PACKAGE LEAFLET: Information for the user

DOLODEX

Solution for injection / infusion – 50 mg / 2 ml

(Dexketoprofen)

Read all of this leaflet carefully before you start using 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 DOLODEX IS AND WHAT IT IS USED FOR

Dolodex solution for injection / infusion, is an analgesic medicinal product that belongs to non-steroidal anti-inflammatory drugs (NSAIDs). It is used for the treatment of moderate to severe acute pain, such as post-operative pain, renal colic (severe kidney pain) and back pain, when oral administration is not suitable.

2. BEFORE YOU USE DOLODEX

Do not use Dolodex solution for injection / infusion:

- if you are allergic to dexketoprofen or to any of the other ingredients of this medicine, listed

in section 6;

- if you are allergic to acetylsalicylic acid (aspirin) or to other NSAIDs;
- if you have asthma or have suffered from asthma attacks, acute allergic rhinitis (short-term inflammation of the nasal mucosa), nasal polyps (allergy-related swelling of the nasal mucosa), urticaria (skin rash), angioedema (swelling of the face, eyes, lips or tongue, or shortness of breath) or a wheezing sound in the chest after taking acetylsalicylic acid (aspirin) or other NSAIDs;
- if you have ever suffered from photoallergic or phototoxic reactions (a certain form of reddening and/or blistering of the areas of skin exposed to sunlight) during treatment with ketoprofen (an NSAID) or fibrates (medicines used to lower blood lipid levels);
- if you have a stomach / duodenal ulcer or gastrointestinal bleeding, or if you have suffered from gastrointestinal bleeding, ulceration or perforation in the past;
- if you suffer or have previously suffered from gastrointestinal bleeding or a gastrointestinal perforation in connection with the use of NSAIDs;
- if you have chronic digestive problems (such as indigestion, heartburn);
- if you have a chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis);
- if you have severe heart failure, moderate to severe kidney function impairment or severe liver function impairment;
- if you have a bleeding disorder or a blood clotting disorder;
- if you are severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhea or insufficient intake of fluids;
- if you are in the last three months of pregnancy or if you are breastfeeding.

Warnings and precautions

Please talk to your doctor or pharmacist before using Dolodex if any of the following applies to you:

- if you have suffered from a chronic inflammatory bowel disease (ulcerative colitis, Crohn's disease) in the past;
- if you currently suffer or have suffered from other gastrointestinal complaints;
- if you are concomitantly taking other medicines that increase the risk of gastrointestinal ulcers or bleeding, such as oral steroids, certain antidepressants (such as SSRIs, that is, selective

serotonin reuptake inhibitors), medicines used for the prevention of blood clots such as acetylsalicylic acid (aspirin), or anticoagulants such as warfarin. If this is the case, you should consult your doctor before using Dolodex, who may also prescribe a medicine that protects the stomach lining (such as misoprostol or a medicine that inhibits stomach acid production);

- if you have heart problems or a history of stroke, or think that you may be at risk for these conditions (e.g. if you have high blood pressure, diabetes, high cholesterol levels or if you are a smoker). Medicines such as Dolodex may be associated with a slightly increased risk of heart attacks (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 suffer from allergies or have suffered from allergies in the past;
- if you have kidney, liver or heart problems (hypertension and/or heart failure), as well as fluid retention in the body or if you have suffered from any of these problems in the past;
- if you are taking diuretics or you are prone to dehydration and reduced blood volume due to excessive fluid loss (e.g. due to very frequent urination, diarrhea or vomiting);
- if you are in the first or second trimester of pregnancy;
- if you suffer from a disorder of blood formation or blood cell development;
- if you suffer from systemic lupus erythematosus or mixed connective tissue disease (diseases of the immune system that affect the connective tissue);
- if you have varicella (chickenpox), as NSAIDs could worsen the infection in exceptional cases;
- if you suffer from asthma in relation to chronic rhinitis, chronic sinusitis and/or nasal polyps because you have a higher risk of allergy to acetylsalicylic acid (aspirin) and/or NSAIDs than the rest of the population. The use of this medicine may cause asthma attacks or shortness of breath due to constriction of the airways (bronchospasm), especially in patients who are allergic to acetylsalicylic acid or NSAIDs.

