

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CELECOXIB 100 ASCENDIS hard gelatin capsules

Contains sugar (lactose as lactose monohydrate 27,07 mg per capsule).

CELECOXIB 200 ASCENDIS hard gelatin capsules

Contains sugar (lactose as lactose monohydrate 54,14 mg per capsule).

Read all of this leaflet carefully before you start taking CELECOXIB ASCENDIS

- 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.
- CELECOXIB ASCENDIS 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 CELECOXIB ASCENDIS is and what it is used for
2. What you need to know before you take CELECOXIB ASCENDIS
3. How to take CELECOXIB ASCENDIS
4. Possible side effects
5. How to store CELECOXIB ASCENDIS
6. Contents of the pack and other information

1. What CELECOXIB ASCENDIS is and what it is used for

CELECOXIB ASCENDIS is used in adults for the relief of signs and symptoms of osteoarthritis and rheumatoid arthritis (symptoms of arthritis such as inflammation, swelling, stiffness and joint pain). It is used for the treatment of pain after dental surgery, or moderate pain after an operation (post-operative), pain in your muscles, bones, ligaments, tendons and nerves (musculoskeletal), pain before and during menstruation (primary dysmenorrhea), and ankylosing spondylitis (a form of arthritis that primarily affects the spine).

CELECOXIB ASCENDIS belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), 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. CELECOXIB ASCENDIS acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

2. What you need to know before you take CELECOXIB ASCENDIS

Do not take CELECOXIB ASCENDIS:

- If you are hypersensitive (allergic) to celecoxib or any of the other ingredients of CELECOXIB ASCENDIS (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 have severe liver disease.
- If you have severe kidney disease.
- If as a result of taking aspirin or any other anti-inflammatory and pain relieving medicine (NSAIDs) you have had asthma, nose polyps (soft and painless growths inside the nose lining), 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 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.
- If you currently have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines.
- If you have an inflammatory disease of the intestines such as inflammatory bowel disease.
- If you are pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor (see Pregnancy, Breastfeeding).
- If you are breastfeeding (see Pregnancy, Breastfeeding).

Warnings and precautions

Take special care with CELECOXIB ASCENDIS:

CELECOXIB ASCENDIS may make you prone to heart damage, damage to your stomach and intestines, or severe skin reactions which may be fatal.
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Talk to your doctor or pharmacist before taking CELECOXIB ASCENDIS:

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

- If you are taking aspirin (even at low dose for heart protective purposes), (see Other medicines and CELECOXIB ASCENDIS).
- 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 ASCENDIS 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 were previously diagnosed as a poor metaboliser, your doctor will want to start with a lower dose.
- 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 ASCENDIS 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.

Children and adolescents

CELECOXIB ASCENDIS is not for use in children and adolescents under the age of 18 years.

Other medicines and CELECOXIB ASCENDIS

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

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

- Warfarin or other warfarin like medicines (“blood-thinning” agents that reduce blood clotting) including newer medicines like apixaban.
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure).
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after organ transplants).
- CELECOXIB ASCENDIS can be taken with low dose aspirin (75 mg or less daily). Ask your doctor for advice before taking both medicines together.
- Dextromethorphan (used to treat coughs).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia).
- Lithium (used to treat some types of depression).
- Neuroleptics (used to treat some mental disorders).
- Fluconazole and rifampicin (used to treat fungal and bacterial infections)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat.
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression).
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders).

CELECOXIB ASCENDIS with food and alcohol

CELECOXIB ASCENDIS can be taken with or without food. CELECOXIB ASCENDIS should not be taken with alcohol (see Warnings and precautions).

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 health care provider for advice before taking CELECOXIB ASCENDIS.

Pregnancy

CELECOXIB ASCENDIS 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 ASCENDIS you should discontinue the treatment and contact your doctor for an alternative treatment.

Breastfeeding

CELECOXIB ASCENDIS must not be used during breastfeeding.

