

## **Package leaflet: Information for the user**

### **Normodex 25 mg film-coated tablets**

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

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

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

1. What Normodex is and what it is used for
2. What you need to know before you take Normodex
3. How to take Normodex
4. Possible side effects
5. How to store Normodex
6. Contents of the pack and other information

#### **1. What Normodex is and what it is used for**

Normodex 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 or joint pain, painful periods (dysmenorrhoea), toothache.

#### **2. What you need to know before you take Normodex**

##### **Do not take Normodex:**

- If you are allergic to dexketoprofen trometamol or to any of the other ingredients of this medicine (listed in section 6);
- If you are allergic to acetylsalicylic acid (aspirin) or to another non-steroidal anti-inflammatory medicine;
- If you have asthma or have suffered asthma attacks, acute allergic rhinitis (a short period of inflammation of the nasal mucosa), nasal polyps (fleshy formations inside the nose due to allergy), urticaria (skin rash), angio-oedema (swelling of the face, eyes, lips or tongue, or difficulty breathing) or wheezing in the chest after taking acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs;
- If you have or have had in the past peptic ulcer, stomach or intestinal bleeding or if you have chronic digestive problems (e.g. indigestion or heartburn);
- If you have had stomach or intestinal bleeding or perforation in the past, due to previous use of non-steroidal anti-inflammatory drugs (NSAIDs) for pain;
- If you have chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis);
- If you have severe heart failure, moderate-to-severe kidney failure or severe liver failure;
- If you have bleeding disorders or blood clotting disorders;
- If you are pregnant or breast-feeding;

- If you are under 18 years of age.

### **Warnings and precautions**

Talk to your doctor or pharmacist before you start taking Normodex:

- If you are allergic or have had allergy problems in the past;
- If you have kidney, liver or heart disease (hypertension and/or heart failure), or fluid retention or you have suffered from any of these problems in the past;
- If you are taking diuretics or you have an insufficient fluid intake and reduced blood volume due to excessive loss of fluids (e.g. from excessive urination, diarrhoea or vomiting);
- If you have heart problems, a history of stroke, or you think you might be at risk of suffering from these disorders (e.g. if you have high blood pressure, diabetes, high cholesterol or are a smoker) you must discuss this treatment with your doctor or pharmacist. Medicines such as Normodex may be associated with a slightly higher risk of heart attack (“myocardial infarction”) or stroke (“cerebrovascular accident”). This risk is more likely with high doses and prolonged treatments. Do not exceed the recommended dose or duration of treatment;
- If you are elderly, you may be more at risk of side effects (see section 4). If these occur, talk to your doctor immediately;
- If you are a woman with fertility problems (Normodex may reduce your fertility, so you must not take it if you are planning to become pregnant or if you are undergoing fertility tests);
- If you suffer from a blood production and blood cell disorder;
- If you have systemic lupus erythematosus or mixed connective tissue disease (immune system diseases that affect connective tissue);
- If you suffer or have suffered in the past from chronic inflammatory bowel disease (ulcerative colitis, Crohn’s disease);
- If you suffer or have suffered in the past from stomach or intestinal disorders;
- If you are taking other medicines that increase the risk of peptic ulcer or bleeding, e.g., oral corticosteroids, some antidepressants (of the SSRI type, Selective Serotonin Reuptake Inhibitors), agents that prevent clotting such as acetylsalicylic acid (aspirin) or anticoagulants like warfarin. In these cases, talk to your doctor before taking Normodex: your doctor may prescribe additional medication to protect your stomach (e.g. misoprostol or other medicines that block the production of gastric acid).

### **Children and adolescents**

Do not take Normodex if you are under 18 years of age.

### **Other medicines and Normodex**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that must not be taken together and other medicines that may need a change of dose if taken together.

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

Combinations that should be avoided:

- Acetylsalicylic acid (aspirin), corticosteroids and other anti-inflammatory drugs;
- Warfarin, heparin and other medicines used to prevent blood clots;
- Lithium, which is used to treat some mood disorders;
- Methotrexate, which is used for rheumatoid arthritis and cancer;
- Hydantoins and phenytoin, which are used for epilepsy;
- Sulfamethoxazole, which is used for bacterial infections;

Combinations that require precaution:

- ACE-inhibitors, diuretics, beta blockers and angiotensin II antagonists, which are used to control high blood pressure and heart problems;
- Pentoxifylline and oxpentifylline, which are used to treat chronic venous ulcers;
- Zidovudine, which is used to treat viral infections;
- Aminoglycoside antibiotics, which are used for the treatment of bacterial infections;
- Chlorpropamide and glibenclamide, which are used for diabetes;

Combinations that should be taken into account:

- Quinolones (e.g. ciprofloxacin, levofloxacin), which are used for bacterial infections;
- Ciclosporin or tacrolimus, which are used to treat immune system diseases and in organ transplant;
- Streptokinase and other thrombolytic and fibrinolytic medicines; i.e., medicines used to dissolve blood clots;
- Probenecid, which is used for gout;
- Digoxin, which is used in the treatment of chronic heart failure;
- Mifepristone, which is used as an abortifacient (to interrupt pregnancy);
- Selective serotonin reuptake inhibitor (SSRI) antidepressants;
- Antiplatelet agents, which are used to reduce platelet aggregation and clotting.

