

Package leaflet: information for the user
Normodex 50 mg/2 ml
solution for injection/ infusion
Dexketoprofen

Read all of this leaflet carefully before you start using 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.

In this leaflet:

1. What Normodex 50 mg/2 ml solution for injection/ infusion is and what it is used for
2. Before you use Normodex 50 mg/2 ml solution for injection/ infusion
3. How to use Normodex 50 mg/2 ml solution for injection/ infusion
4. Possible side effects
5. How to store Normodex 50 mg/2 ml solution for injection/ infusion
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 acute moderate to severe pain, when oral administration is not appropriate, such as post-operative pain, renal colic (severe kidney pain) and low back pain.

2. Before you use Normodex

Do not use Normodex if you:

- Are allergic (hypersensitive) to dexketoprofen trometamol or to any of the other ingredients of to any of the other ingredients of this medicine (see section 6);
- Are allergic to acetylsalicylic acid or to other non-steroidal anti-inflammatory medicines;
- 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;
- Have or have previously suffered from a peptic ulcer;
- Have or have previously suffered in the past from stomach or bowel bleeding, due to previous use of non-steroidal anti-inflammatory drugs (NSAIDs);
- Have chronic digestive problems (e.g. indigestion, heartburn) or bowel disease with chronic inflammation (Crohn's disease or ulcerative colitis);
- Have serious heart failure, moderate or serious kidney problems or serious liver problems;
- Have a bleeding disorder or a blood clotting disorder;
- Suffer or have previously suffered from asthma;
- Are in third trimester of pregnancy or breast feeding;

Warnings and precautions

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

- Have suffered in the past from a chronic inflammatory disease of the bowel (ulcerative colitis, Crohn's disease);
- Have or have suffered in the past from the other stomach or bowel problems;
- 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 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);
- 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;
- Are elderly: you may be more likely to suffer from side effects (see section 4). If any of these occur, consult your doctor immediately;
- Suffer from allergy, or if you have had allergy problems in the past;
- 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;
- 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);
- 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);
- Are in the first or second trimester of pregnancy;
- Suffer from a disorder in the formation of blood and blood cells;
- Have systemic lupus erythematosus or mixed connective tissue disease (immune system disorders that affect connective tissue);
- Are less than 18 years of age;

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, corticosteroids or other non-steroidal 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.

Pregnancy, breast-feeding and fertility

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, as Normodex may not be suitable for you.

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. If taken for more than a few days from 20 weeks of pregnancy onward, Normodex can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

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 ethanol and sodium

Each ampoule of Normodex contains 10% of ethanol equivalent to 200 mg per dose, equivalent to 5 ml beer or 2.08 ml wine per dose. Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially “sodium-free”.

3. How to use Normodex

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

Your doctor will tell you what is the dose of Normodex that you need, according to the type, severity and duration of your symptoms. The recommended dosage is generally 1 ampoule (50 mg) of Normodex every 8 - 12 hours. If needed, the injection can be repeated after only 6 hours. Do not exceed a total daily dose of 150 mg of Normodex (3 ampoules) in any case.

Use the injection treatment 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 Normodex (1 ampoule).

Method of administration:

Normodex can be administered either by intramuscular or by intravenous route (technical details for the intravenous injection are given in the section 7):

When Normodex is given intramuscularly, the solution should be injected immediately after its removal from the coloured ampoule, by slow injection deep into the muscle.

Only a clear and colourless solution should be used.

If you use more Normodex 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 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 use 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 persons and less than 1 out of 10 persons
Uncommon	more than 1 out of 1,000 persons and less than 1 out of 100 persons
Rare	more than 1 out of 10,000 persons and less than 1 out of 1,000 persons
Very rare	less than 1 out of 10,000 persons

Common side effects:

Nausea and/or vomiting, injection site pain, injection site reactions, e.g. inflammation, bruising or haemorrhage.

Uncommon side effects:

Anaemia, headache, dizziness, sleep disturbances, sleepiness, blurred vision, low blood pressure, flushing, abdominal pain, digestive problems, diarrhoea, constipation, vomiting blood, dry mouth, itching, rash, dermatitis, sweating increased, tiredness, feeling cold, fever, pain.

