

## Package leaflet: Information for the user

### Okitask 25 mg Film-Coated Tablets ketoprofen (as lysine salt)

#### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

#### **What is in this leaflet**

1. What Okitask 25 mg Film-Coated Tablets is and what it is used for
2. What you need to know before you take Okitask 25 mg Film-Coated Tablets
3. How to take Okitask 25 mg Film-Coated Tablets
4. Possible side effects
5. How to store Okitask 25 mg Film-Coated Tablets
6. Contents of the pack and other information

#### **1. What Okitask 25 mg Film-Coated Tablets is and what it is used for**

The active substance of this medicine is ketoprofen which belongs to a group of medications called “Non-Steroidal Anti-Inflammatory Drugs” (NSAID). Ketoprofen acts by blocking the chemical substances that normally cause inflammation in your body. Ketoprofen Lysine Salt is a salt of ketoprofen which is absorbed quicker by the body. It is used to relieve mild to moderate pain and fever associated with cold and flu, rheumatic and muscular pain, headache, toothache and period pain in adults 18 years and over.

**You must talk to a doctor if you do not feel better or if you feel worse.**

#### **2. What you need to know before you take Okitask 25 mg Film-Coated Tablets**

##### **Do not take Okitask 25 mg Film-Coated Tablets:**

- if you are **allergic** (hypersensitive) to any of the other ingredients in this medicine (listed in section 6)
- if you suffer from **asthma** or have a history of **allergic** reactions (hypersensitivity) to ketoprofen or any other NSAIDs (e.g. aspirin, ibuprofen)
- during the **third trimester of pregnancy** (from week 29 onwards). See section 2 “Pregnancy and breast-feeding”
- if you have a **severe heart condition** where your heart does not work as well as it should
- if you suffer from, or have a history of **gut-related problems** such as:
  - active peptic ulcer
  - stomach ulcers or ulcers of the intestines
  - gut bleeding
  - holes in the stomach or foodpipe (gastrointestinal perforation)
  - painful or disturbed digestion, may include nausea, vomiting, heartburn, bloating, and stomach discomfort (chronic dyspepsia)

- inflammation of the stomach lining (gastritis)
- if you have a **low blood cell count** (leukocytopenia or thrombocytopenia), **active bleeding** or the **tendency to bleed** on treatment with medicines that help prevent blood clots (anticoagulants)

if you have **kidney** or **liver** problems

### **Warnings and precautions**

If you notice any signs of rash, red and painful skin around body openings (mucous membranes) or allergic reactions after taking Okitask 25 mg Film-Coated Tablets, stop taking this medicine and tell your doctor immediately.

If you notice any signs of bleeding in the stomach or intestines (e.g. bright red faeces, black tarry stools, vomiting blood or dark particles that look like coffee grounds), stop taking this medicine and tell your doctor immediately.

If you notice any signs of ulceration or perforation (symptoms may include: severe stomach pain, chills, nausea, vomiting, heartburn) after taking Okitask 25 mg Film-Coated Tablets, stop taking this medicine and tell your doctor immediately.

Elderly people may experience more side effects with NSAIDs. If you are an elderly patient, the product should be used with caution.

Stop taking this medicine if you experience any sight problems, such as blurred vision.

As Okitask 25 mg Film-Coated Tablets is used to treat symptoms such as fever, it may mask a more serious underlying condition. If your symptoms persist, tell your doctor.

Talk to your doctor or pharmacist before taking Okitask 25 mg Film-Coated Tablets if you:

- are **pregnant, trying to become pregnant**, or are **breastfeeding** (see section 2 “Pregnancy and breast-feeding”)
- suffer from **fluid retention** and **swelling**
- have **high blood pressure**, a **weakened heart**, arterial disease and/or problems with your blood vessels supplying the brain, **diabetes**, **high cholesterol**, a family history of **heart disease** or **stroke**, or if you are a **smoker**
- suffer from a condition named **phenylketonuria**, where your body is unable to break down a substance called phenylalanine
- suffer from liver disease
- suffer from kidney disease
- suffer from any allergies (e.g. hayfever)
- suffer from chronic obstructive pulmonary disease (COPD)
- have hepatic porphyria (a rare disease of the blood characterised by the alteration of the activity of one of the liver enzymes) because the medicine could trigger an attack
- have a condition of the immune system causing joint pain skin changes and other organ disorders (Systemic Lupus Erythematosus).
- have an infection - please see heading “Infections” below.

