

Package Leaflet: Information For The User

Keral 25 mg granules in sachet

Dexketoprofen

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 questions, 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 sign of illness 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 Keral is and what it is used for
2. What you need to know before you take Keral
3. How to take Keral
4. Possible side effects
5. How to store Keral
6. Contents of the pack and other information

1. What Keral is and what it is used for

Keral is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is used in adults for the short term symptomatic treatment of mild to moderate acute pain, such as pain affecting muscles or joints (e.g. backache, sprains and acute trauma), menstrual pain and dental pain.

2. What you need to know before you take Keral

Do not take Keral:

- if you are allergic to dexketoprofen or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to acetylsalicylic acid or to other non-steroidal anti-inflammatory medicines;
- if you have asthma or have suffered attacks of asthma, acute allergic rhinitis (a short period of inflamed lining of the nose), nasal polyps (lumps within the nose due to allergy), urticaria (skin rash), angioedema (swollen face, eyes, lips, or tongue, or respiratory distress) or wheezing in the chest after taking acetylsalicylic acid or other non-steroidal anti-inflammatory medicines;
- if you have suffered from photoallergic or phototoxic reactions (a particular form of reddening and/or blistering of the skin exposed to sunlight) while taking ketoprofen (a non-steroidal anti-inflammatory drug) or fibrates (drugs used to lower the level of fats in the blood);
- if you have a peptic ulcer/stomach or bowel bleeding or if you have suffered in the past from stomach or bowel bleeding, ulceration or perforation
- if you have chronic digestive problems (e.g. indigestion, heartburn);
- if you have suffered in the past from stomach or bowel bleeding or perforation, due to previous use of non-steroidal anti-inflammatory drugs (NSAIDs) used for pain;
- if you have bowel disease with chronic inflammation (Crohn's disease or ulcerative colitis);
- if you have serious heart failure, moderate or serious kidney problems or serious liver problems;
- if you have a bleeding disorder or a blood clotting disorder;
- if you are severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhoea or insufficient intake of fluids;
- if you are in the third trimester of pregnancy or breast feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Keral:

- if you suffer from allergy, or if you have had allergy problems in the past;
- if you have kidney, liver or heart problems (hypertension and/or heart failure) as well as fluid retention, or have suffered from any of these problems in the past;
- if you are taking diuretics or you suffer from very poor hydration and reduced blood volume due to an excessive loss of fluids (e.g. from excessive urination, diarrhoea or vomiting);
- 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; medicines such as Keral 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.
- if you are elderly: you may be more likely to suffer from side effects (see section 4). If any of these occur, consult your doctor immediately;
- if you are a woman with fertility problems (see section 2, "Pregnancy, breast-feeding and fertility") ;
- if you suffer from a disorder in the formation of blood and blood cells;
- if you have systemic lupus erythematosus or mixed connective tissue disease (immune system disorders that affect connective tissue);
- if you have suffered in the past from a chronic inflammatory disease of the bowel (ulcerative colitis, Crohn's disease);
- if you have or have suffered in the past from other stomach or bowel problems;
- if you have an infection - please see heading "Infections" below;
- if you are taking other medicines that increase the risk of peptic ulcer or bleeding, e.g. oral steroids, some antidepressants (those of the SSRI type, i.e. Selective Serotonin Reuptake Inhibitors), agents that prevent blood clots such as aspirin or anticoagulants such as warfarin. In such cases, consult your doctor before taking Keral: he/she may want you to take an additional medicine to protect your stomach (e.g. misoprostol or medicines that block the production of stomach acid).
- if you suffer from asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis as you have a higher risk of allergy to acetylsalicylic acid and/or NSAIDs than the rest of the population. Administration of this medicine can cause asthma attacks or bronchospasm, particularly in patients allergic to acetylsalicylic acid or NSAIDs.

Infections

Dexketoprofen may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

Avoid using Keral if you have varicella.

Children and adolescents

Keral has not been studied in children and adolescent. Therefore, safety and efficacy have not been established and the product should not be used in children and adolescents.

Other medicines and Keral

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. There are some medicines that should not be taken together and others that may need their doses to be altered when taken together.

