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Colours Used

Black

Keyline Unvarnish area

Artwork No.	060118/1
Customer	Ennogen
Description	Ketoprofen Leaflet
Market	UK
Language	English
Dimensions	170 x 450 mm
Min. Font Size	Arial, 9 pt
Version No.	8
Date	08-10-24

Ennogen Pharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ketoprofen Capsules 50mg and 100mg

(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 in this leaflet:

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

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

Ketoprofen Capsules contain a medicine called Ketoprofen. This belongs to a group of medicines called 'non-steroidal anti-inflammatory drugs' (NSAIDs).

Ketoprofen Capsules are used to relieve symptoms of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, fibrositis, cervical spondylitis, low back pain, painful musculoskeletal conditions and period pain.

Ketoprofen reduces joint pain and inflammation, and facilitates an increase in mobility and functional independence.

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

Do not take Ketoprofen Capsules if you:
- Are **allergic** to Ketoprofen or any of the other ingredients in this medicine (see Section 6)
- Are allergic to other non−steroidal anti−inflammatory drugs (NSAIDs), including aspirin. Signs of an allergic reaction are breathing problems, including asthma, swelling to the face or throat, redness and itching of the skin or an itchy running nose
- Have **severe liver, kidney** or **heart** failure
- Are in the **last three months** of pregnancy
- **Previously** have had a stomach or intestinal ulcer, bleeding or perforation
- **Currently** have stomach or intestinal ulcer, bleeding or perforation
- Bruise more easily than usual and have bleeding that lasts a long time

Ketoprofen Capsules should not be used in children.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Ketoprofen Capsules if you:
- Have an infection - please see heading "Infections" below
- Are taking other NSAIDs including COX-2 selective NSAIDs and acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever (see section 2 Other medicines and Ketoprofen Capsules)
- Have reduced **kidney** or **liver** function, there may be increased risk of jaundice (see section 4 Possible side effects)
- Are elderly, your doctor may wish to minimize treatment duration and to see you more often while you are taking this medicine
- Taking other medicines like hydrocortisone (oral corticosteroids), citalopram (SSRIs), furosemide (diuretics/water tablets)
- Suffer from liver **porphyria** (disorder of the red blood pigment)
- Suffer from **SLE** (systemic lupus erythema) or other similar condition with symptoms such as joint pain, skin rash and fever. 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
- Are planning to become pregnant or you have problems becoming pregnant (See section on Pregnancy and Breast-feeding)
- Use an intrauterine contraceptive device (IUCD), as it may be less effective
- Suffer 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
- Have asthma combined with a chronic runny nose, blocked nose or swellings in the nose, as you have a higher risk of allergy to aspirin or NSAIDs
- Suffer from heart failure, cirrhosis of the liver or kidney disease, as close supervision of the amount of urine you pass will be necessary.

Infections
Ketoprofen Capsules may hide signs of infections such as fever and pain. It is therefore possible that Ketoprofen Capsules may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Possible heart problems:
Medicines such as Ketoprofen 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 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.

Other medicines and Ketoprofen Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Remember to take your medicine with you if you have to go to a hospital.

In particular tell your doctor or pharmacist if you are taking any of the following:
- Salicylates e.g. **aspirin** (high dose) or other non-steroidal anti-inflammatory drugs e.g. ibuprofen or celecoxib. You should avoid using these medicines with Ketoprofen (Ketoprofen may increase the risk of ulcers or haemorrhages)
- **Corticosteroids** used to treat inflammation and allergic conditions e.g. hydrocortisone, betamethasone or prednisolone (Ketoprofen may increase the risk of stomach bleeding or ulcers)
- **Anticoagulants**, to stop the blood clotting e.g. **warfarin** or heparin (Ketoprofen may increase the effects of these medicines)
- **Lithium**, used to treat some types of mental illness or methotrexate, used to treat psoriasis/skin cancer (Ketoprofen may increase the toxicity levels of these medicines)
- **Selective serotonin re-uptake inhibitors** (SSRIs) e.g. fluoxetine, citalopram, paroxetine, or sertraline used to treat depression (Ketoprofen may increase the risk of stomach bleeding)
- **Diuretics** (water tablets) e.g. furosemide, the effect may be decreased. Potassium-sparing diuretics may increase the blood levels of potassium
- Medicines used to treat high blood pressure e.g. atenolol (beta−blockers) and, if you have kidney problems, medicines e.g. captopril (ACE inhibitors) and candesartan (angiotensin II antagonists)
- **Ciclosporin** or **tacrolimus,** used after an organ transplantation to help prevent rejection
- **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
- **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
- **Sulphonamides**, used to treat bacterial infections e.g. co−trimoxazole
- **Ticlopidine** or **clopidogre**l, used to prevent excessive blood clotting (Ketoprofen is not recommended. Bleeding time must be supervised)
- **Thrombolytics**, used to dissolve blood clots such as streptokinase, alteplase or reteplase
- **Pentoxifylline**, used to help poor blood circulation in limbs

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

Pregnancy and breast-feeding
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
Do not take Ketoprofen Capsules if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. **It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.** You should not take Ketoprofen Capsules during the first 6 months of pregnancy unless absolutely necessary **and advised by your doctor.** If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. **If taken for more than a few days from 20 weeks of pregnancy onward, Ketoprofen Capsules can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.**

Breast-feeding
If you are breast-feeding, you **should not** take Ketoprofen.

Driving and using machines
You may feel sleepy, dizzy, faint or you may have a fit (convulsion). If this is experienced, you **should not** drive or use machines.

