

Revcox 200mg Capsule

Celecoxib 200mg

WHAT IS IN THIS LEAFLET:

1. What Revcox is used for
2. How Revcox works
3. Before you use Revcox
4. How to use Revcox
5. While you are using it
6. Side effects
7. Storage and Disposal of Revcox
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

WHAT REVCOX IS USED FOR

Celecoxib is used 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).

HOW REVCOX WORKS

Revcox belongs to a group of medicines called cyclo-oxygenase-2 (COX-2) inhibitors. These work by lowering the amount of prostaglandins. Prostaglandins are substances made by your body. Some prostaglandins cause pain and swelling, but others help protect the stomach lining. Revcox reduces the production of prostaglandins that cause pain and swelling and not the ones that protect the stomach.

BEFORE YOU USE REVCOX

When you must not use it

- are allergic to celecoxib or any of the other ingredients of this medicine
- 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 cyclo-oxygenase-2 (COX-2) inhibitors)
- have severe liver disease
- have severe kidney disease
- are breast-feeding
- have an inflammatory disease of the intestines, such as ulcerative colitis or Crohn’s 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)
- 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.

Before you start to use it

Talk to your doctor or pharmacist before taking Revcox if you:

- have heart, liver or kidney problems, your doctor may want to keep a regular check on you
- are taking 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 Revcox 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 may want to keep a regular check on you.

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.

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.

Pregnancy

You must not use Revcox 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.

Breast-feeding

Do not take this medicine if you are breast-feeding.

Fertility

NSAIDs, including Revcox 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.

Children and adolescents

Revcox is for adults only. It is not for use in children.

Taking other medicines

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:

- warfarin or other medicines that reduce blood clotting (oral anticoagulants)
- acetylsalicylic acid (even at low dose for heart protective purposes) or other nonsteroidal anti-inflammatory medicines (e.g. ibuprofen or diclofenac). You should avoid taking celecoxib and non-acetylsalicylic anti-inflammatory medicines concomitantly. Revcox 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
- AIIIRA (angiotensin II receptor antagonists), medicines for treatment of heart problems

Revcox 200mg Capsule

Celecoxib 200mg

- Beta-blockers, medicines for reducing blood pressure
- barbiturates, medicines for treating epilepsy or insomnia
- carbamazepine, a medicine for treating epilepsy 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 excess fluid in the body
- fluconazole, a medicine used to treat fungal infections
- methotrexate, a medicine for treatment of rheumatoid arthritis, psoriasis or leukemia
- rifampicin, a medicine for treatment of bacterial infections
- medicines for treating psychoses and schizophrenia (neuroleptics)

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

HOW TO USE REVCOX

How much to use

- Always take Revcox exactly as your doctor has advised you. You should check with your doctor or pharmacist if you are not sure.
- Your doctor will determine what dose is appropriate for you.
- 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.

For degenerative joint disease (osteoarthritis)

The usual dose is 200 mg each day. 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 usual dose is 100mg or 200 mg twice each day. The dose is usually:

- one 100 mg capsule twice a day; or
- one 200 mg capsule twice a day.

For certain types of inflammation of intervertebral joints (ankylosing spondylitis)

The usual dose is 200 mg each day. The dose is usually:

- one 200 mg capsule once a day; or
- one 100 mg capsule twice a day.

Some patients might be given 400 mg each day but this will depend on your doctor.

For acute or short term pain and dysmenorrhoea

The usual dose is usually 400mg initially, followed by additional 200mg on the first day. On other days, the usual dose is 200mg twice a day when needed.

Lower back pain

The usual dose is 200 mg each day. The dose is usually:

- one 100 mg capsule twice a day; or
- one 200 mg capsule once a day.

Older people

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.

When to use it

You should take your medicine at the same time each day with a drink of water. Celecoxib can be given with or without food.

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

How long to use it

Do not stop taking Revcox unless your doctor tells you to.

If you forget to use it

It is important to take your medicine every day. However, if you forget to take one or

more doses, take another as soon as you remember and then go on as prescribed. Do not take a double dose to replace the forgotten dose.

If you use too much (overdose)

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 been taken.

WHILE YOU ARE USING IT

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Revcox.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Revcox to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

You may feel dizzy or drowsy after taking Revcox. If this happens, do not drive or operate machinery until these effects wear off.

SIDE EFFECTS

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

Very common side-effects

High blood pressure, including worsening of existing high blood pressure

Common side-effects

- 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
- diarrhea

Revcox 200mg Capsule

Celecoxib 200mg

- indigestion
- wind
- nausea (feeling sick)
- vomiting
- difficulty swallowing
- rash, itching of the skin
- painful joints
- fluid buildup with swollen ankles, legs and/or hands
- flu-like symptoms
- accidental injury

Uncommon side-effects

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- high level of blood potassium which can cause 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 heart beat 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
- 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)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF REVCOX

Storage

- Keep out of the reach and sight of children.
- Do not use Revcox 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
- Do not store above 30°C.
- Store in the original package.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRODUCT DESCRIPTION

Revcox 200mg Capsule

What it looks like

200 mg capsule, hard: White body and orange cap, containing white to slightly yellow coloured pellets.

Ingredients

Active Ingredients

The active substance is celecoxib. Each capsule contains 200 mg celecoxib.

Inactive Ingredients

The other ingredients in the capsules are:

Capsule contents: Carrageenan, Sodium laurilsulfate, Lactose monohydrate, Microcrystalline cellulose, Magnesium stearate, Silica colloidal anhydrous, Talc.

Capsule shell: Gelatin, Titanium dioxide, Iron oxide, red, Iron oxide, yellow.

Source of gelatin: bovine.

MAL number

Revcox 200 mg Capsule –
MAL19071008ACZ

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer

Novartis Pharmaceutical Manufacturing LLC
Verovškova ulica 57
1000 Ljubljana
Slovenia

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
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