

Package leaflet: Information for the user

Celecoxib Rowex 100 mg capsules, hard Celecoxib Rowex 200 mg capsules, hard

celecoxib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Celecoxib Rowex is and what it is used for

Celecoxib Rowex contains the active substance celecoxib which belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAID), and specifically a sub-group known as cyclooxygenase-2 (COX-2) inhibitors. These work by lowering the amount of prostaglandins. Prostaglandins are substances made by your body. Some prostaglandins cause pain and inflammation, but others help protect the stomach lining. Celecoxib Rowex reduces the production of prostaglandins that cause pain and inflammation and not the ones that protect the stomach.

Celecoxib Rowex is used in adults for pain relief and to alleviate swelling of tissue in the degenerative joint disease (osteoarthritis), inflammatory rheumatic joint disease (rheumatoid arthritis) and in certain types of inflammation of intervertebral joints (ankylosing spondylitis).

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 Celecoxib Rowex

Do not take Celecoxib Rowex if you:

- are **allergic** to celecoxib or any of the other ingredients of this medicine (listed in section 6)
- have had an **allergic reaction** to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections)
- have currently **stomach or duodenal ulcer** or **bleeding in the stomach or intestine**
- 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 as a result of taking acetylsalicylic acid or any other anti-inflammatory and pain relieving medicine (NSAID, e.g. ibuprofen, including cyclooxygenase-2 (COX-2) inhibitors)
- have **severe liver disease**
- have **severe kidney disease**
- are **pregnant** or are in your fertile period (if it is **possible** for you to **become pregnant** during ongoing treatment you should discuss methods of contraception with your doctor)
- are **breast-feeding**

- have an inflammatory disease of the intestines, such as **ulcerative colitis** or **Crohn's disease**
- 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
- 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 think any of the above conditions apply to you consult your doctor or pharmacists.

Warnings and precautions

Talk to your doctor or pharmacist before taking Celecoxib Rowex if you:

- have heart, liver or kidney problems, your doctor may want to keep a regular check on you
- are dehydrated due to vomiting, diarrhoea or the use of diuretics (used to treat excess fluid in the body)
- have oedema (fluid retention, such as swollen ankles and feet)
- have previously had a stomach or duodenal (intestinal) ulcer or bleeding in the stomach or intestines
- feel ill due to an infection or think you have an infection, as Celecoxib Rowex may mask a fever or other signs of an infection and inflammation
- smoke, have diabetes, raised blood pressure or raised levels of cholesterol in your blood
- have had a serious allergic reaction or a serious skin reaction to any medicines
- are over 65 years of age: your doctor will want to monitor you regularly.

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 Rowex 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).

Children and adolescents

Celecoxib Rowex is for adults only. It is not for use in children.

Other medicines and Celecoxib Rowex

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

In particular, it is very important to tell your doctor if you are taking any of the following medicines:

- medicines to reduce blood clotting, e.g. **warfarin/coumarin like anticoagulants** or novel oral anti-clotting medicines such as **apixaban, dabigatran** or **rivaroxaban**
- medicines called **corticosteroids** (e.g. prednisone)
- **acetylsalicylic acid** (even at low dose for heart protective purposes) or **other nonsteroidal anti-inflammatory medicines (NSAIDs)**, e.g. ibuprofen or diclofenac. You should avoid taking celecoxib and non-acetylsalicylic acid anti-inflammatory medicines concomitantly. Celecoxib Rowex can be taken with low dose acetylsalicylic acid (75 mg or less daily). Ask your doctor for advice before taking both medicines together.
- **ACE inhibitors**, medicines for treatment of heart problems
- **angiotensin II receptor antagonists**, medicines for treatment of heart problems
- **beta blockers**, medicines used for high blood pressure and heart failure
- **barbiturates**, medicines for treating epilepsy/fits or insomnia

