PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

COXLEON® 100 (capsules)

COXLEON® 200 (capsules)

Celecoxib

Each 100 mg capsule contains sugar (7 mg lactose monohydrate).

Each 200 mg capsule contains sugar (14 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking COXLEON:

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

1. What COXLEON is and what it is used for

COXLEON is used to treat mild to moderate pain and help relieve symptoms of arthritis (e.g. osteoarthritis and rheumatoid arthritis), such as inflammation, swelling, stiffness and joint pain. COXLEON does not cure arthritis.

COXLEON is also used to treat pain after a dental operation, surgical procedures, muscle pain and ankylosing spondylitis (which is a type of arthritis that affects the joints in the spine). COXLEON may also be used to treat pain caused by menstruation.

2. What you need to know before you take COXLEON

Do not take COXLEON:

- If you are allergic (hypersensitive) to celecoxib, sulphonamides or any other ingredients of COXLEON (see What COXLEON is and what it is used for).
- If you have a severe liver or kidney disorder.
- If as a result of taking acetylsalicylic acid or any other anti-inflammatory and pain-relieving medicine (NSAIDs) 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 have a heart disorder or had heart surgery.
- 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.
- If you suffer from stomach ulcers or intestines, or bleeding in your stomach or intestines.
- If you have an irritable digestive system.
- If you are pregnant (in your third trimester of pregnancy or later) or planning to fall pregnant.
- If you are breastfeeding.

Warnings and precautions

Take special care with COXLEON:

- If you have any stomach ulcers or bleeding, or a history thereof.

- If you are taking acetylsalicylic acid (even at low dose for heart protective purposes).
- If you are 20 weeks or later in your pregnancy, your baby may be at risk of kidney damage.
- The consumption of alcohol and anti-inflammatory and pain-relieving medicine (NSAIDs) may increase the risk of gastrointestinal problems.
- If you have a history of heart disorders (e.g. heart failure, myocardial infarction or stroke).
- If you have bone disease (osteoarthritis).
- If you have any heart risk factors (e.g. diabetes, smoking or high cholesterol).
- If you have fluid retention (such as swollen ankles and feet).
- If you have high blood pressure.
- If you have a kidney disorder (e.g. kidney damage or impaired kidney function).
- If you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (used to treat high blood pressure in instances with excess fluid in the body).
- If you have a liver disorder (e.g. hepatitis, liver failure, liver transplant).
- If you develop a skin rash at the beginning of treatment.
- If you have had a serious allergic reaction or a serious skin reaction to any medicine.
- If you feel ill due to an infection or think you have an infection, as COXLEON may mask a fever or other signs of infection and inflammation.
- 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 over 65 years of age your doctor will want to monitor you regularly.
- If you are lactose intolerant.

Other medicines and COXLEON

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

- Warfarin or other warfarin like medicines ("blood-thinning" medicines helps prevent formation of blood clots) including newer medicines like apixaban.
- ACE-inhibitors, angiotensin II antagonists or beta-blockers (used for the treatment of high blood pressure).
- Aspirin (used for pain, inflammation and fever).
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants).
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia).
- Lithium (used in the treatment of bipolar disorder or epilepsy/fits/seizures).
- Oral contraceptives (used for the prevention of pregnancy).
- Glibenclamide/ tolbutamide (used to treat diabetes).
- Fluconazole and rifampicin (used to treat fungal and 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 (used to treat fungal infections) and antacids (used to relieve heartburn, indigestion or an upset stomach.

- Diuretics (used in the treatment of heart failure and high blood pressure).

COXLEON with food, drink and alcohol

COXLEON capsules should be taken by mouth, swallowed with liquid and may be taken with or without food.

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 COXLEON.

DO NOT use COXLEON if you are pregnant or suspect that you are pregnant. Contact your doctor immediately.

DO NOT use COXLEON if you are breastfeeding your baby.

Consider discontinuing COXLEON if you are planning on falling pregnant, as COXLEON may affect conception.

If you are a woman of childbearing potential, you should use effective contraception.

You should not take COXLEON during the second and third trimester of pregnancy.

Driving and using machines

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

COXLEON contains Lactose monohydrate

COXLEON contains lactose monohydrate, which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take COXLEON.

