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What Novexib 200mg Capsules is used for

Management and treatment for of acute pain in adults, primary dysmenorrhoea, inflammation of arthritis, ankylosing spondylitis and low back pain

How Novexib 200mg Capsules works

Celecoxib belongs to a group of medicines 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. Celecoxib acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

Before you use Novexib 200mg Capsules

- When you must not use it

- 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 (NSAIDs).
- If you are pregnant, trying to get pregnant or think you may be pregnant. Breastfeeding mothers also should not take this medication. Please ask your doctor or pharmacist before taking this medicine.

- If you are at known risk of heart disease such as stroke or ischemic heart disease

- Before you start to use it

Talk to your doctor or pharmacist before taking Novexib 200mg Capsules:

- If you are allergic to celecoxib or any other ingredients of this product
- 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 or bleeding in your digestive tract
- If you are allergic to a group of drugs called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)
- If you have severe liver and kidney disease
- If you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease
- If you have or have had problems with your blood circulation (peripheral arterial disease)
- If you have had surgery on the arteries of your legs

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you.

In particular, tell your doctor if you take any of the following:

- Medicine to treat cough (Dextromethorphan)
- Medicine for high blood pressure and heart failure (ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics)
- Medicine used for fungal and bacterial infections (Fluconazole and rifampicin)
- Warfarin or other warfarin like medicines ("blood-thinning" agents that reduce blood clotting) including newer medicines like apixaban

- Medicine to treat depression (Lithium etc)
- Medicine to treat sleep disorders, high blood pressure or an irregular heartbeat
- Medicine to treat some mental disorders (Neuroleptics)
- 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)

Celecoxib can be taken with low dose acetylsalicylic acid (75 mg or less daily).

Ask your doctor for advice before taking both medicines together.

- Pregnancy and lactation

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.

How to use Novexib 200mg Capsules

Method of administration:

Novexib 200mg Capsules is for oral use.

- How much to use

For Osteoarthritis: The recommended dose is 200mg administered as a single dose or as 100mg twice per day.

For Rheumatoid Arthritis (RA): The recommended dose is 100mg or 200 mg twice per day.

For Ankylosing Spondylitis (AS): The recommended dose is 200 mg administered as a single dose or 100mg twice per day. Some patients may benefit from a total daily dose of 400mg.

Management of Acute Pain: The recommended dose is 400mg, initially followed by an additional 200mg dose, if needed on the first

Celecoxib

day. On subsequent days, the recommended dose is 200mg twice daily, as needed.

Treatment of Menstrual Pain: The recommended dose of celecoxib is 400 mg, initially, followed by an additional 200 mg dose, if needed on the first day. On subsequent days, the recommended dose is 200 mg twice daily, as needed.

Low Back Pain (LBP): Usual dosage for adults is 100 mg of celecoxib orally twice daily, morning and evening after meal, or 200 mg once daily (100 mg and 200 mg only).

The elderly: No dosage adjustment is generally necessary. However, for elderly patients with a lower-than-average body weight (<50kg), it is advisable to initiate therapy at the lowest recommended dose.

Hepatic impairment: No dosage adjustment is necessary in patients with mild hepatic impairment (Child-Pugh Class A). Introduce celecoxib at half the recommended dose in arthritis or pain patients with moderate hepatic impairment (Child-Pugh Class B).

Patients with severe hepatic impairment (Child-Pugh Class C) have not been studied.

Renal impairment: No dosage adjustment is necessary in patients with mild or moderate renal impairment. There is no clinical experience in patients with severe renal impairment

Children: Celecoxib is not indicated for use in children.

CYP2C9 Poor Metabolisers: Patients who are known, or suspected to be CYP2C9 poor metabolisers based on genotyping or previous history/experience with other CYP2C9 substrates should be administered celecoxib with caution as the risk of dose-dependent adverse effects is increased.

Consider reducing the dose to half the lowest recommended dose.

- When to use it

Novexib 200mg Capsules can be taken with or without food.

- 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 a forgotten dose.

- If you use too much (overdose)

If you or anyone else takes too many Novexib 200mg Capsules, you should immediately go to your nearest hospital emergency department or tell your doctor.

Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining medicine you have with you.

Appropriate supportive medical care should be provided e.g., by eliminating the gastric contents, clinical supervision and, if necessary, the institution of symptomatic treatment.

- Things you must not do

Do not stop taking Novexib 200mg Capsules 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.