### **Infections**

Okitask 25 mg Film-Coated Tablets may hide signs of infections such as fever and pain. It is therefore possible that Okitask 25 mg Film-Coated Tablets 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** Okitask 25 mg Film-Coated Tablets should not be used in children and adolescents under 18 years.

### **Other medicines and Okitask 25 mg Film-Coated Tablets**

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

You must **tell your doctor or pharmacist** if you are taking any of the following:

- medicines to **improve the flow of blood** such as anti-coagulants (aspirin, warfarin, heparin, ticlopidin, dabigatran or clopidogrel), thrombolytics (reteplase, streptokinase), pentoxifylline, prasugrel, coumarins
- certain **antibiotics** (e.g. quinolones, sulphonamides)
- medicines used after an **organ transplant** to help prevent rejection (e.g. ciclosporin, tacrolimus)
- medicines used for some types of **mental illness** and **depression** (e.g. lithium, venlafaxine, and selective serotonin reuptake inhibitors (SSRIs))
- **other NSAIDs** (e.g. aspirin, ibuprofen) or paracetamol)
- **diuretics** (water tablets) such as bendroflumethiazide
- **glucocorticosteroids** (steroid hormones such as hydrocortisone or prednisolone)
- anti-retroviral medicines used to treat **HIV** infections (e.g. ritonavir, zidovudine)
- medicines to treat **high blood pressure** (e.g. ramipril, captopril, enalapril, losartan, irbesartan)
- **muscle relaxants** such as baclofen
- medicines used to treat **heart failure** and **to control the rate of your heart beat** (e.g. digoxin, digitoxin)
- medicines to treat **diabetes** (e.g. gliclazide)
- medicines used to treat **cancer** (e.g. erlotinib, pemetrexed, methotrexate)
- medicines to treat **gout** (e.g. probenecid)
- **diphenylhydantoin** – an anti-epileptic medicine
- **pentoxifylline** – a medicine used for the treatment of muscle pain
- **penicillamine** – a medicine used for the treatment of rheumatoid arthritis

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

Do not take this medicine if you are in your 3<sup>rd</sup> trimester of pregnancy. It is advised that you avoid this medicine if you are in your 1<sup>st</sup> or 2<sup>nd</sup> trimester of pregnancy as a precaution.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

If, after taking Okitask 25 mg Film-Coated Tablets, you feel sleepy, dizzy, have blurred vision, or have convulsions, do not drive, use machinery, or perform activities that require a high level of alertness (see section 4 “Possible side effects”).

**Okitask 25 mg Film-Coated Tablets contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.**

## **3. How to take Okitask 25 mg Film-Coated Tablets**

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

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 section 2).

This product is for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.

The recommended dose is 1 tablet up to 3 times a day as required

Wait at least for four hours before taking another tablet.

**Do not exceed the recommended dose.**

Swallow the tablet whole, with water if necessary.

If symptoms persist or the pain worsens, or if any new symptoms occur, consult your doctor or pharmacist.

#### **Use in the elderly**

Okitask 25 mg Film-Coated Tablets should be used with caution in the elderly. Do not take more than 1 tablet of Okitask 25 mg Film-Coated Tablets in 24 hours.

#### **If you take more Okitask 25 mg Film-Coated Tablets than you should**

If you accidentally take more Okitask 25 mg Film-Coated Tablets than advised, you may feel drowsy or nauseous. You should seek medical advice immediately, even if you feel well.

#### **If you forget to take Okitask 25 mg Film-Coated Tablets**

**Do not take a double dose to make up for a forgotten dose.**

If you forget to take Okitask 25 mg Film-Coated Tablets, take it as soon as possible. However, if it is almost time to take the next dose do not take the dose that you have missed; just take the next dose as normal.

