

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Enantyum 25 mg tablets**

### **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.

**In this leaflet:**

1. What Enantyum is and what it is used for
2. Before you take Enantyum
3. How to take Enantyum
4. Possible side effects
5. How to store Enantyum
6. Further information

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

Enantyum is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

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

## **2. BEFORE YOU TAKE ENANTYUM**

**Do not take Enantyum:**

- If you are allergic (hypersensitive) to dexketoprofen trometamol or to any of the other ingredients of Enantyum (see 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 aspirin or other non-steroidal anti-inflammatory medicines;
- 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 pregnant or breast feeding;
- If you are less than 18 years of age.

**Take special care with Enantyum:**

- 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 Enantyum 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 a woman with fertility problems (Enantyum 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 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 Enantyum: 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).

### **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 their doses to be altered when taken together.

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

Inadvisable combinations:

- Acetylsalicylic acid (aspirin), corticosteroids or other anti-inflammatory drugs
- Warfarin, 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
- Sulphamethoxazole, 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 and oxpentifylline, 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 Enantyum, consult your doctor or pharmacist.

**Taking Enantyum 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.

**Children and adolescents**

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

**Pregnancy and breast-feeding**

Do not use Enantyum during 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 Enantyum may not be right for you.
- you must not take Enantyum if you are breast-feeding. Ask your doctor for advice.

**Driving and using machines**

Enantyum 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.

**3. HOW TO TAKE ENANTYUM**

Always use Enantyum exactly as your doctor has told you. You should check with your doctor if you are not sure.

The dose of Enantyum 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 dosage 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 Enantyum has been well tolerated.

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 “Taking Enantyum with food and drink”).

**If you use more Enantyum 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 Enantyum**

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 use Enantyum”).

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

**4. POSSIBLE SIDE EFFECTS**

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

Possible side effects are listed below according to how likely they are to occur. This table tells you how many patients might get these side effects:

Common side effects	more than 1 out of 100 persons and less than 1 out of 10 persons.
Uncommon side effects	more than 1 out of 1000 persons and less than 1 out of 100 persons.
Rare side effects	more than 1 out of 10000 persons and less than 1 out of 1000 persons.
Very rare side effects	more than 1 out of 10000 persons, including isolated reports.

**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 Enantyum 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 Enantyum may be associated with a small increased risk of heart attack ("myocardial infarction") or 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 ENANTYUM

Keep out of the reach and sight of children.

Do not use Enantyum 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.

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 Enantyum contains

The active substance is dexketoprofen trometamol (36.90 mg) corresponding to dexketoprofen (INN) 25 mg. The other ingredients are maize starch, microcrystalline cellulose, sodium starch glycollate, glycerol palmitostearate, hypromellose, titanium dioxide, propylene glycol, macrogol 6000.

### What Enantyum looks like and contents of the pack

Enantyum is supplied in packs containing 4, 10, 20 or 50 film-coated tablets. Not all pack sizes may be marketed. The tablets can be divided into equal halves.

### Marketing Authorisation Holder and Manufacturer

*Marketing Authorisation Holder:*

MENARINI INTERNATIONAL O.L.S.A..

1, Avenue de la Gare, L-1611

Luxembourg

*Manufacturer:*

LABORATORIOS MENARINI, S.A.,

Alfonso XII 587, 08918-Badalona (Barcelona), SPAIN

or

A. MENARINI MANUFACTURING LOGISTICS and SERVICES srl,

Via Campo di Pile s/n Loc. Campo di Pile - L'AQUILA, Italy

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>Spain (RMS)</b>	<b><i>Enantyum</i></b>	<b>Italy</b>	<b><i>Enantyum</i></b>
<b>Austria</b>	<b><i>Enantyum</i></b>	<b>Latvia</b>	<b><i>Kettesse</i></b>
<b>Belgium</b>	<b><i>Enantyum</i></b>	<b>Lithuania</b>	<b><i>Kettesse</i></b>
<b>Czech republic</b>	<b><i>Kettesse</i></b>	<b>Luxembourg</b>	<b><i>Enantyum</i></b>
<b>Denmark</b>	<b><i>Enantyum</i></b>	<b>Norway</b>	<b><i>Orodek</i></b>
<b>Estonia</b>	<b><i>Kettesse</i></b>	<b>Poland</b>	<b><i>Kettesse</i></b>
<b>Finland</b>	<b><i>Enantyum</i></b>	<b>Portugal</b>	<b><i>Enantyum</i></b>
<b>France</b>	<b><i>Enantyum</i></b>	<b>Slovakia</b>	<b><i>Kettesse</i></b>
<b>Germany</b>	<b><i>Enantyum</i></b>	<b>Slovenia</b>	<b><i>Kettesse</i></b>
<b>Greece</b>	<b><i>Viaxal</i></b>	<b>Sweden</b>	<b><i>Enantyum</i></b>
<b>Hungary</b>	<b><i>Enantyum</i></b>	<b>The Netherlands</b>	<b><i>Enantyum</i></b>
<b>Iceland</b>	<b><i>Enantyum</i></b>	<b>United Kingdom</b>	<b><i>Enantyum</i></b>
<b>Ireland</b>	<b><i>Enantyum</i></b>		

**This leaflet was last approved in 06/2011.**