3. How to take COXLEON

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

Always take COXLEON exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the correct dose for your condition.

The usual dose is one COXLEON 100 or COXLEON 200 capsule, once or twice daily with or without food, as instructed by your doctor.

If you have the impression that the effect of COXLEON capsules is too weak or too strong, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with COXLEON will last. The duration of treatment should not continue for more than 14 days without review.

If you take more COXLEON 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 COXLEON

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your COXLEON capsules at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

COXLEON can have side effects.

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

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

- Swelling of your face, lips, mouth, tongue, eyes or throat (angioedema).
- Difficulty breathing, dizziness (severe hypersensitivity).
- Severe skin rash, blistering itching or peeling of the skin.
- Dizziness or fainting.

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

Tell your doctor if you notice any of the following side effects that have been reported frequently:

- Yellowing of the skin and eyes, also called jaundice.
- Sleeping problems.
- Chest pain, heart failure.
- High blood pressure, fast or irregular heartbeats.
- Joint pain.
- Dizziness, extreme tension of the muscles.
- Bronchitis, coughing, sore throat, runny nose, inflammation of the sinuses.
- Stomach pain, diarrhoea, indigestion, flatulence.
- Skin rash, itching of the skin.
- Infection in the urinary tract (bladder).
- Hallucinations.
- Worsening of existing allergies.
- Nausea, vomiting, difficulty in swallowing.
- Flu-like symptoms, swelling of tissues due to the accumulation of fluid.

Tell your doctor if you notice any of the following side effects that have been reported less frequently:

- Looking pale, bleeding or bruising more easily than normal.
- Swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing.
- Feeling anxious, depression.
- High levels of potassium in blood test results (can cause nausea (feeling sick), fatigue, muscle weakness or palpitations).
- Ulcers (bleeding) in the stomach, gullet or intestines; or rupture of the intestine (can cause stomach ache, fever, nausea, vomiting, intestinal blockage), dark or black stools, inflammation of the pancreas (can lead to stomach pain), inflammation of the gullet (oesophagus).
- Eye inflammation, bleeding in the eye, blockage of an artery or vein in the eye leading to partial or complete loss of vision.
- Drowsiness.
- Confusion.
- Stroke.
- Impaired or blurred vision, ringing in the ears, mouth pain and sores, difficulty hearing.
- Blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse.
- Constipation, burping, stomach inflammation (indigestion, stomach ache or vomiting), worsening of inflammation of the stomach or intestine.
- Severe liver inflammation (hepatitis). Symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellow discolouration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills.
- 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 delayed allergic reaction with possible symptoms such as rash, swelling of the face, fever, swollen glands.
- Muscle pain and weakness.
- 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 (oedema), foamy urine, fatigue and a loss of appetite).
- Low levels of sodium in the blood (a condition known as hyponatraemia).
- Menstrual disturbances.
- Fast or irregular heartbeats.
- Flushing.
- Unusual hair thinning or loss.
- Fatigue.

Tell your doctor if you notice any of the following side effects that have been reported where the frequency is unknown:

- Meningitis (inflammation of the membrane around the brain and spinal cord).
- Difficulty falling pregnant.

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 COXLEON.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store COXLEON

- Store at or below 25 °C.
- Do not remove blisters from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COXLEON contains

Active ingredient:

Each COXLEON 100 capsule contains 100 mg celecoxib.

Each COXLEON 200 capsule contains 200 mg celecoxib.

The other ingredients are:

Carrageenan, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium laurilsulfate.

Body composition: gelatine, titanium dioxide.

COXLEON 100 mg cap composition: gelatine, indigo-carmine FD&C Blue 2, titanium dioxide.

COXLEON 200 mg cap composition: gelatine, red iron oxide, titanium dioxide, yellow iron oxide.

What COXLEON looks like and contents of the pack

COXLEON 100: Blue capsule with white body, which contains white to slightly yellowish pellets.

COXLEON 200: Orange capsule with white body, which contains white to slightly yellowish pellets.

COXLEON is packed in:

COXLEON 100 and 200 mg capsules are packed into Al/PVC/TE/PVDC blisters.

Pack sizes: COXLEON 100 and COXLEON 200 are packed in 10's, 30's and 60's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07