Ketoprofen Capsules contain lactose
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 CAPSULES

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

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Ketoprofen Capsules should be swallowed whole with a glass of water, with food.

The recommended dose is:

Adults:
1-2 capsules (50-100mg), twice a day.
This dose may be altered by your doctor.

For dysmenorrhea:
1 capsule (50mg), up to three times a day.
Treatment is usually 3-4 days from the onset of menstruation.

Elderly:
As adult dose. The lowest effective dose should be given. Your doctor will monitor you regularly.

Use in children
Ketoprofen Capsules should not be used in children under 12 years of age.

If you take more Ketoprofen Capsules than you should
Contact your doctor, casualty department or pharmacist immediately if you have taken more Ketoprofen Capsules than is stated in this leaflet, or more than prescribed to you by your doctor.

Symptoms of overdose may include stomach pain, feeling or being sick, diarrhoea, drowsiness, kidney failure, fits, headache, disorientation, ringing in the ears, excitement, coma, fainting and liver damage.

If you forget to take Ketoprofen Capsules
If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. 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 Capsules
Do not stop taking Ketoprofen Capsules without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine may cause side effects, although not everybody gets them.

If you experience any of the following side effects with Ketoprofen Capsules at any time during your treatment, **STOP TAKING your capsules and seek immediate medical help:**
- Vomiting any blood or dark particles that look like coffee grounds or bloody or black, tarry stools (symptoms of stomach bleeding)
- Severe allergic reaction which causes difficulty in breathing, dizziness, or shock (anaphylactic reaction)
- Swelling of the face or throat (angioedema)
- A form of **meningitis** (aseptic) causing a combination of symptoms such as headache, fever, stiff neck, tiredness, feeling or being sick and disorientation
- Severe abdominal or stomach pain, heartburn or indigestion (symptoms of a peptic ulcer or stomach perforation)
- Blistering of the skin, mouth, eyes and genitals (Stevens−Johnson syndrome) or blistering of the skin (toxic epidermal necrolysis)
- 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 or swelling, especially of your legs, ankles or feet (symptoms of serious kidney problems)

Some anti-inflammatory/pain relieving medicines (particularly at high doses and in long term treatment) may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Common side effects (may affect up to 1 in 10 people):
- Indigestion, heartburn, stomach pain or cramps, feeling or being sick, diarrhoea, flatulence, loss of appetite, constipation, mouth ulcers, worsening of ulcerative colitis or Crohn's disease, inflammation of the pancreas or tongue
- Skin rash, itching, skin eruptions, eczema, Erythema multiforme (round, red patches on skin)

Uncommon side effects (may affect up to 1 in 100 people)
- Headache
- Dizziness
- Feeling sleepy
- Constipation
- Diarrhoea
- Wind (flatulence)
- Pain or discomfort in the upper abdomen (gastritis)
- Rash, itching or skin eruptions
- Slight swelling of feet and hands due to water retention (oedema)

Rare side effects (may affect up to 1 in 1,000 people)
- Pale skin, weakness or breathlessness due to a loss of blood (haemorrhagic anaemia)
- Tingling or numbness in the hands or feet
- Ringing in the ears (tinnitus)
- Coughing, wheezing, shortness of breath or tightness of the chest (asthma)
- Inflammation of the mucous lining of the mouth
- Inflammation of liver (hepatitis), which can cause tiredness, pains in abdomen, muscle and joint aches
- Increase in liver enzymes or bilirubin (detected through blood tests)
- Increased weight

Very rare side effects (may affect up to 1 in 10,000 people)
- Abdominal pain, fever or an increased heart rate could be a sign of pancreatitis

Not known: (frequency cannot be estimated from the available data)
- Severe reduction in number of white blood cells which makes infections more likely (agranulocytosis commonly as neutropenia, symptoms include ulcers, abscesses and rash)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Tiredness, prone to infections or easily bruised due to bone marrow failure
- Difficulty in getting to sleep (insomnia)
- Mood change
- Fits
- Abnormal taste
- Stiff neck, headache, feeling or being sick, fever or feeling disorientated (symptoms of aseptic meningitis)
- Depression
- Confusion
- Seeing or hearing things that are not real (hallucinations)
- Feeling unwell (malaise)
- Drowsiness
- Feeling of dizziness or "spinning" (Vertigo)
- Visual disturbances
- Painful inflammation of the optic nerve in your eye
- Shortness of breath or ankle swelling (heart failure)
- High blood pressure
- Reddening of the face (vasodilatation)
- Difficulty in breathing or wheezing
- 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)
- Itchy rash
- Swollen ankles or high blood pressure due to inflammation of the kidney
- Abnormal kidney function tests
- Tiredness

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 CAPSULES

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

Do not store above 25°C. Store in the original package. Protect from moisture.

Do not use Ketoprofen Capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ketoprofen Capsules 50mg and 100mg contain:
Ketoprofen Capsules 50mg contain 50mg of the active ingredient ketoprofen.
The other ingredients are: magnesium stearate and lactose.
The capsule shell contains gelatin, erythrosine (E127), indigotine (E132), titanium dioxide (E171) and quinoline yellow (E104).

Ketoprofen Capsules 100mg contain 100mg of the active ingredient ketoprofen.
The other ingredients are: magnesium stearate and lactose.
The capsule shell contains gelatin, red iron oxide (E172) and titanium dioxide (E171).

What Ketoprofen Capsules 50mg and 100mg look like and contents of the pack

Ketoprofen Capsules 50mg and 100mg
Available in amber glass bottles in pack sizes of 28, 30, 56, 60, 84, 90, 100, 112, 500.
Not all pack sizes may be marketed.

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This leaflet was last revised in October 2024

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