Rare side effects:

Laryngeal oedema, increased blood sugar level, decreased blood sugar level, increased triglyceride fats concentration in blood, abnormal sensation, fainting, ringing in the ears (tinnitus), extrasystole (isolated heart skip), tachycardia (fast heartbeat), high blood pressure, inflammation of a superficial vein due to a blood clot (superficial thrombophlebitis), too-slow breathing, peptic ulcer, peptic ulcer haemorrhage or peptic ulcer perforation, liver cell injury (hepatitis), jaundice, itchy rash, acne, muscle stiffness, joint stiffness, muscle cramp, back pain, acute renal failure, passing water frequently, renal pain, ketonuria (ketone bodies in the urine), proteinuria (proteins in the urine), menstrual disorders, prostate problems, feeling feverish and shivering, peripheral oedema, abnormal liver tests.

Very rare:

Hematological reaction (reduced white blood cell count, reduced platelet count), anaphylactic reaction (hypersensitive reaction which may also lead to a collapse), breathlessness due to contraction of the muscles around the airways (bronchospasm), shortness of breath, liver cell injury, pancreatitis, renal damage, ulceration of the skin, mouth, eyes and genital areas (Stevens Johnson and Lyell's syndromes), skin sensitivity reactions and skin over-sensitivity to light, facial swelling or swelling of the lips and throat (angioedema).

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 on the mucous surfaces (e.g. the surface along the inside of the mouth), or any sign of allergy.

During treatment with non-steroidal anti-inflammatory drugs, fluid retention and swelling (especially in the ankles and legs), a raise in 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 systemic lupus erythematosus or mixed connective tissue disease (immune system disorders that affect connective tissue), anti-inflammatory medicines may rarely cause fever, headache and stiffness of the back of the neck.

Tell your doctor immediately if signs of infection occur or get worse whilst using Normodex.

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 Normodex

Keep out of the reach and sight of children.

Keep the ampoule in the outer carton in order to protect it from light.

Do not use Normodex after the expiry date which is stated on the carton and on the ampoule. The expiry date refers to the last day of that month.

Do not use Normodex if you notice that the solution is not clear and colourless, but shows signs of deterioration (e.g. particles). Normodex is for single use only and should be used immediately once opened. Discard any unused quantity of the product.

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 Normodex contains

Each ampoule contains 50 mg of Dexketoprofen (as dexketoprofen trometamol)
The other ingredients are alcohol (ethanol), sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What the product looks like and contents of the pack

Normodex is supplied in packs containing coloured ampoules. Each pack contains 6 ampoules.

Marketing Authorisation Holder and Manufacturer

LABORATORIOS NORMON S.A.

Ronda de Valdecarrizo, 6 - 28760 Tres Cantos- Madrid (SPAIN)

This leaflet was last approved in March 2023.

Detailed information on this medicine is available on the website of Spanish Agency for Medicines and Medical Devices (AEMPS) <http://www.aemps.gob.es/>

7. INFORMATION FOR THE HEALTH PROFESSIONAL

Intravenous use:

Intravenous infusion: the content of one ampoule (2 ml) of Normodex should be diluted in a volume of 30 to 100 ml of Normal Saline, 5% glucose or ringer lactate solution. The diluted solution should be given as a slow intravenous infusion, lasting 10 to 30 min. The solution must be always protected from natural daylight.

Intravenous bolus: if necessary, the content of one ampoule (2 ml) Normodex can be given in a slow intravenous bolus over no less than 15 seconds.

Normodex is contraindicated for intrathecal or epidural administration due to its ethanol content.

Instructions on handling the product:

When Normodex is given as intravenous bolus the solution should be injected immediately after its removal from the coloured ampoule.

For administration as intravenous infusion, the solution should be diluted aseptically and protected from natural daylight.

Only a clear and colourless solution should be used.

Compatibilities:

Normodex has shown to be compatible when **mixed in small volumes** (e.g. in a syringe) with injectable solutions of heparin, lidocaine, morphine and theophylline.

The solution for injection diluted as indicated is a clear solution.

Normodex diluted **in a volume of 100 ml** of normal saline or glucose solution has been shown to be compatible with the following solutions for injection: dopamine, heparin, hydroxyzine, lidocaine, morphine, pethidine and theophylline.

No absorption of the active ingredient has been found when diluted solutions Normodex have been stored in plastic bags or administration devices made of Ethyl Vinyl Acetate (EVA), Cellulose Propionate (CP), Low Density Polyethylene (LDPE) and Polyvinyl Chloride (PVC).