

Package leaflet: information for the user

NORMOCOXIB 200 mg hard capsules 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, please 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 symptoms 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 NORMOCOXIB is and what it is used for
2. What you need to know before you take NORMOCOXIB
3. How to take NORMOCOXIB
4. Possible side effects
5. How to store NORMOCOXIB
6. Contents of the pack and other information

1. What NORMOCOXIB is and what it is used for

NORMOCOXIB is used in adults for the relief of signs and symptoms of **rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.**

NORMOCOXIB contains the active substance celecoxib and belongs to a group of medicinal products called nonsteroidal anti-inflammatory drugs (NSAID), 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.

NORMOCOXIB acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

2. What you need to know before you take NORMOCOXIB

You have been prescribed NORMOCOXIB by your doctor. The following information will help you get the best results with NORMOCOXIB. If you have any further questions please ask your doctor or pharmacist.

Do not take NORMOCOXIB

Tell your doctor if any of the following are true for you as patients with these conditions should not take NORMOCOXIB:

- if you are allergic to celecoxib or any of the other ingredients of this medicine (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 **currently** have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines

- if as a result of taking acetylsalicylic acid or any other anti-inflammatory medicine 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 are pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor
- if you are breast-feeding
- if you have severe liver disease
- if you have severe kidney disease
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease
- 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

Warnings and precautions

Talk to your doctor or pharmacist before taking NORMOCOXIB:

- if you have **previously** had an ulcer or bleeding in your stomach or intestines. (**Do not take NORMOCOXIB** if you **currently** have an ulcer or bleeding in your stomach or intestine)
- if you are taking acetylsalicylic acid (even at low dose for heart protective purposes)
- if you use medicines to reduce blood clotting (e.g. warfarin)
- if you are taking NORMOCOXIB 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 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 NORMOCOXIB may mask a fever or other signs of infection and inflammation
- if you are over 65 years of age your doctor may want to keep a regular check on you

As with other anti-inflammatory medicines (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.

NORMOCOXIB 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, breast-feeding and fertility).

Other medicines and NORMOCOXIB

Some medicines can affect the way other medicines work. Tell your doctor or pharmacist

if you are taking, have recently taken or might take any other medicines.

- Dextromethorphan (used to treat coughs)
- ACE inhibitors or angiotensin II antagonists (used for high blood pressure and heart failure)
- Diuretics (used to treat excess fluid in the body)
- Fluconazole and rifampicin (used to treat fungal and bacterial infections)
- Warfarin or other oral anticoagulants (agents that reduce blood clotting)
- Lithium (used to treat some types of depression)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat
- Neuroleptics (used to treat some mental disorders)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants)

NORMOCOXIB can be taken with low dose acetylsalicylic acid (75mg or less daily). Ask your doctor for advice before taking both medicines together.

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.

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

NORMOCOXIB must not be used during breast-feeding.

Driving and using machines

You should be aware of how you react to NORMOCOXIB before you drive or operate machinery. If you feel dizzy or drowsy after taking NORMOCOXIB, do not drive or operate machinery until these effects wear off.

NORMOCOXIB contains lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take NORMOCOXIB

Always take this medicine 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 NORMOCOXIB is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you what dose you should take. 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 NORMOCOXIB 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 osteoarthritis treatment

The usual dose is 200 mg a day that can be taken:

One 200 mg capsule *once a day*

If needed your doctor can increase the dose to a maximum of 400 mg as:

One 200 mg capsule *twice a day*

For rheumatoid arthritis treatment

The recommended initial dose is 200 mg a day:

One 100 mg capsule twice a day (*This 100 mg twice a day recommended initial dose cannot be administrated with this medicine. There are other medicines with a concentration of 100 mg celecoxib*). Please ask your doctor.

If needed your doctor can increase the dose to a maximum of 400 mg:

One 200 mg capsule *twice a day*

For ankylosing spondylitis treatment

The recommended initial dose is 200 mg a day:

One 200 mg capsule *once a day*

If needed your doctor can increase the dose to a maximum of 400 mg:

One 200 mg capsule *twice a day* or two 200 mg capsules *once a day*

Maximum daily dose:

Do not take more than 400 mg of celecoxib per day.

Patients with kidney or liver problems: make sure your doctor knows if you have liver or kidney problems as you may need a lower dose.

Patients older than 65 years, 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: NORMOCOXIB is for adults only, it is not for use in children.

Method of administration:

This medicine is taken by oral route.

The capsule should be swallowed whole with a drink of water and can be taken at any time of the day, with or without food. However, try to take each dose of NORMOCOXIB at the same time each day.

If you take more NORMOCOXIB than you should

You should not take more capsules than your doctor tells you to. If too many capsules are taken by accident contact your doctor, pharmacist or hospital and take your medicine with you.

If you forget to take NORMOCOXIB

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

If you stop taking NORMOCOXIB

Suddenly stopping your treatment with NORMOCOXIB may lead to your symptoms getting worse. Do not stop taking NORMOCOXIB 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

Like all medicines, NORMOCOXIB 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 you have any of the following side-effects, stop taking NORMOCOXIB 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)).

