Package leaflet: information for the user

Keral 25 mg oral solution 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 further 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 signs 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

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2. What you need to know before you take Keral
3. How to take Keral
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1. What Keral is and what it is used for

This medicinal product is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
It is used for short term symptomatic treatment of mild to moderate acute pain, such as acute muscular pain or joint pain, painful periods (dysmenorrhoea), toothache. This medicinal product is indicated in adult patients.

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 cerebrovascular accident (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 (This medicine may impair your fertility, therefore you should not take it if you are planning to become pregnant or you are doing fertility tests);
- 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 this medicinal product: 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.

Children and adolescents
Dexketoprofen has not been studied in children and adolescents. 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 a dose adjustment if used together.

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

Inadvisable combinations:
- Acetylsalycilic 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
- Sulphametoxazole, 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
- Sulfonylureas (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, deferasirox, pemetrexed.

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

Keral with food, drink and alcohol
It is recommended to take it with meals to reduce the possibility of causing stomach upsets (see section 3 "Method of administration").
You should not drink alcohol while using this medicinal product. Some side effects, such as those affecting gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as Keral.
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. Do not use this medicinal product during the final three months of pregnancy or when breast feeding. 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 Keral 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, Keral 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.

The use of this medicinal product is not recommended while attempting to conceive or during investigation of infertility.
With regard to potential effects on female fertility, see also section 2, "Warnings and precautions".

Driving and using machines
This medicinal product may slightly affect your ability to drive and handle machines, due to the possibility of dizziness or drowsiness and visual disturbances 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 methyl parahydroxybenzoate (E 218)
This medicine may cause allergic reactions (possibly delayed) as it contains methyl parahydroxybenzoate.

Keral contains sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains 2.0 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus.

Keral contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Keral

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
The dose that you need depends on the type, severity and duration of your pain. 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 from the age of 18
The recommended dose is generally 1 sachet (25 mg of dexketoprofen) every 8 hours, with no more than 3 sachets daily (75 mg).

If you are elderly, or if you suffer from kidney or liver problems, you should start treatment with a total daily dose of no more than 2 sachets (50 mg of dexketoprofen).
In elderly this initial dose can later be increased to that generally recommended (75 mg) if dexketoprofen has been well tolerated.

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

Method of administration The oral solution may be taken directly from the sachet or after stirring the whole content in a glass of water. Once the sachet opens, take all its content.
Take the sachets with food, as it helps to decrease the risk of stomach or bowel side effects (see also section 2 in this leaflet). If your pain is intense and you need a quicker relief, take the sachets on an empty stomach, i.e. at least 15 minutes before meals, as this helps the medicine start working a little faster.

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. Because the peak plasma levels of dexketoprofen for the oral solution formulation are higher than those reported for the tablet formulation, a potentially increased risk for side (gastrointestinal) effects cannot be excluded.

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 this medicine 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 aseptic meningitis, which might predominantly occur in patients with systemic lupus erythematosus or mixed connective tissue disease and 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 or pharmacist. 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 medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Keral contains

- The active substance is dexketoprofen (as dexketoprofen trometamol). Each sachet of oral solution contains 25 mg of dexketoprofen as dexketoprofen trometamol.
- The other ingredients are ammonium glycyrrhizate, neohesperidin-dihydrochalcone, methyl parahydroxybenzoate (E-218), saccharin sodium, sucrose, macrogol 400, lemon aroma, povidone K-90, anhydrous disodium phosphate, sodium dihydrogen phosphate dihydrate, purified water (see section 2, Keral contains sucrose).

What Keral looks like and contents of the pack
Slightly coloured solution with lemon odour and sweet lemon-citrus flavour, supplied in packs containing 2, 4, 10 or 20 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Menarini International Operations Luxembourg S.A.
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Manufacturer
LABORATORIOS MENARINI, S.A.
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This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, , Finland, France, Italy, Luxembourg, Portugal, Spain: Ketesse
Cyprus, Greece: Nosatel
Estonia, Latvia, Lithuania: Dolmen
Germany: Sympal
Hungary: Ketodex
Ireland, Malta, United Kingdom (Northern Ireland): Keral
Netherlands: Stadium
Poland: Dexak
Slovak Republic: Dexadol

Slovenia: Menadex

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