Children and adolescents

This medicine has not been studied in children and adolescents. Therefore, safety and efficacy have not been established and the product should not be used in children and adolescents.

Taking other medicines

Please contact your doctor or pharmacist if you are taking, have recently taken / used or intend to take / use other medicines, including those taken / used without a prescription. Some medicines should not be used together and for others the dose must be adjusted if used at the same time.
Please always inform your doctor or pharmacist if you are taking / using any of the following medicines in addition to Dolodex:

Combinations not recommended:

- Acetylsalicylic acid (aspirin), corticosteroids or other NSAIDs
- Warfarin, heparin or other medicines used to prevent blood clots
- Lithium (used to treat some mental illnesses)
- Methotrexate (used to treat rheumatic diseases and cancer)
- Hydantoins and phenytoin (used to treat epilepsy)
- Sulfamethoxazole (used to treat bacterial infections)

Combinations whose use requires precautionary measures:

- ACE inhibitors, diuretics, beta-blockers and angiotensin II receptor antagonists (used to treat high blood pressure and heart disease)
- Pentoxifylline and oxpentifylline (used to treat chronic venous ulcers)
- Zidovudine (used to treat viral infections)
- Aminoglycoside antibiotics (used to treat bacterial infections)
- Chlorpropamide and glibenclamide (used to treat diabetes mellitus)

Combinations that must be carefully considered:

- Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin) (used to treat bacterial infections)
- Ciclosporin or tacrolimus (used to treat immune disorders and to prevent transplant rejection)
- Streptokinase and other thrombolytic or fibrinolytic medicines (used to dissolve blood clots)
- Probenecid (used to treat gout)
- Digoxin (used to treat chronic heart failure)

- Mifepristone, an abortifacient (used for the termination of pregnancy)
- Antidepressants of the selective serotonin reuptake inhibitor (SSRI) type
- Antiplatelet agents (used to reduce platelet aggregation and prevent blood clots)

If you are not sure whether Dolodex can be used together with other medicines, ask your doctor or pharmacist.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, or if you think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.
This medicinal product must not be used in the last three months of pregnancy or while breastfeeding.

Dolodex must not be used if you are in the last 3 months of pregnancy as it could harm your unborn baby or cause problems at birth. It can cause kidney and heart problems to your unborn child. It may affect your and your baby's bleeding tendency and cause the birth process to start later or last longer than expected. You should not take/use dexketoprofen during the first 6 months of pregnancy unless absolutely necessary and recommended by your doctor. If you need to be treated during this period or while you are trying to conceive, the lowest dose should be used for the shortest possible period of time. From the 20th week of pregnancy, taking/using dexketoprofen for more than a few days may cause kidney problems in your unborn baby, resulting in low levels of amniotic fluid surrounding your baby (oligohydramnios). If you need to be treated for more than a few days, your doctor may recommend additional monitoring.

Dolodex can make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you are having problems getting pregnant.

Driving and using machines

Dolodex may have a slight influence on the ability to drive and use machines due to the possible side effects: dizziness or drowsiness.
If you notice such side effects, do not drive a vehicle and do not operate any machines until the

symptoms have subsided. Ask your doctor for advice.

Important information about the excipients of Dolodex
Dolodex contains ethanol and sodium.

Ethanol: Each ampoule of Dolodex contains 200 mg ethanol 96%, equivalent to 5 ml beer or 2.08 ml wine.
There is a health risk for patients with liver disorders, alcoholics and epileptics, among others, patients with organic brain disease, pregnant women, breastfeeding mothers and children.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per dose, which means it is practically “sodium-free”.

