

Package leaflet: information for the user

Normodex 25 mg film-coated tablets

Dexketoprofen

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. 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. See section 4.

In this leaflet:

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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 pain, painful periods (dysmenorrhoea), toothache.

2. Before you take Normodex

Do not take Normodex:

- If you are allergic (hypersensitive) to dexketoprofen trometamol or to any of the other ingredients of this medicine (see section 6).
- If you are allergic to acetylsalicylic acid (aspirin) 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 (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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Normodex:

- 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 Normodex may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke ("cerebrovascular accident"). 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 (Normodex 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 acetylsalicylic acid (aspirin) or anticoagulants such as warfarin. In such cases, consult your doctor before taking Normodex: 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).

Children and adolescents

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

Other medicines and Normodex

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. 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 Normodex:

Inadvisable combinations:

- Acetylsalicylic acid (aspirin), corticosteroids or other antiinflammatory 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.
- Sulfamethoxazole, used for bacterial infections.

Combinations requiring precautions:

- ACE inhibitors, diuretics, beta-blockers and angiotensin II antagonists, used for high blood pressure and heart conditions.
- 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 Normodex, consult your doctor or pharmacist.

Taking 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 during pregnancy or when breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

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

You must 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 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.

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

The dose of Normodex 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 Normodex 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 Normodex with food and drink”).

If you take more Normodex than you should

If you take too much of this medicine, tell your doctor or pharmacist immediately or go to the emergency department of your nearest hospital, indicating the medicine and the amount taken. Please remember to take this medicine pack or this leaflet with you.

If you forget to take Normodex

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

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

4. Possible side effects

Like all medicines, Normodex 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	more than 1 out of 100 people and less than 1 out of 10 people
Uncommon	more than 1 out of 1,000 people and less than 1 out of 100 people
Rare	more than 1 out of 10,000 people and less than 1 out of 1,000 people
Very rare	less than 1 out of 10,000 people

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.

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 Normodex 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 Normodex may be associated with a small increased 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 neck stiffness.

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 out of the sight and reach of children.

Do not use Normodex 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.

Store below 30 °C.

Store in the original package 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. Contents of the pack and other information

What Normodex contains

The active substance is dextetoprofen trometamol (36.90 mg) equivalent to 25 mg of dextetoprofen.

The other ingredients (excipients) are: Core: Maize starch, microcrystalline cellulose, sodium starch glycolate type A (potato starch), colloidal anhydrous silica, magnesium stearate. Coating: Titanium Dioxide (E-171), hypromellose, macrogol 6000, talc.

What Normodex looks like and contents of the pack

Normodex 25 mg are white or almost white, round, biconvex and scored on one side film-coated tablets. It is supplied in packs containing 20 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last reviewed in: December 2021