Fertility

NSAIDs (medicines used to treat inflammation), including CELECOXIB ASCENDIS, 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

It is not always possible to predict to what extent CELECOXIB ASCENDIS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CELECOXIB ASCENDIS affects you. If you feel dizzy or drowsy after taking CELECOXIB ASCENDIS, do not drive or operate machinery until these effects wear off.

CELECOXIB ASCENDIS contains lactose

CELECOXIB ASCENDIS 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 CELECOXIB ASCENDIS.

3. How to take CELECOXIB ASCENDIS

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

Always take CELECOXIB ASCENDIS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. 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 CELECOXIB ASCENDIS for longer than necessary to control symptoms.

The usual dose is:

- For osteoarthritis, the usual dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.
- For rheumatoid arthritis, the usual dose is 100 mg or 200 mg twice per day.
- For pain post dental surgery, the usual dose is 100 mg to 200 mg, up to a maximum daily dose of 400 mg. Dosing intervals should not be less than 4 hours.

- For mild to moderate post-operative pain the recommended dose is 200 mg twice daily.
- For mild to moderate musculoskeletal pain the recommended dose is 200 mg once daily.
- For mild to moderate primary dysmenorrhea the recommended dose is 400 mg initially, followed by an additional 200 mg dose if needed. On the subsequent days, the recommended dose is 200 mg twice daily.
- For ankylosing spondylitis, the usual dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

You should not take more than 400 mg per day.

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.

Use in children: CELECOXIB ASCENDIS is for adults only, it is not for use in children under the age of 18 years.

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

Method of administration

CELECOXIB ASCENDIS capsules can be taken any time of the day, with or without food and with a sufficient quantity of liquid (e.g. one glass of water).

However, taking each dose of CELECOXIB ASCENDIS at the same time each day will have the best effect.

If you take more CELECOXIB ASCENDIS 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 CELECOXIB ASCENDIS

Do not take a double dose to make up for forgotten individual dose. Take the dose as soon as you remember. However, do not take the next dose within 4 hours of taking the forgotten dose.

If you stop taking CELECOXIB ASCENDIS

Suddenly stopping your treatment with CELECOXIB ASCENDIS may lead to your symptoms getting worse. Do not stop taking CELECOXIB ASCENDIS unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

4. Possible side effects

CELECOXIB ASCENDIS can have side effects.

Not all side effects reported for CELECOXIB ASCENDIS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking CELECOXIB ASCENDIS, please consult your health care provider for advice.

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

- 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 bloodstained 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 CELECOXIB ASCENDIS. 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:

- Heart attack (myocardial infarction)
- Fluid build-up with swollen ankles, legs and/or hands
- Difficulty swallowing
- Stroke, bleeding inside the brain (it can be fatal)
- Blurred vision, inflammation or swelling of the white part of the eye, bleeding in the eye, blockage of an artery or vein in the eye leading to partial or complete loss of vision
- Tightness of chest with difficulty to breath (bronchospasm), inflammation of air sacs in lungs
- Bleeding from any area from the mouth to the rectum (gastrointestinal tract)
- Abnormal liver function, (symptoms of liver problems may include nausea

(feeling sick), diarrhoea, jaundice (yellow discolouration of the skin or eyes), dark urine, pale stools, itching or chills), abnormalities in liver-related blood tests, liver failure, liver damage and severe liver inflammation (fulminant hepatitis) (sometimes fatal or requiring liver transplant), liver problems (such as cholestasis and cholestatic hepatitis)

- Raised itchy rash, skin discolouration (bruising), swelling under skin/hives, hair loss, reaction to the sun, itchy, dry skin or a rash on swollen, reddened skin (dermatitis), peeling of the skin, serious skin conditions such as Stevens-Johnson syndrome, 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)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Sinus inflammation, sinus infection, blocked or painful sinuses (sinusitis), upper respiratory tract infection, inflammation of the back of the throat (pharyngitis), urinary tract infection, low blood cell count (pancytopenia)
- Difficulty sleeping
- Dizziness, muscle stiffness, headache
- High blood pressure
- Running nose (rhinitis), coughing, difficulty breathing
- Nausea, stomach pain, diarrhoea, indigestion, wind/gas (flatulence), vomiting
- Rash, itching
- Pain in joints (arthralgia)

