.
- if you are breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking CELEXII

Take special care with CELEXII:

- If you smoke, have diabetes, high blood pressure or high blood cholesterol.
- If you have had a serious allergic reaction or a serious skin reaction to any medicines.
- If you have previously had an ulcer or bleeding in your stomach or intestines. (**Do not take CELEXII** if you currently have an ulcer or bleeding in your stomach or intestine).
- If you are taking corticosteroid medicines (for example prednisone).
- If you are taking aspirin (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 are taking CELEXII at the same time as other non-aspirin NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided.
- If you have fluid retention (such as swollen ankles and feet).
- If you have heart failure or other heart problems.

- If you have high blood pressure.
- If your liver or kidneys are not working well, as your doctor may want to keep a regular check on you.
- Dangerously low levels of potassium (hypokalaemia) and high levels of acid in the blood (renal tubular acidosis - caused by the kidneys not removing acids from the blood into the urine as they should) have been reported when other NSAIDs medicines (such as ibuprofen) have been used for long periods of time at higher than recommended doses. Caution is advised with the use of CELEXII.
- If you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (medicines used to get rid of excess fluid in the body).
- If you feel ill due to an infection, or think you have an infection, as CELEXII may mask a fever or other signs of infection and inflammation.
- If you are above 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.

CELEXII may lead to an increase in blood pressure. Your doctor may want 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.

Other medicines and CELEXII

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

Before you take CELEXII, make sure your doctor knows if you are taking the following medicines:

- Warfarin (used to prevent blood from clotting).
- ACE inhibitors, angiotensin II receptor antagonists, beta blockers (used for high blood pressure and heart failure).
- Diuretics (used to treat fluid retention).
- Ciclosporin and tacrolimus (used for immune system suppression e.g., after transplants).
- Aspirin (used for pain and fever). CELEXII can be taken with low dose aspirin (75 mg or less daily). Ask your doctor for advice before taking both medicines together. CELEXII has no antiplatelet effect and is therefore not a substitute for aspirin for prevention of thrombosis.
- Neuroleptics (used to treat some mental disorders).
- Medicines for anxiety (diazepam) or to treat depression (citalopram, imipramine).
- Medicines to treat an irregular heartbeat (amiodarone, quinidine).
- Dextromethorphan (used to treat coughs).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia).
- Lithium (used to treat some types of depression).
- Oral contraceptives.
- Glibenclamide, tolbutamide (medicines used in the management of type 2 diabetes).
- Phenytoin, a medicine used in epilepsy (seizure disorder).
- Fluconazole (used to treat fungal infection).
- 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).
- Ketoconazole (an antifungal medicine).

- Antacids (used for heartburn).

Pregnancy, breastfeeding and fertility

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

Pregnancy

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

Breastfeeding

CELEXII must not be used during breastfeeding.

Fertility

NSAIDs, including CELEXII, 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 CELEXII before you drive or operate machinery. If you feel dizzy or drowsy after taking CELEXII, do not drive or operate machinery until these effects wear off.

CELEXII contains ~~l~~actose

CELEXII contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CELEXII.

3. How to take CELEXII

Do not share medicines prescribed for you with any other person. Always take CELEXII 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 CELEXII is too strong or too weak, talk to your doctor or pharmacist.

Use the lowest effective dose for the shortest possible time.

Your doctor will tell you what dose you should take.

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

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

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

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 daily.

If you have liver problems, or if you weigh less than 50 kg, your doctor will recommend the lowest recommended dose.

Children

No information is available on the use of CELEXII in children and it is therefore not recommended for use in children.

Method of administration:

CELEXII is for oral use. Swallow the capsules whole with a glass of water at any time of the day, with or without food. However, try to take each dose of CELEXII at the same time each day. Do not chew or crush the granules.

Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

If you take more CELEXII than you should

You should not take more capsules than your doctor tells you to.

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 CELEXII

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

If you stop taking CELEXII

Suddenly stopping your treatment with CELEXII may lead to your symptoms getting worse.

Do not stop taking CELEXII unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

CELEXII can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- A serious skin reaction with rash, blistering or peeling of the skin.
- Fever, swollen lymph nodes (painful, warm or red lumps under the skin).

These are all very serious side effects. If you have them, you may have had a serious reaction to CELEXII. 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:

- Weakness or clumsiness of a hand, arm or leg, difficulties with speech and swallowing, vision problems and headache. These may be signs of a stroke or bleeding in the brain, which may be fatal.
- Shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm (heart attack).
- Problems breathing, shortness of breath, chest pain. You may have a blood clot in the

lung (pulmonary embolism) and will need urgent medical attention.