- **carbamazepine**, a medicine for treating epilepsy/fits or some types of pain or depression
- **citalopram, imipramine**, medicines for treating depression, or **lithium** (used to treat manic phase in bipolar disorder (type of depression))
- other medicines to treat **depression** (tricyclics and SSRIs-selective serotonin reuptake inhibitors)
- **ciclosporin** or **tacrolimus**, medicines used to prevent rejection in transplant patients
- **dextromethorphan**, a medicine used in some cough mixtures
- **diazepam**, a medicine to treat insomnia or anxiety
- **diuretics**, medicines to treat high blood pressure, heart failure or excess fluid in the body
- **fluconazole**, a medicine used to treat fungal infections
- **methotrexate**, a medicine for treatment of rheumatoid arthritis, psoriasis or leukaemia
- **rifampicin**, a medicine for treatment of bacterial infections
- medicines for treating **psychoses** and **schizophrenia** (neuroleptics)
- medicines for treating **sleep disorders, high blood pressure** or an **irregular heartbeat** (anti-arrhythmics).

Ask your doctor if you are not sure which of these medicines you are taking.

Celecoxib Rowex with alcohol

The consumption of alcohol is not recommended when taking Celecoxib Rowex since it may increase the risk of gastrointestinal problems.

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 this medicine.

- You **must not use Celecoxib Rowex** if you 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** while taking this medicine, **stop taking it immediately** and tell your doctor.
- **Do not take** this medicine if you are **breast-feeding**.
- NSAIDs, including Celecoxib Rowex, 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 may feel dizzy or drowsy after taking Celecoxib Rowex. If this happens, do not drive or operate machinery until these effects wear off.

Celecoxib Rowex 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 this medicine.

Celecoxib Rowex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Celecoxib Rowex

Always take this medicine 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 this medicine for longer than necessary to control symptoms.

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

The recommended dose is:

For degenerative joint disease (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 inflammatory rheumatic joint disease (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 certain types of inflammation of intervertebral joints (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.

Do not take more than 400 mg per day in all therapeutic uses.

The elderly

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.

Kidney or liver problems

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

Method of use

Celecoxib Rowex is for oral use.

Take your capsule(s):

- swallow them whole with a glass of water
- preferably at the same time each day
- with or without food.

If you have difficulty swallowing capsules: The entire capsule contents can be sprinkled onto a level teaspoon of semi-solid food (such as cool or room temperature applesauce, rice gruel, yogurt or mashed banana) and swallowed immediately with a glass of water.

To open the capsule, hold upright to contain the granules at the bottom then gently squeeze the top and twist to remove, taking care not to spill the contents. **Do not chew or crush the pellets.**

If you take more Celecoxib Rowex than you should

If you take too many capsules, contact your nearest hospital casualty department or tell your doctor immediately. Take your medicine with you to show the doctor what you have taken.

If you forget to take Celecoxib Rowex

It is important to take your medicine every day. However, if you forget to take one or more doses, take it as soon as you remember and then continue with your normal schedule.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Celecoxib Rowex

Always consult your doctor, before you stop taking this medicine. Even if you feel well, your doctor may decide that it is necessary to continue taking this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects listed below were observed in arthritis patients who took celecoxib. Side effects marked with an asterisk (*) are listed below at the higher frequencies that occurred in patients who took celecoxib to prevent colon polyps. Patients in these studies took celecoxib at high doses and for a long duration.

If any of the following happen, stop taking Celecoxib Rowex and tell your doctor immediately:

- 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)).

Possible side effects:

Very common, may affect more than 1 in 10 people

- high blood pressure, including worsening of existing high blood pressure.*

Common, may affect up to 1 in 10 people

- inflammation of the sinuses (sinusitis)
- upper respiratory tract infection
- urinary infection
- worsening of existing allergies
- difficulty sleeping, dizziness
- muscle stiffness
- headache
- heart attack*
- cough
- breathing difficulty*
- sore throat
- runny or stuffy nose, sneezing
- stomach ache
- diarrhoea
- indigestion
- wind
- nausea (feeling sick)
- vomiting *
- difficulty swallowing*
- rash, itching of the skin
- painful joints
- fluid build-up with swollen ankles, legs and/or hands
- flu-like symptoms
- accidental injury.