Very common side-effects (may affect more than 1 user in 10 people):

- High blood pressure*

Common side-effects (may affect up to 1 in 10 people):

- Heart attack*
- Fluid build up with swollen ankles, legs and/or hands
- Urinary infections
- Shortness of breath*, sinusitis (sinus inflammation, sinus infection, blocked or painful sinuses), blocked or runny nose, sore throat, coughs, colds, flu-like symptoms
- Dizziness, difficulty sleeping
- Vomiting*, stomach ache, diarrhoea, indigestion, wind
- Rash, itching
- Muscle stiffness
- Difficulty swallowing*
- Worsening of existing allergies

Uncommon side-effects (may affect up to 1 in 100 people):

- Stroke*

- Heart failure, palpitations (awareness of heart beat), fast heart rate
- Worsening of existing high blood pressure
- Abnormalities in liver-related blood tests
- Abnormalities in kidney-related blood tests
- Anaemia (changes in red blood cells that can cause fatigue and breathlessness)
- Anxiety, depression, tiredness, drowsiness, tingling sensations
- High levels of potassium in blood test results (can cause nausea (feeling sick), fatigue, muscle weakness or palpitations)
- Impaired or blurred vision, ringing in the ears, mouth pain and sores, difficulty hearing*
- Constipation, burping, stomach inflammation (indigestion, stomach ache or vomiting), worsening of inflammation of the stomach or intestine
- Leg cramps
- Raised itchy rash (hives)

Rare side effects (may affect up to 1 in 1,000 people):

- 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 gullet (can cause difficulty in swallowing), inflammation of the pancreas (can lead to stomach pain)
- Reduced number of white blood cells (which help protect the body from infection) and blood platelets (increased chance of bleeding or bruising)
- Difficulty coordinating muscular movements
- Feeling confused, changes in the way things taste
- Increased sensitivity to light
- Loss of hair

Not known frequency (frequency cannot be estimated from the available data):

- Bleeding within the brain causing death
- Serious allergic reactions (including potentially fatal anaphylactic shock) which can cause skin rash, swelling of the face, lips, mouth, tongue or throat, wheezing or difficulty breathing; difficulty swallowing
- Bleeding of the stomach or intestines (can lead to bloody stools or vomiting), inflammation of the intestine or colon, nausea (feeling sick)
- 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 (red swollen area with numerous small pustules)
- A delayed allergic reaction with possible symptoms such as rash, swelling of the face, fever, swollen glands, and abnormal test results (e.g., liver, blood cell (eosinophilia, a type of raised white blood cell count))
- Liver failure, liver damage and severe liver inflammation (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
- Kidney problems (possible kidney failure, inflammation of the kidneys)

- Blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse
- Irregular heartbeat
- Meningitis (inflammation of the membrane around the brain and spinal cord)
- Hallucinations
- Worsening of epilepsy (possible more frequent and/or severe seizures)
- Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
- Blockage of an artery or vein in the eye leading to partial or complete loss of vision, inflammation of the conjunctiva, bleeding in the eye
- 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)
- Chest pain
- Impaired sense of taste
- Skin discolouration (bruising), muscle pain and weakness, painful joints
- Menstrual disturbances
- Headache, flushing
- Low levels of sodium in blood test results (can cause loss of appetite, headache, nausea (feeling sick), muscle cramps and weakness)

In clinical studies not associated with Arthritis or other arthritic conditions, where Celecoxib was taken at doses of 400mg per day for up to 3 years, the following additional side effects have been observed:

Common side effects (may affect up to 1 in 10 people):

- Heart problems: angina (chest pain)
- Stomach problems: irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind)
- Kidney stones (which may lead to stomach or back pain, blood in urine), difficulty passing urine
- Weight gain

Uncommon side effects (may affect up to 1 in 100 people):

- Deep vein thrombosis (blood clot usually in the leg, which may cause pain, swelling or redness of the calf or breathing problems)
- Stomach problems: stomach infection (which can cause irritation and ulcers of the stomach and intestines)
- Lower limb fracture
- Shingles, skin infection, eczema (dry itchy rash), pneumonia (chest infection (possible cough, fever, difficulty breathing))
- Floaters in the eye causing blurred or impaired vision, vertigo due to inner ear troubles, sore, inflamed or bleeding gums, mouth sores
- Excessive urination at night, bleeding from piles/haemorrhoids, frequent bowel movements
- Fatty lumps in skin or elsewhere, ganglion cyst (harmless swellings on or around joints and tendons in the hand or foot), difficulty speaking, abnormal or very heavy bleeding from the vagina, breast pain

- High levels of sodium in blood test results

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.

5. How to store NORMOCOXIB

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

Do not use this this medicine after the expiry date which is stated on the carton after EXP.

The expiry date refers to the last day of that month.

Store below 30 °C. Protect from humidity.

6. Contents of the pack and other information

What NORMOCOXIB contains

The active substance is celecoxib. Each capsule contains 200 mg of celecoxib. The other ingredients are: lactose monohydrate, sodium laurilsulfate, povidone, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate. Capsule shells contain gelatin, titanium dioxide (E171) and yellow iron oxide (E172).

What NORMOCOXIB looks like and contents of the pack

NORMOCOXIB are hard capsules with a yellow cap and a white body.

The pack contains 30 hard capsules.

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last revised in: April 2014