Always inform your doctor, dentist or pharmacist if you are using or receiving any of the following medicines in addition to Keral:

Inadvisable combinations:

- Acetylsalicylic acid, corticosteroids or other anti-inflammatory drugs
- Warfarin, heparin or other medicines used to prevent blood clots
- Lithium, used to treat certain mood disorders
- Methotrexate (anti-cancer medicine or immunosuppressant), used at high doses of 15 mg/week
- Hydantoins and phenytoin, used for epilepsy

- Sulfamethoxazole, used for bacterial infections

Combinations requiring precautions:

- ACE inhibitors, diuretics and angiotensin II antagonists, used for high blood pressure and heart problems
- Pentoxifylline and oxpentifylline, used to treat chronic venous ulcers
- Zidovudine, used to treat viral infections
- Aminoglycosides antibiotics, used to treat bacterial infections
- Sulfonamides (e.g. chlorpropamide and glibenclamide), used for diabetes
- Methotrexate, used at low doses, less than 15 mg/week

Associations to be considered carefully:

- Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin) used for bacterial infections
- Cyclosporin or tacrolimus, used to treat immune system diseases and in organ transplant
- Streptokinase and other thrombolytic or fibrinolytic medicines, i.e. medicines used to break-up blood clots
- Probenecid, used in gout
- Digoxin, used to treat chronic heart failure
- Mifepristone, used as an abortifacient (to terminate a pregnancy)
- Antidepressants of the selective serotonin reuptake inhibitors type (SSRIs)
- Anti-platelet agents used to reduce platelet aggregation and the formation of blood clots
- Beta-blockers, used for high blood pressure and heart problems
- Tenofovir, deferiprone, pemetrexed.

If you have any doubt about taking other medicines with Keral, consult your doctor or pharmacist.

Keral with food, drink and alcohol

In general, it is recommended to take it with meals to reduce the possibility of causing stomach upsets (see also section 3, “Method of administration”).

Using NSAIDs in combination with alcohol can worsen adverse reactions caused by the active substance.

Pregnancy, breast-feeding and fertility

Do not use Keral during the final three months of the pregnancy or when breast feeding.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as Keral may not be right for you.

Use of Keral should be avoided by women who are planning a pregnancy or are pregnant. Treatment at any time in pregnancy should only take place as directed by a doctor.

The use of Keral may impair the fertility, therefore it is not recommended while attempting to conceive or during investigation of infertility.

Driving and using machines

Keral may slightly affect your ability to drive and handle machines, due to the possibility of dizziness or drowsiness as side effects of treatment. If you notice such effects, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

Keral contains sodium

This medicinal product contains less than 1 mmol sodium (23mg) per dosage unit, that is to say essentially “sodium-free”.

3. How to take Keral

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

Your doctor will tell you how many sachets you must take daily, and for how long.

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).

Adults over age 18

The recommended dose is generally 1 sachet (25 mg) every 8 hours, with no more than 3 sachets daily (75 mg).

Elderly, hepatic and renal impairment

If you are elderly, or if you suffer from mild kidney problems or mild to moderate liver problems, you should start treatment with a total daily dose of no more than 2 sachets (50 mg).

In elderly patients this initial dose can later be increased to that generally recommended (75 mg) if Keral has been well tolerated.

You should not use Keral if you suffer from moderate or serious kidney problems or serious liver problems. Check with your doctor or pharmacist if you are not sure.

Use in children and adolescents

This medicine should not be used in children and adolescents (under age 18).

Method of administration

Place the full dose of granules directly on the tongue and swallow as soon as they dissolve in the mouth, or by drinking a glass of water.

It can be taken with or without food. Taking Keral with food helps to decrease the risk of stomach upsets, however if your pain is intense and you need quicker relief, take the granules on an empty stomach (at least 30 minutes before any meal or any food intake) because they will be more easily absorbed (see section 2 “Keral with food, drink and alcohol”).

If you use more Keral than you should

If you use too much of this medicine, tell your doctor or pharmacist immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

If you forget to use Keral

Do not take a double dose to make up for a forgotten sachet. Take the next regular dose when it is due (according to section 3 “How to take Keral”).