Uncommon, may affect up to 1 in 100 people

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- high level of blood potassium which can cause muscle weakness, twitching or abnormal heart rhythm

- anxiety, depression, tiredness
- stroke*
- tingling or numbness (paraesthesia), sleepiness
- blurred vision, eye inflammation (conjunctivitis)
- ringing in the ears, difficulty hearing*
- heart failure
- faster heartbeat or feeling your heartbeat
- difficulty breathing (bronchospasm)
- constipation, burping, stomach inflammation, worsening of inflammation of the stomach or intestine
- mouth pain and sores
- changed liver function, increased levels of liver enzymes in the blood such as SGOT, SGPT
- raised itchy rash (hives)
- skin discolouration (bruising)
- leg cramps
- changes in kidney-related blood tests: increased levels of creatinine and blood urea nitrogen
- face swelling
- chest pain (generalised pain not related to the heart).

Rare, may affect up to 1 in 1,000 people

- reduced number of white blood cells, which help protect the body from infection (leucopenia)
- reduced number of blood platelets, which increases risk of bleeding or bruising
- confusion
- hallucinations
- difficulty in controlling movements (ataxia)
- changes in the way things taste
- bleeding in the eye
- irregular heartbeat
- blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse.
- acute reaction that may lead to lung inflammation
- flushing
- bleeding of the stomach or intestines (can lead to bloody stools or vomiting), inflammation of the intestine or colon
- ulcers (bleeding) in the gullet, stomach, intestines or rupture of the intestine (can cause stomach ache, fever, nausea, vomiting, intestinal blockage)
- inflammation of the gullet with difficulty in swallowing (oesophagitis)
- dark or black stools
- inflammation of pancreas, which causes severe pain in the abdomen and back
- 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.
- swelling of the face, lips, mouth, tongue or throat, or difficulty swallowing
- loss of hair
- increased sensitivity to light
- acute kidney failure
- low blood levels of sodium which can cause tiredness, confusion, muscle twitching, fits and coma
- menstrual disturbances.

Very rare, may affect up to 1 in 10,000 people

- a reduction in the number of red and white blood cells and platelets (may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections)
- serious allergic reactions including possibly fatal anaphylactic shock

- bleeding within the brain including fatal cases
- inflammation of the membrane around the brain and spinal cord not caused by infection (aseptic meningitis)
- fits or worsening of epilepsy (possible more frequent and/or severe seizures)
- loss of sense of taste
- loss of sense of smell
- blockage of an artery or vein in the eye leading to partial or complete loss of vision
- inflammation of a blood vessel which can cause fever, aches and purple blotches on the skin
- liver failure, liver damage, severe inflammation of the liver (fulminant hepatitis) (sometimes fatal or requiring liver transplant). Symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellow discolouration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills.

Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.

- liver problems such as cholestasis and cholestatic hepatitis, which may be accompanied by symptoms such as discoloured stools, nausea and yellowing of the skin or eyes
- serious skin conditions such as Stevens-Johnson syndrome, exfoliative dermatitis, 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 and abnormal test results, concerning e.g. the liver or blood cells (eosinophilia, a type of raised white blood cell count). This reaction is called drug rash with eosinophilia and systemic symptoms (DRESS) or hypersensitivity syndrome.
- muscle inflammation with 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 loss of appetite).

Frequency not known (frequency cannot be estimated from the available data)

- decreased fertility in females, which is usually reversible after you stop taking this medicine.

