Patient information leaflet for Ketesse 50 mg/2 mL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

Ketesse 50 mg/2 mL solution for injection/infusion

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

Ketesse is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is used to treat acute moderate to severe pain, when taking tablets is not appropriate, such as post-operative pain, renal colic (severe kidney pain) and low back pain. Ketesse is for short term use only, for up to two days.

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 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 (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 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 pregnant or are breastfeeding your baby.

Warnings and precautions

Take special care with Ketesse:

- 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 the other stomach or bowel problems.
- 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 Ketesse.
- 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 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 (two days) 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 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 poor hydration and reduced blood volume due to an excessive loss of fluids (e.g. from excessive urination, diarrhoea or vomiting).
- if you are a woman with fertility problems (Ketesse may impair your fertility, therefore you should not use 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 varicella (chickenpox), since exceptionally NSAIDs, such as Ketesse, could worsen the infection.

- 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.

Children and adolescents

Ketesse 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 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 (anti-cancer 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 heart problems
- Pentoxifylline (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
- 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)
- 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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking Ketesse.

Do not use Ketesse during pregnancy or when breast feeding 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 receiving 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 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.

Ketesse contains ethanol and sodium

Each ampoule of Ketesse contains 12,35 % *v/v* ethanol (alcohol), i.e. up to 200 mg per dose.

Harmful for those suffering from alcoholism.

To be considered in children and high-risk groups such as patients with liver disease, or epilepsy.

Ketesse contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially "sodium-free".

3. How to use Ketesse

Ketesse will be administered as an injection by a suitably trained

Healthcare professional.

You should check with your doctor or pharmacist if you are unsure of the effect on you.

If you have the impression that the effect of Ketesse is too strong or too weak, tell your doctor or pharmacist.

The recommended dose is generally 1 ampoule (50 mg) of Ketesse every 8 - 12 hours. The daily dose should not exceed 150 mg (3 ampoules).

Ketesse is for use of no longer than two days. Switch to an oral pain killer when possible.

The elderly with renal dysfunction and patients with kidney or liver problems should not exceed a total daily dose of 50 mg of Ketesse (1 ampoule).

Method of administration:

Your health care professional will administer Ketesse either by intramuscular or by intravenous injection.

Use in children and adolescents

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

If you receive 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. Please remember to take this medicine pack or this leaflet with you.

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 healthcare 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), which is a severe allergic reaction
- 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.

Other side effects you may experience include the following:

Frequent side effects:

- nausea and/or vomiting
- injection site pain, injection site reactions, e.g. inflammation, brushing or haemorrhage

Less frequent side effects:

- vomiting blood
- low blood pressure

- fever
- blurred vision
- dizziness
- sleep disturbances
- headache
- anaemia
- abdominal pain
- constipation
- digestive problems
- diarrhoea
- dry mouth
- flushing
- rash
- dermatitis
- itching
- sweating increased
- tiredness
- pain
- feeling cold
- peptic ulcer, peptic ulcer perforation or bleeding (which may be seen as vomiting blood or black stools)
- high blood pressure
- too-slow breathing
- inflammation of a superficial vein due to a blood clot (superficial thrombophlebitis)
- isolated heart skip (extrasystole)
- fast heartbeat
- peripheral swelling (e.g. swollen ankles)
- laryngeal swelling

- feeling feverish and shivering
- ringing in the ears (tinnitus)
- itchy rash
- acne
- back pain
- renal pain
- passing water frequently
- menstrual disorders
- prostate problems
- muscle stiffness
- joint stiffness
- muscle cramp
- abnormal liver tests (blood tests)
- increased blood sugar level (hyperglycaemia)
- decreased blood sugar level (hypoglycaemia)
- increased triglyceride fats concentration in blood (hypertriglyceridemia)
- ketone bodies in the urine (ketonuria)
- proteins in the urine (proteinuria)
- liver cell injury (hepatitis)
- acute renal failure
- pancreatitis
- skin sensitivity reactions and skin over-sensitivity to light
- renal damage
- reduced white blood cell count (neutropenia)
- reduced platelet count (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 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 healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

5. How to store Ketesse

- Store at or below 30 °C.
- Keep the ampoules in the outer carton in order to protect it from the light.
- For single dose only. Discard any unused portion
- 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 ampoule of 2 mL contains 50 mg dexketoprofen (as dexketoprofen trometamol).

The other ingredients are ethanol (96 % *v/v*), sodium chloride, sodium hydroxide (for pH adjustment), water for injection.

What Ketesse looks like and contents of the pack:

Clear and colourless solution.

Type I glass coloured ampoules containing 2 mL of solution for injection/infusion.

Packs containing: 1, 5, 6, 10, 20, 50 or 100 ampoules.

Not all pack sizes may be marketed.

Holder of certificate of Registration and Manufacturer:

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6, Ground Floor

10 Church Street

Durbanville

7551

087 551 3245

This leaflet was last revised in:

Registration number:

54/2.7/0534