- Things to be careful of

Novexib 200mg Capsules should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Side effects

Like all medicines, Novexib 200mg Capsules can cause side effects although not everybody gets them. If any of the following happen, stop taking Novexib 200mg Capsules and tell your doctor immediately:

Infections and infestations:

Common: Sinusitis, upper respiratory tract infection, pharyngitis, urinary tract infection

Blood and lymphatic system disorders:

Uncommon: Anaemia

Rare: Leukopenia,

Thrombocytopenia

Very rare: Pancytopenia

Immune system disorders:

Common: Hypersensitivity

Very rare: Anaphylactic shock, anaphylactic reaction

Metabolism and nutrition disorders:

Uncommon: Hyperkalaemia

Psychiatric disorders:

Common: Insomnia

Uncommon: Anxiety, depression, fatigue

Rare: Confusional state, hallucinations

Nervous system disorders:

Common: Dizziness, hypertonia, headache

Uncommon: Cerebral infarction,

paraesthesia, somnolence

Rare: Ataxia, dysgeusia

Very rare: Haemorrhage intracranial (including fatal intracranial haemorrhage), meningitis aseptic, epilepsy (including aggravated epilepsy), ageusia, anosmia

Eye disorders:

Uncommon: Vision blurred, conjunctivitis

Rare: Eye haemorrhage

Very rare: Retinal artery occlusion, retinal vein occlusion.

Ear and labyrinth disorders:

Uncommon: Tinnitus, hypoacusis

Cardiac disorders:

Common: Myocardial infarction

Uncommon: Cardiac failure, palpitations, tachycardia

Rare: Arrhythmia

Vascular disorders:

Very common: Hypertension (including aggravated hypertension)

Rare: Pulmonary embolism, flushing

Very rare: Vasculitis

Respiratory, thoracic, and mediastinal disorders:

Common: Rhinitis, cough, dyspnoea

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Celecoxib

Uncommon: Bronchospasm
Rare: Pneumonitis

Gastrointestinal disorders:

Common: Nausea, abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting, dysphagia

Uncommon: Constipation, gastritis, stomatitis, gastrointestinal inflammation (including aggravation of gastrointestinal inflammation), eructation

Rare: Gastrointestinal haemorrhage, duodenal ulcer, gastric ulcer, oesophageal ulcer, intestinal ulcer, large intestinal ulcer, intestinal perforation, oesophagitis, melaena, pancreatitis colitis

Hepatobiliary disorders:

Uncommon: Hepatic function abnormal, hepatic enzyme increased (including increased SGOT and SGPT)

Rare: Hepatitis

Very rare: Hepatic failure (sometimes fatal or requiring liver transplant), hepatitis fulminant (some with fatal outcome), hepatic necrosis, cholestasis, hepatitis cholestatic, jaundice

Skin and subcutaneous tissue disorders:

Common: Rash, pruritus (includes pruritus generalised)

Uncommon: Urticaria, ecchymosis

Rare: Angioedema, alopecia, photosensitivity

Very rare: Dermatitis exfoliative, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), dermatitis bullous

Musculoskeletal and connective tissue disorders:

Common: Arthralgia

Uncommon: Muscle spasms (leg cramps)

Very rare: Myositis

Renal and urinary disorders:

Uncommon: Blood creatinine increased, blood urea increased

Rare: Renal failure acute, hyponatraemia

Very rare: Tubulointerstitial nephritis, nephrotic syndrome, glomerulonephritis minimal lesion

Reproductive system and breast disorders:

Rare: Menstrual disorder

Frequency not known: Infertility female (female fertility decreased)

General disorders and administrative site conditions:

Common: Influenza-like illness, oedema peripheral/fluid retention

Uncommon: Face oedema, chest pain

Injury, poisoning and procedural complications:

Common: Injury (accidental injury)

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

Storage and Disposal of Novexib 200mg Capsules

- Storage

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 blister and carton.

Do not store Novexib 200mg Capsules above 30°C.

- Disposal

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.

Product Description

- What it looks like

Hard capsule color aqua blue (cap) and aqua blue (body).

- Ingredients

- Active ingredient: Celecoxib
- Inactive ingredients: Croscarmellose sodium, lactose

monohydrate, povidone, magnesium stearate, sodium lauryl sulphate and purified water

- Packing

Packed in a box of 3 strips x 10 capsules/10 strips x 10 capsules

- MAL number:

MAL21036030AZ

Manufacturer

PT. Novell Pharmaceutical Laboratories

Jl. Wanaherang No. 35, Tlajung Udik, Gunung Putri, Bogor 16962 – Indonesia

Product Registration Holder

Celestema Pharma Sdn. Bhd.

3 Jalan 19/1, 46300 Petaling Jaya Selangor, Malaysia

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