Ketoprofen Controlled Release Capsules 200mg
(Ketoprofen)

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 further questions, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet:
1. What Ketoprofen Controlled Release Capsules are and what they are used for
2. What you need to know before you take Ketoprofen Controlled Release Capsules
3. How to take Ketoprofen Controlled Release Capsules
4. Possible side effects
5. How to store Ketoprofen Controlled Release Capsules
6. Contents of the pack and other information

1. WHAT KETOPROFEN CONTROLLED RELEASE CAPSULES ARE AND WHAT THEY ARE USED FOR

Ketoprofen Controlled Release Capsules belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Ketoprofen Controlled Release Capsules are used to relieve symptoms caused by osteoarthritis, rheumatoid arthritis and ankylosing spondylitis (rheumatism of the spine) such as swelling, stiffness or joint pain. It does not cure arthritis and will help you only as long as you continue to take it. It is also useful to relieve pain in the back and leg (sciatica), acute gout and painful periods.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KETOPROFEN CONTROLLED RELEASE CAPSULES

Do not take Ketoprofen Controlled Release Capsules if you:
- Are allergic to ketoprofen or any of the other ingredients of this medicine (listed in section 6)
- Have previously suffered from asthma, hives or a runny nose caused by an allergy to salicylates (e.g. Aspirin) or other NSAIDs such as ibuprofen, as it may increase risk of a bronchospasm
- Have severe liver, kidney or heart failure
- Are in the last three months of pregnancy
- Previously had a stomach or intestinal ulcer, bleeding or perforation
- Currently have stomach or intestinal ulcer, bleeding or perforation
- Have or had a history of gastrointestinal bleeding or perforation associated with NSAID treatment. You should not take this medicine. That is those with inflammation of the stomach or intestines such as ulcerative colitis, Crohn’s disease, gastrointestinal cancers and diverticulitis (inflamed or infected pouches/pockets of the colon)
- Have a history of blood disorders where you bleed for a long time.

If any of these apply to you, you should not be given Ketoprofen Controlled Release Capsules. Tell your doctor immediately.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Ketoprofen Controlled Release Capsules if you:
- Are taking other NSAIDs including COX-2 selective NSAIDs and aspirin, a substance present in many medicines used to relieve pain and lower fever (see section 2, Other medicines and Ketoprofen Controlled Release Capsules)
- Have reduced kidney or liver function, there may be increased risk of jaundice (see section 4, Possible side effects)
- Have a history of asthma or have previously shown an allergic reaction to ketoprofen you are at an increased risk of breathing difficulties
- Have a history of ulcers or you are elderly as there is an increased risk of stomach bleeding and perforation
- Are taking other medicines like corticosteroids, certain drugs for depression called selective serotonin reuptake inhibitors (SSRIs), anticoagulants such as warfarin, or anti-platelet agents such as aspirin to prevent blood clotting. Your doctor may prescribe you another medicine (e.g. misoprostol) with Ketoprofen Controlled Release Capsules to protect your stomach and intestines
- Suffer from SLE (systemic lupus erythema) or other connective tissue disorders. There may be an increased risk of aseptic meningitis
- Have heart problems, have had a stroke, or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist
- Have been treated with diuretics for water retention
- Are being treated for high blood pressure
- Are trying to get pregnant (see section 2, Pregnancy, breast-feeding and fertility)
- Have a history of suffering from a disease of the bowel or intestine, such as ulcerative colitis or Crohn’s disease
- Have an infectious disease as this medicine may mask the usual signs of the disease becoming worse e.g. a fever.
Possible heart problems:
Medicines such as Ketoprofen Controlled Release Capsules may cause a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not take more than the recommended dose or use for longer than recommended.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Possible stomach problems:
Some evidence suggests that ketoprofen, the active ingredient of Ketoprofen Controlled Release Capsules, may be associated with a high risk of serious stomach problems, such as bleeding, ulcers or perforation, relative to other NSAIDs. This is more likely if you take a high dose of Ketoprofen Controlled Release Capsules.