#### **If you stop taking Okitask 25 mg Film-Coated Tablets**

You should stop taking this medicine as soon as you feel better. If you have any further questions on the use of this medicine, ask a doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them

**Stop taking Okitask 25 mg Film-Coated Tablets and seek medical advice immediately** if at any time during treatment with Okitask 25 mg Film-Coated Tablets you develop:

- **signs of intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **signs of rashes, severe skin reactions and blistering of the skin, mouth, and eyes**
- **signs of a serious allergic reaction** such as:
  - difficulties in breathing or unexplained wheezing,
  - dizziness or faster heartbeat
  - swelling of your lips, face, throat or tongue
- exacerbation worsening of **Crohn's disease** and **colitis** (a chronic inflammatory disease of the gut with the symptoms of abdominal pain, diarrhoea, fever, and weight loss)

**Tell your doctor if you experience:**

- fever, sore throat, mouth ulcers, headache, vomiting, unexplained bleeding and bruising, severe exhaustion
- indigestion, stomach or abdominal pain, constipation, diarrhoea, flatulence or if you feel sick, chest pain or fast irregular heart beat
- liver and kidney problems associated with swelling in your arms and legs.

**Side effects with Okitask 25 mg Film-Coated Tablets may include:**

**Common** (may affect up to 1 in 10 people)

- poor digestion (dyspepsia), nausea, abdominal pain, vomiting

**Uncommon** (may affect up to 1 in 100 people)

- headache, dizziness, drowsiness
- constipation, diarrhoea, flatulence (wind), inflammation in the lining of the stomach
- swelling due to accumulation of fluid
- itching and rashes
- fatigue

**Rare** (may affect up to 1 in 1000 people)

- iron deficiency (anaemia) caused by bleeding
- numbness, tingling
- blurred vision
- ringing in the ear (tinnitus)
- asthma
- inflammation of the lining of mouth
- stomach ulcer
- liver inflammation (Hepatitis), increases in liver enzymes, yellowing of the skin or the whites of the eyes (jaundice)
- weight gain

**Not known** (the frequency cannot be estimated from the available data)

- change in blood cell and platelet counts
- allergic reactions (anaphylaxis)
- impairment of the glands located on top of the kidneys (adrenal gland)
- high blood pressure, flushing (vasodilation)
- heart failure
- kidney failure, inflammation in the kidneys, abnormal kidney test results
- colitis
- inflammation of the intestines (Crohn's disease)
- worsening of gastrointestinal conditions
- dark or black stools
- vomiting blood
- blocked and runny nose (rhinitis)
- swelling of the throat
- swelling of the deep layers of skin, caused by excess fluid (e.g. face, hands)
- difficulty breathing (dyspnoea)
- headache
- breathing distress caused by narrowing of the airways
- uncontrolled contractions of the muscles (convulsion)
- sensitivity to sun light or UV lamps
- taste disturbances
- mood swings
- change in behaviour

- hair loss
- itchy rash
- bleeding of the stomach, symptoms can include severe stomach pain, chills, nausea, vomiting, heartburn
- bleeding of the intestines, symptoms can include bright red faeces, black tarry stools, vomiting blood or dark particles that look like coffee grounds

Following the instructions in this leaflet will reduce the risk of side effects.

### **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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store Okitask 25 mg Film-Coated Tablets**

Keep this medicine out of the sight and reach of children.

Store in the original packaging in order to protect against light and moisture.

Do not use this medicine after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Okitask 25 mg Film-Coated Tablets contains**

- The active substance is ketoprofen. Each tablet contains 25 mg ketoprofen (as lysine salt).
- The other ingredients are: mannitol (E421), crospovidone, sodium laurilsulfate, silica colloidal anhydrous, sodium stearyl fumarate, polyvinyl alcohol (E1203), macrogol, titanium dioxide (E171), talc (E553B), brilliant blue (E133), quinoline yellow (E104).

#### **What Okitask 25 mg Film-Coated Tablets looks like and contents of the pack**

Okitask 25 mg Film-Coated Tablets are film-coated blue tablets, with a non-functional score line on one side. The tablets are supplied in blister packs of 8, 10, 15, 16 or 20 tablets. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Dompé Farmaceutici S.p.A.  
Via San Martino 12  
20122, Milan  
Italy

#### **Manufacturer**

Abiogen Pharma S.p.A.  
Via Meucci, 36  
56121 Ospedaletto

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

Estonia	Okitask 25 mg õhukese polümeerikattega tabletid
Ireland	Okitask 25 mg film-coated tablets
United Kingdom	Okitask 25 mg film-coated tablets