

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Kettesse 25 mg granules for oral solution

#### Dexketoprofen trometamol

#### **Read all of this leaflet carefully before you start taking this medicine**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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#### **1. WHAT KETESSE IS AND WHAT IT IS USED FOR**

Kettesse 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.

#### **2. BEFORE YOU TAKE KETESSE**

##### **Do not take Kettesse:**

- If you are allergic (hypersensitive) to dexketoprofen trometamol or to any of the other ingredients of Kettesse (see section 6);
- If you are allergic to the acetylsalicylic acid (aspirin) 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 aspirin 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 or have suffered in the past from a peptic ulcer, stomach or bowel bleeding or 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;

- If you are less than 18 years of age.

### **Take special care with 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 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 (Kettese 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 varicella (chickenpox), since exceptionally NSAIDs could worsen the infection;
- 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 Kettese: 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).

### **Further warnings about the use of NSAIDs:**

- The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.
- The risk appears greater at higher doses.
- It was previously thought that all NSAIDs may have a similar risk. Newer information makes it less clear that the risk for heart attack or stroke is similar for all NSAIDs; however, this newer information is not sufficient for us to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID.
- NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.
- In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.
- Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.
- There is an increased risk of heart failure with NSAID use.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken 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 any of the following medicines in addition to Kettesse:

Inadvisable combinations:

- Acetylsalicylic acid (aspirin), corticosteroids or other anti-inflammatory drugs
- Warfarin or heparin or other medicines used to prevent blood clots
- Lithium, used to treat certain mood disorders
- Methotrexate, used for rheumatoid arthritis and cancer
- Hydantoins and phenytoin, used for epilepsy
- Sulphametoxazole, used for bacterial infections

Combinations requiring precautions:

- ACE inhibitors, diuretics, beta-blockers and angiotensin II antagonists, used for high blood pressure and heart problems
- Pentoxifylline, used to treat chronic venous ulcers
- Zidovudine, used to treat viral infections
- Aminoglycosides antibiotics, used to treat bacterial infections
- Chlorpropamide and glibenclamide, used for diabetes

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.

### **Taking Kettesse with food and drink**

If you have acute pain, 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.

### **Children and adolescents**

Do not take Kettesse if you are less than 18 years of age.

### **Pregnancy and breast-feeding**

Do not use Kettesse during the third trimester of pregnancy or when breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine:

- tell your doctor if you are pregnant or if you are planning to become pregnant, as Kettesse may not be right for you.
- you must not take Kettesse if you are breast-feeding. Ask your doctor for advice.

### **Driving and using machines**

Kettesse may slightly affect your ability to drive and handle machines, due to the possibility of dizziness, 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.

### **Important information about some of the ingredients of KETESSE**

This medicine contains sucrose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

### 3. HOW TO TAKE KETESSE

Always use Kettesse exactly as your doctor has told you. You should check with your doctor 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 sachets you must take daily, and for how long.

The recommended dosage 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).

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

If your pain is intense and you need quicker relief, take the sachets on an empty stomach (at least 15 minutes before food) because they will be more easily absorbed (see section 2 “Taking Kettesse with food and drink”).

#### **Instructions for a correct use**

Dissolve the whole contents of each sachet in a glass of water; shake well to help to dissolve. The obtained solution should be immediately ingested after reconstitution.

#### **If you use more Kettesse 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 Kettesse**

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 Kettesse”).

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

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Kettesse can cause side effects, although not everybody gets them.

Possible side effects are listed below according to how likely they are to occur. Since the list is based in part on side effects from the tablet formulation of Kettesse, and Kettesse granules is absorbed faster than the tablets, it is possible that the actual frequency of (gastrointestinal) side effects could be higher with Kettesse granules. This table tells you how many patients might get these side effects:

Common side effects	affects 1 to 10 users in 100
Uncommon side effects	affects 1 to 10 users in 1,000
Rare side effects	affects 1 to 10 users in 10,000
Very rare side effects	affects less than 1 user in 10,000

#### **Common side effects:**

Nausea and/or vomiting, stomach pain, diarrhoea, digestive problems (dyspepsia).

#### **Uncommon side effects:**

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

**Rare side effects:**

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:**

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 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 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE KETESSE**

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What Kettesse contains**

Each sachet contains 25 mg of dexketoprofen (as dexketoprofen trometamol).

The other ingredients are Ammonium glycyrrhizinate, neohesperidin-dihydrochalcone, quinoline yellow (E104), lemon aroma, sucrose and silica, colloidal hydrated.  
Each sachet contains 2.40 – 2.44 g of sucrose with colloidal silica.

**What Kettese looks like and contents of the pack**

Kettese 25 mg is supplied in sachets containing lemon yellow coloured granules.  
Kettese 25 mg is supplied in packs containing 20 sachets.

**Marketing Authorisation Holder:**

Menarini International Operations Luxembourg S.A.,  
Avenue De la Gare L-1611, Luxembourg.

**Manufacturer:**

LABORATORIOS MENARINI, S.A.  
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