Other medicines and Ketoprofen Controlled Release Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially if you are taking:
• High dose salicylates such as Aspirin or other non-steroidal anti-inflammatory drugs for pain relief
• Corticosteroids (e.g hydrocortisone) given to treat a variety of conditions such as allergies and hormone imbalances
• Anticoagulants such as warfarin to prevent blood clots, as there is an increased risk of bleeding. If co-administration is unavoidable you will be closely monitored by your doctor
• Lithium (medicine to treat depression) or digoxin (medicine to treat impaired heart function) - increase in blood levels of these medicines
• Serotonin re-uptake inhibitors (SSRIs) e.g fluoxetine used to treat depression
• Diuretics (water tablets) effect may be decreased. Potassium-sparing diuretics may increase the blood levels of potassium
• Ace-inhibitors e.g captopril (medicines used to treat high blood pressure) blood pressure lowering effect may be reduced
• Ciclosporin or tacrolimus (medicines used to prevent rejection after a transplant) - may harm kidney function especially if you are elderly
• Quinolones e.g ciprofloxacin (antibiotics used to treat infections) - may cause fits
• Medicines to treat diabetes e.g metformin - a dose adjustment of these medicines may be necessary as blood sugar may drop too low
• Methotrexate (to treat psoriasis, rheumatoid arthritis and certain tumours)
• Mifepristone (used to induce abortion) NSAIDs should not be used for 8-12 days after taking mifepristone as NSAIDs can reduce mifepristone's effectiveness
• Cardiac glycosides such as digoxin (used for some heart conditions) may worsen heart failure
• Probenecid used to treat gout
• Zidovudine used to treat viral infections
• Hydantoins used to treat seizures e.g. phenytoin
• Sulphonamides used to treat bacterial infections e.g. co-trimoxazole
• Aminoglycosides used to treat bacterial infections e.g. amikacin
• Pentoxifylline, used to help poor blood circulation in limbs
• Thrombolytics used to dissolve blood clots such as streptokinase, alteplase or reteplase

Laboratory tests
Regular liver and kidney function tests and monitoring of blood counts are necessary during long-term 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.

Fertility
Ketoprofen Controlled Release Capsules 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 becoming pregnant.

Pregnancy and breast-feeding
You should not take Ketoprofen Controlled Release Capsules during the first 6 months of pregnancy unless directed by your doctor and must not take Ketoprofen Controlled Release Capsules during the last 3 months of pregnancy as damage to the baby and reduced labour may occur. You should only use Ketoprofen Controlled Release Capsules whilst breast-feeding if advised by your doctor.

Driving and using machines
Ketoprofen Controlled Release Capsules may affect your ability to drive and operate machinery by causing headaches, fatigue, nausea, confusion, blurred vision, dizziness, drowsiness. You may have a fit (convulsion) while taking this medicine. If you do experience any effects, do not drive or operate machinery.

Ketoprofen Controlled Release Capsules contain sucrose
Ketoprofen Controlled Release Capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE KETOPROFEN CONTROLLED RELEASE CAPSULES
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Ketoprofen Controlled Release Capsules must not be taken long-term, blood tests should be carried out if taken for more than a few days.
The capsules must be swallowed **whole** with a glass of water, **with food**.

The usual dose is:
- **Adults**: One capsule once a day
- **Elderly**: As adult dose. The lowest effective dose should be taken and your doctor will need to monitor you regularly. If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment

**Use in children and adolescents**

*Ketoprofen Controlled Release Capsules are not recommended for children and adolescents.*

**If you take more Ketoprofen Controlled Release Capsules than you should**
Contact your doctor, local hospital casualty department or pharmacist if you have taken more Ketoprofen Controlled Release Capsules than stated in this leaflet or more than what your doctor has prescribed (and you feel unwell). Symptoms of overdose may be gastrointestinal disorders, feeling or being sick, diarrhoea, kidney failure, fits, headache, disorientation, excitement, coma, drowsiness, dizziness, ringing in the ears, fainting and liver damage.

**If you forget to take Ketoprofen Controlled Release Capsules**
Do not take a double dose to make up for a forgotten dose. Continue the treatment as advised by your doctor.

**If you stop taking Ketoprofen Controlled Release Capsules**
Changes to dosage or stopping of treatment should only be as directed by your doctor.

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.