Furthermore, the following previously unknown side effects occurred in polyp prevention studies, where patients were taking 400 mg celecoxib daily:

- Common (may affect up to 1 in 10 people): chest pain (angina pectoris), irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind), kidney stones (which may lead to stomach or back pain, blood in urine), blood creatinine increased, benign prostatic hyperplasia with difficulty passing urine, weight increased
- Uncommon (may affect up to 1 in 100 people): stomach infection, which can cause irritation and ulcers of the stomach and intestines (Helicobacter infection), shingles, superficial infection of the skin (erysipelas), lung infection (bronchopneumonia - chest infection [possible cough, fever, difficulty breathing]), inner ear infection, gum infection, fatty lumps in skin or elsewhere (lipoma), floaters in the eye causing blurred or impaired vision, conjunctival bleeding, deep vein thrombosis (blood clot usually in the leg, which may cause pain, swelling or redness of the calf or breathing problems), voice disorder (difficulty speaking), bleeding from piles (haemorrhoids), frequent bowel movements, mouth sores, allergic dermatitis, ganglion cyst, a harmless swellings on or around joints and tendons in the hand or foot, excessive urination at night, abnormal or very heavy bleeding from the vagina, breast pain, lower limb fracture, blood sodium increased.

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 directly via the national reporting system: HPRA Pharmacovigilance; Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Celecoxib Rowex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Celecoxib Rowex contains

Celecoxib Rowex 100 mg capsules, hard:

- The active substance is celecoxib. Each hard capsule contains 100 mg celecoxib.

Celecoxib Rowex 200 mg capsules, hard:

- The active substance is celecoxib. Each hard capsule contains 200 mg celecoxib.
- The other ingredients are:
Contents of capsule Celecoxib Rowex 100 mg and 200 mg capsules, hard:
Carrageenan (E407), sodium laurilsulphate, lactose monohydrate, microcrystalline cellulose (E460), magnesium stearate (E470b), silica colloidal anhydrous (E551), talc (E553b).

Capsule shell Celecoxib Rowex 100 mg capsules, hard:

Gelatin (E441), titanium dioxide (E171), indigo carmine (E132).

Capsule shell Celecoxib Rowex 200 mg capsules, hard:

Gelatin (E441), titanium dioxide (E171), iron oxide, red (E172), iron oxide, yellow (E172).

What Celecoxib Rowex looks like and contents of the pack

Celecoxib Rowex 100 mg capsules, hard:

Capsules (length 17.7 – 18.3 mm) have white body and blue cap, containing white to slightly yellowish pellets.

Celecoxib Rowex 200 mg capsules, hard:

Capsules (length 19.1 – 19.7 mm) have white body and orange cap, containing white to slightly yellowish pellets.

Celecoxib Rowex hard capsules are packed in PVC/TE/PVDC/Alu foil blisters. Box contains: 10, 20, 30, 50, 60, 90 or 100 hard capsules.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

Lek S.A. ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Celecoxib Sandoz 100 mg capsules, hard Celecoxib Sandoz 200 mg capsules, hard
Bulgaria	Celecoxib Sandoz 100 mg capsules, hard Celecoxib Sandoz 200 mg capsules, hard
Cyprus	Celecoxib, Sandoz, 200MG, CAPSULE, HARD
Finland	Celecoxib Sandoz 100mg kapselit, kovat Celecoxib Sandoz 200mg kapselit, kovat
Germany	Celecoxib – 1 A Pharma 100 mg Hartkapseln Celecoxib – 1 A Pharma 200 mg Hartkapseln
Ireland	Celecoxib Rowex 100 mg capsules, hard Celecoxib Rowex 200 mg capsules, hard
Luxembourg	Celecoxib Sandoz 100 mg gélule Celecoxib Sandoz 200 mg gélule
Malta	Celecoxib Sandoz 100 mg capsules, hard Celecoxib Sandoz 200 mg capsules, hard
Slovenia	Celekoksib Lek 100 mg trde capsule Celekoksib Lek 200 mg trde capsule
Sweden	Celecoxib Sandoz 100mg kapslar, harda Celecoxib Sandoz 200mg kapsel, hard

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