

HOVID-CELECOXIB CAPSULE 200 mg

Celecoxib (200 mg)

What is in this leaflet

1. What hovid-Celecoxib Capsule 200 mg is used for
2. How hovid-Celecoxib Capsule 200 mg works
3. Before you use hovid-Celecoxib Capsule 200 mg
4. How to use hovid-Celecoxib Capsule 200 mg
5. While you are using hovid-Celecoxib Capsule 200 mg
6. Side effects
7. Storage and Disposal of hovid-Celecoxib Capsule 200 mg
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What hovid-Celecoxib Capsule 200 mg is used for

- For the management of acute pain in adults and for the treatment of primary dysmenorrhoea.
- Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis.
- Relief of signs and symptoms of ankylosing spondylitis.
- For relief of low back pain.

How hovid-Celecoxib Capsule 200 mg works

Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID). It works by reducing hormones that cause inflammation and pain in the body.

Before you use hovid-Celecoxib Capsule 200 mg

- When you must not use it

Do not take this medicine if:

- You are allergic to celecoxib or any of the other ingredients of this medicine.
- You have had an allergic reaction to a group of medicines called “sulfonamides” (e.g. some antibiotics used to treat infections)

- You currently have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines.
- As a result of taking acetylsalicylic acid or any other anti-inflammatory and pain-relieving medicine (NSAID) 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.
- You are pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor.
- You are breast-feeding
- You have severe liver disease
- You have severe kidney disease.
- You have an inflammatory disease of the intestines such as ulcerative colitis or Crohn’s disease.
- 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.
- 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 are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

- Before you start to use it

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as they may interact with hovid-Celecoxib Capsule 200 mg.

- Taking other medicines

hovid-Celecoxib Capsule 200 mg may affect or be affected by other medicines when both medicines interacted:

- Dextromethorphan (used to treat coughs).
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure)
- Fluconazole and rifampicin (used to treat fungal and bacterial infections)
- Warfarin or other warfarin like medicines (“blood-thinning” agents that reduce blood clotting) including newer medicines like apixaban.
- 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).
- hovid-Celecoxib can be taken with low dose acetylsalicylic acid (75mg or less daily). Ask your doctor for advice before taking both medicines together.

How to use hovid-Celecoxib Capsule 200mg

- How much to use

- 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 hovid-Celecoxib for longer than necessary to control symptoms.
- The recommended dose for osteoarthritis, Rheumatoid arthritis

and Ankylosing spondylitis is usually 200mg each day.

- The recommended dose for management of Acute Pain and treatment of Primary Dysmenorrhea is 400mg initially, followed by an additional 200mg dose, if needed on the first day. On subsequent days, the recommended dose is 200mg twice daily, as needed.
- For Low Back Pain, the usual dose is 100mg twice daily or 200mg once daily.
- You should not take more than 400mg per day.
- The elderly, especially those with a weight less than 50kg; if you are over 65 years of age and especially if you weigh less than 50kg, your doctor may want to monitor you more closely.
- Use in children: Celecoxib is for adults only, it is not for use in children.

- When to use it

Use as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How long to use it

- Suddenly stopping your treatment with hovid-Celecoxib may lead to your symptoms getting worse. Do not stop taking hovid-Celecoxib 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 product, ask your doctor or pharmacist.

- If you forget to use it

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

- If you use too much (overdose)

You should not take more capsules than your doctor tells you to. If you take too many capsules contact your doctor,

pharmacist or hospital and take your medicine with you.

While you are using hovid-Celecoxib Capsule 200 mg

- Things you must do

Tell your doctor:

- If you experience allergic reactions/ any of the unwanted side effects while taking the medicine.
- If you become pregnant while taking this medication
- If you develop stomach pain, nausea or vomiting.

Take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not:

- give hovid-Celecoxib Capsule 200 mg to anyone else even if they have the same condition as you
- breast-feed your baby
- If a woman becomes pregnant during treatment, celecoxib should be discontinued.

- Things to be careful of

Driving and using machines

You should be aware of how you react to hovid-Celecoxib Capsule 200mg before you drive or operate machinery. If you feel dizzy or drowsy after taking hovid-Celecoxib Capsule 200mg do not drive or operate machinery until these effects wear off.

Contact your doctor if you are feeling abnormal or unusual problems.

Side effects

Common:

- 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.
- Headache
- Nausea (feeling sick).
- Painful joints
- Worsening of existing allergies.
- Accidental injury

Very common

- High blood pressure, including worsening of existing high blood pressure

Uncommon

- Heart failure, palpitations (awareness of heart beat), fast heart rate.
- 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 (pins and needles).
- 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).
- Eye inflammation.
- Difficulty breathing.
- Skin discolouration (bruising).
- Chest pain (generalised pain not related to the heart)
- Face swelling

Rare

- Ulcers (bleeding) in the stomach, gullet or intestines; or rupture of the

HOVID-CELECOXIB CAPSULE 200 mg

Celecoxib (200 mg)

- 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)
- Low levels of sodium in the blood (a condition known as hyponatraemia)
 - Reduced number of white blood cells (which help to protect the body from infection) or 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
 - Hallucinations
 - Bleeding in the eye
 - Acute reaction that may lead to lung inflammation
 - Irregular heartbeat
 - Flushing
 - Blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse
 - Bleeding of the stomach or intestines (can lead to bloody stools or vomiting), inflammation of the intestine or colon
 - 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
 - Acute kidney failure
 - Menstrual disturbances
 - Swelling of the face, lips, mouth, tongue or throat, or difficulty swallowing

Very rare

- Serious allergic reactions (including potentially fatal anaphylactic shock)
- 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, and abnormal test results (e.g., liver, blood cell (eosinophilia, a type of raised white blood cell count))
- Bleeding within the brain causing death
- Meningitis (inflammation of the membrane around the brain and spinal cord)
- Liver failure, liver damage and severe liver inflammation (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
- 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)
- 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)
- Worsening of epilepsy (possible more frequent and/or severe seizures)
- Blockage of an artery or vein in the eye leading to partial or complete loss of vision
- Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
- 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)
- Muscle pain and weakness
- Impaired sense of smell
- Loss of taste

You may consult doctor/pharmacist for further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by calling Tel: 03-78835490, or visiting the website portal.npra.gov.my (Public) → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of hovid-Celecoxib Capsule 200mg

- Storage

Keep out of reach of children.

Store below 30°C.

- 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

- What it looks like

hovid-Celecoxib Capsule 200mg is a white opaque / white opaque capsule with “CL200” printed on one end and “hovid” printed on the other end and filled with white to off-white granules. Capsule size : Size 0.

- Ingredients

- Active ingredients
hovid-Celecoxib Capsule 200mg contains Celecoxib 200 mg
- Inactive ingredients
Magnesium Stearate
Lactose Monohydrate
Dodecyl sulphate sodium (Sodium dodecyl sulfate)
Polyethylene glycol 400
Polyvinylpyrrolidone
Crospovidone
Purified Water

- MAL Number (s)

MALXXXXXXXXXA

Manufacturer

HOVID Bhd.

Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.

121, Jalan Tunku Abdul Rahman (Jalan
Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Date of revision

30/04/2019

Serial Number

NPRA (R2)19/42