- Influenza-like illness, swelling of the hand and feet / retention of fluids

Less frequent

- Low red blood cells (anaemia), Low white blood cells (leukopenia), low blood platelet count may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections, (thrombocytopenia)
- High blood potassium levels
- Anxiety, depression, feeling tired or lack of energy (fatigue), confusional state, hallucinations
- Sensation of pins and needles, sleepiness, uncoordinated movement (ataxia), impaired sense of taste, meningitis aseptic, epilepsy (including aggravated epilepsy), loss of taste functions of the tongue (ageusia), impaired sense of smell (anosmia)
- Noise or ringing in the ears, partial loss of hearing
- Heart failure, sensation that the heart is pounding or racing, rapid heartbeat, irregular heartbeat
- Blockage of arteries in lungs, rapid reddening of neck and face (flushing), inflammation of blood vessels resulting in restricted blood flow to organs
- Constipation, inflammation of the stomach lining, painful swelling and sores inside the mouth, inflammation of all or part of the digestive tract, burping, sores in the gastrointestinal tract, ruptured bowel, inflammation of the tube running from the mouth to the stomach (oesophagus), dark sticky faeces containing partly digested blood, inflammation of the pancreas, inflammation of the colon
- Muscle spasms (leg cramps), inflammation of the muscles (weak, swelled and painful muscles) used to move the body
- Abnormalities in kidney-related blood tests
- Menstrual disorder, decreased fertility in females, which is usually reversible

- Swelling of the face, chest pain

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 CELECOXIB ASCENDIS.

5. How to store CELECOXIB ASCENDIS

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the outer unit carton until required for use.
- Do not use after the expiry date stated on the label/blister/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 CELECOXIB ASCENDIS contains

- The active substance is celecoxib.

Each CELECOXIB 100 ASCENDIS capsule contains 100 mg celecoxib.

Each CELECOXIB 200 ASCENDIS capsule contains 200 mg celecoxib.

- The other ingredients for the capsule content are lactose monohydrate,

croscarmellose sodium, sodium lauryl sulphate, povidone, magnesium stearate.

- The ingredients for the hard gelatin capsule shell are gelatin, purified water, titanium dioxide (CI 77891), sodium lauryl sulphate.
- The ingredients for the printing ink are shellac (E904), dehydrated alcohol (E1510), isopropyl alcohol, butyl alcohol, propylene glycol (E1520), strong ammonia solution (E527), indigo carmine (E132).

What CELECOXIB ASCENDIS looks like and contents of the pack

CELECOXIB ASCENDIS is available as hard gelatin capsules.

CELECOXIB 100 ASCENDIS: Size “2” capsules opaque white with a blue band reverse printed “100” in white on body and “CEL” in white on cap.

CELECOXIB 200 ASCENDIS: Size “2” capsules opaque white with a yellow band reverse printed “200” in white on body and “CEL” in white on cap.

CELECOXIB ASCENDIS capsules are packed in:

- Aluminium foil and triplex PVC/PE/PVDC clear blisters strips of 10 capsules. Blister strips are stored in an outer unit carton in pack sizes of 10’s, 20’s, 30’s, 60’s and 100’s.
- 100 capsules packed in a white round HDPE container with a white HDPE cap along with a silica gel bag and sealed with an aluminium tagger. Each container is packed in an outer unit carton.

Holder of Certificate of Registration

Ascendis Pharma (Pty) Ltd.

31 Georgian Crescent East

Bryanston

Ascendis Pharma (Pty) Ltd

Date: 10 August 2022

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CELECOXIB 100 ASCENDIS: 53/3.1/0015

CELECOXIB 200 ASCENDIS: 53/3.1/0016

Access to the corresponding Professional Information

To be confirmed