

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

KETESSE 25 mg film-coated tablets

Dexketoprofen trometamol

Sugar free.

Read all of this leaflet carefully before you start taking KETESSE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- KETESSE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What KETESSE is and what it is used for
2. What you need to know before you take KETESSE
3. How to take KETESSE
4. Possible side effects
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1. What KETESSE is and what it is used for

KETESSE is a painkiller from the group of medicines called nonsteroidal antiinflammatory drugs (NSAIDs). It is used for the short-term treatment of mild to moderate pain, such as muscular pain, painful periods (dysmenorrhoea), toothache.

2. What you need to know before you take KETESSE

Do not take KETESSE:

- If you are allergic to dexketoprofen or any of the other ingredients of KETESSE (listed in section 6).
- If you are allergic to acetylsalicylic acid or to other nonsteroidal 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 nonsteroidal 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 nonsteroidal anti-inflammatory drug) or fibrates (medicines 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 nonsteroidal antiinflammatory 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 pregnant or are breastfeeding your baby.
- If you have porphyria (a rare, inherited disorder that can cause nerve or skin problems).

Warnings and precautions:

If you are taking KETESSE for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to your stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Take special care with KETESSE:

- 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 KETESSE may be associated with an increased risk of heart attack ("myocardial infarction") or stroke. Do not exceed the recommended dose or duration of treatment.
- If you are an elderly person, 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 (KETESSE 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.
- If you have or have suffered in the past from other stomach or bowel problems.
- If you have varicella (chickenpox), since 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 (selective serotonin reuptake inhibitors), medicines that

prevent blood clots such as aspirin or anticoagulants such as warfarin. In such cases, consult your doctor before taking KETESSE: 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 KETESSE can cause asthma attacks or bronchospasm, particularly in patients allergic to acetylsalicylic acid or NSAIDs.

Children and adolescents:

KETESSE has not been studied in children and adolescents. Therefore, safety and efficacy have not been established and KETESSE should not be used in children and adolescents.

Other medicines and KETESSE:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not use the following medicines if you take KETESSE:

- 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 (anticancer medicine or immunosuppressant), used at high doses of 15 mg/week.
- Hydantoins and phenytoin, used for epilepsy.
- Sulfamethoxazole, used for bacterial infections.

Tell your doctor or pharmacist before you take KETESSE if you use:

- ACE inhibitors, diuretics and angiotensin II antagonists, used for high blood pressure and

- Pentoxifylline (oxpentifylline), used to treat chronic venous ulcers.
- Zidovudine, used to treat viral infections.
- Aminoglycoside 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.
- Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin) used for bacterial infections.
- Ciclosporin 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).
- Antiplatelet medicines used to reduce platelet aggregation and the formation of blood clots.
- Beta-blockers, used for high blood pressure and heart problems.
- Tenofovir, deferasirox, pemetrexed.

KETESSE 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.

Pregnancy and breastfeeding:

Do not use KETESSE during pregnancy or when breastfeeding your baby.

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.

Use of KETESSE should be avoided by women who are planning a pregnancy.

The use of KETESSE 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:

KETESSE may 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.

3. How to take KETESSE

Do not share medicines prescribed for you with any other person.

Always take KETESSE exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of KETESSE is too strong or too weak, tell your doctor or pharmacist. Your doctor will tell you how many tablets you must take daily, and for how long.

The recommended dose is 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 KETESSE has been well tolerated.

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

Use in children and adolescents:

KETESSE should not be used in children and adolescents (under the age of 18 years).

If you take more KETESSE than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

If you forget to take KETESSE:

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 3 “How to take KETESSE”).

4. Possible side effects

KETESSE can have side effects.

Not all side effects reported for KETESSE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking KETESSE, please consult your health care provider for advice.

If any of the following happens, stop taking KETESSE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Anaphylactic reaction (hypersensitive reaction which may also lead to fainting).
- Face swelling or swelling of the lips and throat (angioedema).
- Breathlessness due to narrowing of the airways (bronchospasm), shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious reaction to KETESSE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- KETESSE, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly

from your blood into the urine (renal tubular acidosis). It can also cause very low levels of

potassium in your blood (see section 2). Signs and symptoms include muscle weakness and light-headedness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea and/or vomiting
- abdominal pain
- diarrhoea
- digestive problems (dyspepsia)

Less frequent side effects:

- spinning sensation (vertigo)
- dizziness
- sleepiness, disturbed sleep
- 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)
- peptic ulcer, peptic ulcer perforation or bleeding (which may be seen as vomiting blood or black stools)

- high blood pressure
- too-slow breathing
- water retention and peripheral swelling (e.g. swollen ankles)
- laryngeal oedema
- loss of appetite (anorexia)
- 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
- open sores on skin, mouth, eyes and genital areas (Stevens-Johnson and Lyell's syndromes)
- fast heartbeat, low blood pressure
- inflammation of the pancreas
- blurred vision
- ringing in the ears (tinnitus)
- 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 antiinflammatory drugs, and especially if you are elderly.

Stop using KETESSE 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of KETESSE.

5. How to store KETESSE

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Do not remove the tablets from the blister strips until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What KETESSE contains

The active substance is dexketoprofen (as dexketoprofen trometamol).

Each film-coated tablet contains 25 mg of dexketoprofen.

The other ingredients are maize starch, microcrystalline cellulose, sodium starch glycollate, glycerol distearate, hypromellose, titanium dioxide, propylene glycol and macrogol 6000.

What KETESSE looks like and contents of the pack:

White, round, scored film-coated tablet.

Opaque white or transparent PVC/aluminium or aluminium/aluminium blister strips in an outer carton.

Pack sizes: 4, 10, 20, 30, 50 or 500 film-coated tablets.

Menarini South Africa (Pty) Ltd
KETESSE 25 mg
Not all pack sizes may be marketed.

Dexketoprofen (as dexketoprofen trometamol)
Film-coated tablet

Holder of Certificate of Registration:

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Access to the corresponding Professional Information:

Request via the email address: info@menarini.co.za