- Throbbing or cramping pain in a leg, swelling in a leg, warm skin around painful area (deep vein thrombosis).
- Severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood.
- Liver failure (symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow)).
- Bladder or kidney infections. Some signs may be fever, chills, blood in the urine or frequent urination.
- Acute renal failure/nephrotic syndrome (decreased urine output, swelling of legs, fatigue, foamy urine, loss of appetite), inability of the kidneys to remove acids from the blood into the urine (renal tubular acidosis).
- Painful blisters, sensitive to touch (shingles).
- Red, swollen, painful skin with fever (a bacterial skin infection, known as erysipelas).
- Ache or burning pain in your abdomen (Helicobacter infection).

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:

- Infections of the airways such as sinusitis (swelling and redness of the nasal sinuses) or bronchitis (inflammation of the mucous membranes of the airways).
- Worsening of existing allergies.
- Weight gain.
- Trouble sleeping.
- Dizziness, abnormal muscle tension.
- Headache.

- High blood pressure, worsening of existing high blood pressure. (You may not know that you have high blood pressure unless you have your blood pressure tested).
- Runny nose, sore throat, shortness of breath.
- Nausea (feeling sick), vomiting (being sick).
- Indigestion, windiness, pain on stomach.
- Problem swallowing.
- Sore teeth.
- Skin rash, itching skin.
- Accidental injury.
- Flu-like illness.
- Keeping fluid back in the body tissues, with swollen ankles, legs and/or hands.

Less frequent side effects:

- Inflammation or infection of the inner ear (dizziness or feeling that everything is spinning around you).
- Infection of the gums.
- Blood disorders, such as anaemia (too few red blood cells or their haemoglobin content is too low), leukopenia (a lowered white blood cell count) or thrombocytopenia (deficiency of platelets in the blood)*.

  * You will only know that you have these disorders if your doctor orders blood tests. See your doctor if you are pale and tired, get more infections than usual or have problems to stop bleeding, or if you have unexpected bruising.
- Increased sodium in blood, increased potassium in blood (determined by blood tests).
- Feeling tired, confused.
- Feeling anxious or depressed.
- Seeing or hearing things that do not exist (hallucinations).

- Blurred vision, eye inflammation and bloodshot eyes, vitreous floaters (seeing spots or strings that move when you move your eyes), bleeding in an eye, painful eyes.
- Ringing in the ears, above normal hearing sense, voice disorder.
- Irregular heart rhythm, increased heart rate.
- Flushing, inflammation of a blood vessel (you may feel unwell with fever, sweats and tiredness).
- Tightness in the chest with coughing and wheezing (bronchospasm).
- Shortness of breath, cough, fatigue (inflammation of the lung tissues - pneumonitis).
- Abdominal pain, cramping, bloating, constipation.
- Mouth ulcers, numbness, burning sensation in the mouth (stomatitis).
- Hair loss.
- Muscle spasms (leg cramps), muscle pain.
- Lower limb fracture.
- Kidney function disorders (shown by laboratory tests).
- Frequent urination during the night (nocturia).
- Menstrual disorders.
- Swollen face.
- Chest pain.

Frequency unknown:

- Sleepiness.
- Abnormal skin sensations (tingling or tickling or itching or burning).
- Problems with coordination and speech (ataxia).
- No sense of smell or taste, or taste affected.
- Worsening of existing epilepsy (seizure disorder).
- Female fertility decreased.
- Vaginal bleeding.

- Tender breasts.
- Low levels of potassium in the blood (hypokalaemia).

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, pharmacist or nurse.

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 CELEXII.

5. How to store CELEXII

Store all medicines out of reach of children.

Store at or below 25 ºC.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CELEXII contains

The active substance is celecoxib.

1 capsule contains 100 mg or 200 mg celecoxib.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone K-30, printing ink (containing black iron oxide, potassium

hydroxide and shellac), sodium lauryl sulphate.

CELEXII 100 capsules shells also contain carmoisine, gelatine, patent blue V, sodium lauryl sulphate and titanium dioxide.

CELEXII 200 capsules shells also contain gelatine, iron oxide yellow, sodium lauryl sulphate and titanium dioxide.

What CELEXII looks like and contents of the pack

CELEXII 100: An opaque blue, size 3, hard gelatine capsule, 1308 imprinted with black ink on the cap and 100 imprinted with black ink on the body, containing a white to off-white granular powder.

CELEXII 200: An opaque yellow, size 1, hard gelatine capsule, 1309 imprinted with black ink on the cap and 200 imprinted with black ink on the body, containing a white to off-white granular powder.

White, opaque PVC/PVdC-Alu blister strips.
Each blister strip contains 10 capsules.
Pack sizes: 30’s and 60’s.

Holder of certificate of registration

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South Africa

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