**Stop taking and see your doctor or go to a hospital straight away if you develop the following symptoms:**
- Pass blood in your stools or black, tarry stools, vomit any blood or dark particles that look like coffee grounds (possible symptoms of stomach bleeding)
- Indigestion or heartburn, severe abdominal or stomach pain or other abnormal stomach symptoms (possible symptoms of peptic ulcer or stomach perforation)
- Allergic reactions: swelling of the hands, face, feet, eyelids, lips, tongue, throat, difficulty breathing, itching, dizziness (anaphylactic reaction)
- Blistering of the skin (Toxic Epidermal Necrolysis), mouth, eyes or genitals (Stevens-Johnson Syndrome)
- Swelling of the face or throat (angioedema)
- Eye problems, such as blurred vision
- Lack of energy, shortness of breath or weakness (symptoms of kidney failure) or blood in your urine, a change in the amount of urine you produce, swelling, especially of your legs, ankles or feet (symptoms of serious kidney problems).

**Common** (may affect up to 1 in 10 people)
- Indigestion (dyspepsia), heartburn, stomach pain, these are reduced by taking the medicine with food
- Feeling sick (nausea) or being sick (vomiting).

**Uncommon** (may affect up to 1 in 100 people)
- Constipation, diarrhoea, wind, pain or discomfort in the upper abdomen (gastritis)
- Rash and itching
- Water retention which may cause swollen arms or legs
- Headaches, feeling dizzy, feeling sleepy, feeling tired.

**Rare** (may affect up to 1 in 1,000 people)
- Ringing in your ears (tinnitus)
- Weight gain
- Inflamed mouth (stomatitis)
- Changes in liver enzymes or bilirubin (shown by a blood test) and hepatitis (swelling of the liver)
- Pale skin, weakness or breathlessness due to a loss of blood (haemorrhagic anaemia)
- Tingling or numbness in the hands or feet (paraesthesia)
- Coughing, wheezing, shortness of breath or tightness of the chest (asthma)
- Tiredness, pains in abdomen, muscle and joint aches, yellowing of skin and eyes (inflammation of the liver [jaundice])
- Inflammation of the pancreas
- Damage to the liver.

**Not known** (frequency cannot be estimated from the available data)
- Abnormally low level or decrease of white blood cells in the blood &/or making infections more likely (neutropenia/agranulocytosis)
- Reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia)
- Tiredness, prone to infections or easily bruised due to bone marrow failure
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- Mood change
- Fits
- Abnormal sense of taste (dysgeusia)
- Visual disturbances
- Painful inflammation of the optic nerve in your eye (optic neuritis)
• Shortness of breath or ankle swelling (heart failure)
• High blood pressure
• Reddening of the face (vasodilatation)
• Worsening of asthma or bronchospasm i.e. coughing, wheezing, shortness of breath or tightness of the chest
• Runny nose (rhinitis)
• Worsening of abdominal pain or diarrhoea (symptoms of colitis) or diarrhoea and weight loss (symptoms of crohn’s disease)
• Increased sensitivity of the skin to sunlight (photosensitivity)
• Loss of hair (alopecia)
• Skin rash resulting from bleeding into the skin (purpura)
• Red patches of the skin (erythema multiforme) or scaling of the skin (exfoliative dermatitis)
• Itchy rash
• Kidney problems or worsening of existing kidney problems
• Swollen ankles or high blood pressure due to inflammation of the kidney
• Abnormal kidney function tests
• Feeling generally unwell
• Trouble Sleeping (insomnia)
• Vertigo
• Aseptic meningitis (symptoms may include stiff neck, headache, nausea, vomiting, fever or disorientation.

Medicines such as ketoprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Blood tests
The results of a blood test may show changes in the way your liver or kidneys are working.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE KEToprofen CONTROLLED RELEASE CAPSULES

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. The expiry date refers to the last day of that month. Do not store above 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 Ketoprofen Controlled Release Capsules contain
The active substance is ketoprofen.
The other ingredients are polyethylene glycol, ethylcellulose, purified stearic acid, talc, polymers of methacrylic acid, acrylic esters and methacrylic acid esters, sucrose (see section 2), corn starch, gelatine, erythrosine (E127) and titanium dioxide (E171).

What Ketoprofen Controlled Release Capsules look like and contents of the pack
These capsules are supplied in blister packs of 28, 30, 56, 60 and 100.

Marketing Authorisation Holder and Manufacturer
Ennogen Pharma Limited
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The Product Licence number is PL 40147/0053

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