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.

Possible side effects are listed below according to how likely they are to occur.

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

Nausea and/or vomiting, mainly upper quadrants abdominal pain, diarrhoea, digestive problems (dyspepsia).

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

Spinning sensation (vertigo), dizziness, sleepiness, disturbed sleep, nervousness, headache, palpitations, flushing, inflammation of the stomach lining (gastritis), constipation, dry mouth, flatulence, skin rash, tiredness, pain, feeling feverish and shivering, generally feeling unwell (malaise).

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

Peptic ulcer, peptic ulcer perforation or bleeding (which may be seen as vomiting blood or black stools), fainting, high blood pressure, too-slow breathing, water retention and peripheral swelling (e.g. swollen ankles), laryngeal oedema, loss of appetite (anorexia), abnormal sensation, itchy rash, acne, increased sweating, back pain, passing water frequently, menstrual disorders, prostate problems, abnormal liver function tests (blood tests), liver cell injury (hepatitis), acute renal failure.

Very rare: may affect up to 1 in 10,000 people

Anaphylactic reaction (hypersensitive reaction which may also lead to collapse), open sores on skin, mouth, eyes and genital areas (Stevens Johnson and Lyell's syndromes), face swelling or swelling of the lips and throat (angioedema), breathlessness due to narrowing of the airways (bronchospasm), shortness of breath, fast heartbeat, low blood pressure, inflammation of the pancreas, blurred vision, ringing in the ears (tinnitus), sensitive skin, sensitivity to light, itching, kidney problems. Reduced white blood cell count (neutropenia), fewer platelets in the blood (thrombocytopenia).

Tell your doctor immediately if you notice any stomach/bowel side effects at the start of treatment (e.g. stomach pain, heartburn or bleeding), if you have previously suffered from any such side effects due to long-term use of anti-inflammatory drugs, and especially if you are elderly.

Stop using Keral as soon as you notice the appearance of a skin rash, or any lesion inside the mouth or on the genitals, or any sign of an allergy.

During treatment with non-steroidal anti-inflammatory drugs, fluid retention and swelling (especially in the ankles and legs), increased blood pressure and heart failure have been reported.

Medicines such as Keral may be associated with a small increased risk of heart attack ("myocardial infarction") or cerebrovascular accident (stroke).

In patients with immune system disorders that affect connective tissue (systemic lupus erythematosus or mixed connective tissue disease), anti-inflammatory medicines may rarely cause fever, headache and neck stiffness.

The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, worsening of colitis and Crohn's disease have been reported following administration. Less frequently, inflammation of the stomach lining (gastritis) has been observed.

As with other NSAIDs haematological reactions (purpura, aplastic and haemolytic anaemia, and rarely agranulocytosis and medullar hypoplasia) may appear.

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Keral

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 and on the sachet after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

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 Keral contains

- The active substance is dexketoprofen (as dexketoprofen trometamol). Each sachet contains 25 mg of dexketoprofen.
- The other ingredients are basic butylated methacrylate copolymer, silica colloidal anhydrous, mannitol (E-421), lime flavour (containing natural lime flavouring, arabic gum and medium chain triglycerides), sucralose.

What Keral looks like and contents of the pack

Slightly yellow to white granules packaged in single dose sachets.

It is available in packs containing 2, 4, 10, 20, 30, 50 or 100 sachets and in multipacks comprising 5 cartons, each containing 100 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Menarini International Operations Luxembourg S.A.
1 Avenue de La Gare
L-1611 Luxembourg

Manufacturer:

LOSAN PHARMA GmbH
Otto-Hahn-Strasse 13
79395 Neuenburg, Baden-Wuerttemberg GERMANY

This medicinal product is authorised in the Member States of the EEA under the following names:

Spain, Italy: Enantyum/Kettesse
Czech Republic: Dexoket
Estonia, Lithuania, Latvia: Dolmen
Hungary: Ketodex
Ireland, United Kingdom (Northern Ireland): Keral
Austria, Belgium, Luxembourg, Portugal: Ketesse
The Netherlands: Stadium
Greece: Viaxal/Nosatel
Poland: Dexak
Slovakia: Dexadol

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