

KETESSE[®] 25mg FILM COATED TABLET

Dexketoprofen Trometamol (25mg)

What is in this leaflet?

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This leaflet answers some of the common questions people ask about KETESSE. It does not contain all the information that is known about KETESSE.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking KETESSE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

1. What Kettese is used for

Kettese is a pain killer used to treat mild to moderate pain, such as muscular pain, painful periods (dysmenorrhoea), toothache.

2. How Kettese works

Kettese is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). You must talk to a doctor if you do not feel better or if you feel worse after 3-4 days.

3. Before you use Kettese

- When you must not take it

Do not take Kettese:

or to 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 from 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;

Use in children and adolescents

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

- Before you start to take it

Warnings and precautions

Talk to your doctor or pharmacist before taking Kettese:

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 Kettese 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 allergic to dexketoprofen 1

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If you are a woman with fertility problems (Kettesse 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 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 attack 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

Kettesse 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.

- Taking other medicines

Other medicines and Kettesse

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.

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 Kettesse: 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).

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

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), cancer 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

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

Beta-blockers, used for high blood pressure and heart problems

Tenofovir, deferiasirox, pemetrexed

Kettesse contains sodium

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

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4. How to use Kettesse

- How much to use

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

The dose of Kettesse that you need depends on the type, severity and duration of your pain. Your doctor will tell you how many tablets you must take daily, and for how long.

The recommended dose is generally 1 tablet (25 mg) every 8 hours, with no more than 3 tablets 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 tablets (50 mg).

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

- When to use it

If your pain is intense and you need quicker relief, take the tablets on an empty stomach (at least 30 minutes before food) because they will be more easily absorbed (see section 2 "Kettesse with food and drink").

- How long to use it

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 warnings and precautions).

- If you forget to use it

Do not take a double dose to make up for a forgotten tablet. Take the next regular dose when it is due (according to section 5 "How to take Kettesse").

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

- If you use too much (overdose)

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.

5. While you are using it

- Things you must do

Kettesse with food and drink

Take the tablets with an adequate amount of water. Take your tablets with food, as it helps to decrease the risk of stomach or bowel side effects. However, if you have acute pain, take the tablets on an empty stomach, i.e. at least 30 minutes before meals, as this helps the medicine start working a little faster.

- Things you must not do

Driving and using machines

Kettesse 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.

- Things to be careful of

Pregnancy, breast-feeding and fertility

Do not use Kettesse 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 Kettesse may not be right for you.

Use of Kettesse 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 Kettesse is not recommended while attempting to conceive or during investigation of infertility.

With regard to potential effects on female fertility, see also, "Warnings and precautions".

6. 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**

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

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(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 Kettesse 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 Kettesse may be associated with a small increased risk of heart attack ("myocardial infarction") or lining (gastritis), (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.

Warning

Risk of GI Ulceration, Bleeding and Perforation with NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, if you are treated with NSAID therapy.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

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. By reporting side effects you can help provide more information on the safety of this medicine.

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

7. Storage and Disposal of Kettesse

- 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 carton and on the blister. The expiry date refers to the last day of that month.

Do not store above 30 °C. Keep the blister packs in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste.

- Disposal

Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

8. Product Description

- What it looks like?

White, round, scored film-coated tablet, with convex sides.

Kettesse is available in packs containing 20 film-coated tablets. Not all pack sizes may be marketed.

- Ingredients

- The active substance is dexketoprofen (as dexketoprofen trometamol) Each film-coated tablets contains 25 mg of dexketoprofen.
- Inactive ingredients : The other ingredients are: Tablet core: maize starch, microcrystalline cellulose, sodium starch glycollate, glyceroldistearate,

Film-coating: dry laquer (composed of hypromellose, titanium dioxide, macrogol 6000), propylene glycol

- MAL number:

MAL20061602AZ

9. Manufacturer

A.MENARINI
MANUFACTURING LOGISTICS
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Via Campo di Pile s/n Loc. Campo
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10. Product Registration Holder

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