If you have any doubt about taking other medicines with Normodex, talk to your doctor or pharmacist.

#### **Normodex with food, drink and alcohol**

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, breast-feeding and fertility**

Do not use Normodex when breast-feeding.

Do not take Normodex if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Normodex during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. From 20 weeks of pregnancy, Normodex can cause kidney problems in your unborn baby, if taken for more than a few days, which can lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios). If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Ask your doctor or pharmacist for advice before taking any medication.

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

- Do not take Normodex if you are breast-feeding. Ask your doctor for advice.

### **Driving and using machines**

Normodex may slightly affect your ability to drive and use machines, as it can cause drowsiness or vertigo as side effects of the treatment. If you notice these effects, do not use machines or drive until these symptoms disappear. Ask your doctor for advice.

### **Normodex contains sodium**

This medicine contains less than 23 mg sodium (1 mmol) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Normodex**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose of Normodex that you need may vary, depending on the type, severity and duration of the pain. Your doctor will tell you how many tablets to take per day and for how long.

The recommended dose is generally 1 tablet (25 mg of dexketoprofen) every 8 hours, with no more than 3 tablets daily (75 mg).

If you are elderly or suffer from kidney or liver disease, the recommended starting dose is a maximum of 2 tablets a day (50 mg).

In elderly patients this initial dose may subsequently be increased in accordance with the general recommended dose (75 mg of dexketoprofen) if Normodex has been well tolerated.

If your pain is intense and requires rapid relief, take the tablets on an empty stomach (at least 30 minutes before a meal), as they will be absorbed more easily (see section 2 "Normodex with food and drink").

### **If you take more Normodex than you should**

If you take too much medicine, inform your doctor or pharmacist immediately or go to the nearest hospital emergency department. Please remember to take the box of the medication or this package leaflet with you. In case of overdose or accidental intake, talk to your doctor or pharmacist immediately, or call the Toxicology Information Service (Spanish phone: +34 91 562 04 20), specifying the medicine and the amount taken.

### **If you forget to take Normodex**

Do not take a double dose to make up for a forgotten dose. Take the next dose when due (according to section 3 "How to take Normodex").

### **If you stop using Normodex:**

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The possible side effects are listed below according to their frequency. The following table shows how many patients may get these side effects:

Common	May affect between 1 and 10 in every 100 patients
Uncommon	May affect between 1 and 10 in every 1,000 patients
Rare	May affect between 1 and 10 in every 10,000 patients
Very rare	May affect less than 1 in every 10,000 patients

**Common side effects:**

Nausea and/or vomiting, stomach ache, diarrhoea, digestive disorders (dyspepsia).

**Uncommon side effects:**

Spinning sensation (vertigo), dizziness, drowsiness, sleep disorders, nervousness, headache, palpitations, hot flushes, stomach problems, constipation, dry mouth, flatulence, skin rash, fatigue, pain, feverish sensation and shivering, 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, 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 kidney failure.

**Very rare:**

Anaphylactic reaction (hypersensitivity reaction that may also lead to collapse), ulcers on the skin, mouth, eyes and genital areas (Stevens-Johnson syndrome and Lyell's syndrome), swelling of the face or of the lips and throat (angioedema), difficulty breathing due to narrowing of the airways (bronchospasm), shortness of breath, tachycardia, low blood pressure, inflammation of the pancreas, blurred vision, ear buzzing (tinnitus), sensitive skin, sensitivity to light, itching, kidney problems. Reduction in the number of white blood cells (neutropenia), reduction in the number of platelets (thrombocytopenia).

Tell your doctor immediately if you notice any gastrointestinal side effect when you start the treatment (e.g. stomach ache, heartburn or bleeding) or if you have previously had any of these side effects due to long-term treatment with anti-inflammatory drugs, especially if you are elderly.

Stop taking Normodex immediately if you notice the appearance of a skin rash or any lesion inside the mouth or on the genitals, or any other sign of allergy.

During treatment with non-steroidal anti-inflammatory drugs, water retention and swelling (especially in the ankles and legs), increased blood pressure and heart failure have been reported.

Medicines such as Normodex may be associated with a slightly higher risk of heart attack (“myocardial infarction”) or stroke (“cerebrovascular accident”).

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 stiffness of the neck.

**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. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Normodex**

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

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

Do not store above 30°C.

Store in the original package to protect it from light.

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 Normodex contains**

- The active substance is dexketoprofen trometamol (36.90 mg) corresponding to dexketoprofen (INN) 25 mg.
- The other ingredients (excipients) are: Tablet core: maize starch, microcrystalline cellulose, sodium carboxymethyl starch type A (potato starch), colloidal anhydrous silica, magnesium stearate. Coating: titanium dioxide (E-171), hypromellose, macrogol 6000 and talc.

### **What Normodex looks like and contents of the pack**

Normodex 25 mg are white or off-white, round and biconvex tablets scored on one side. It comes in packs containing 20 and 500 film-coated tablets (clinical package).

### **Marketing Authorisation Holder and Manufacturer**

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