3. HOW TO USE DOLODEX

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will tell you what dose of Dolodex you need, considering the nature, severity and duration of your symptoms.

The recommended dose is 1 ampoule (50 mg dexketoprofen) every 8 to 12 hours. If necessary, the injection can be repeated after 6 hours. The maximum daily dose of 150 mg dexketoprofen (3 ampoules) must never be exceeded.

The medicine may only be used during the acute pain phase (that is, no longer than two days).
It should be switched to treatment with an oral painkiller as soon as possible.

Elderly patients with impaired kidney function and patients with kidney or liver disorders should not exceed the maximum daily dose of 50 mg dexketoprofen (1 ampoule).

Method of administration

Dolodex can be administered either by intramuscular or intravenous injection.

When Dolodex is used intramuscularly, the solution should be administered by injecting slowly deep into the muscle immediately withdrawal from the ampoule.

Use only if the solution is clear and colorless.

Use in children and adolescents

This medicine should not be used in children and adolescents (under 18 years of age).

If you use more Dolodex than you should

If you use an excessive dose of this medicine, tell your doctor or pharmacist immediately or go to the nearest hospital emergency department. Remember to take the package of this medicine or this package insert with you.

If you forget to use Dolodex

Do not use a double dose (or higher) to make up for a forgotten dose (doses).
Apply the next regular dose at the scheduled time (according to section 3, "How to use Dolodex").

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 in order of frequency of occurrence.

Common side effects: may affect up to 1 in 10 people treated

Nausea and/or vomiting, pain at the injection site, reactions at the injection site, such as inflammation, bruising or bleeding.

Uncommon side effects: may affect up to 1 in 100 people treated

Vomiting blood, low blood pressure, fever, blurred vision, dizziness, drowsiness, insomnia, headache, anemia, abdominal pain, constipation, digestive problems, diarrhea, dry mouth, feeling hot, rash, dermatitis, itching, increased sweating, fatigue, pain, feeling cold.

Rare side effects: may affect up to 1 in 1,000 people treated

Stomach ulcer, intestinal ulcer, bleeding or rupture of a stomach ulcer or intestinal ulcer, high blood pressure, fainting, slowed breathing, inflammation of a superficial vein due to a blood clot (superficial thrombophlebitis), feeling of a missed heartbeat (extrasystole), accelerated heartbeat, water retention in the limbs (peripheral edema), laryngeal edema, altered sensations, fever and chills, ringing in the ears (tinnitus), itchy rash, jaundice, acne, back pain, kidney pain, frequent urination, menstrual disorders, prostate problems, muscle stiffness, joint stiffness, muscle cramps, abnormal values in liver tests (blood tests), increased blood sugar levels (hyperglycemia), reduced blood sugar levels (hypoglycemia), increased blood levels of certain fats (hypertriglyceridemia), pins-and-needles sensations, numbness or other tingling sensations (paresthesia), excretion of so-called “ketone bodies” (ketonuria) or proteins (proteinuria) through urine, liver cell damage (hepatitis), acute kidney failure.

Very rare side effects: may affect up to 1 in 10,000 people treated

Anaphylactic reaction (hypersensitivity reaction that can even lead to collapse), ulceration of the skin, mouth, eyes and genital area (Stevens-Johnson or Lyell syndrome), swelling of the face, lips or the throat (angioedema), shortness of breath due to contractions of the airway muscles (bronchospasm), shortness of breath, pancreatitis, hypersensitivity reactions of the skin and hypersensitivity of the skin to light, kidney damage, reduced number of white blood cells (neutropenia) or blood platelets (thrombocytopenia).

Inform your doctor immediately if you notice any stomach or intestinal side effects at the beginning of treatment (e.g. abdominal pain, heartburn or bleeding) or if you have already suffered from such side effects in the past with long-term use of NSAIDs, especially if you are older.

Stop using Dolodex immediately if you experience rash or mucosal lesions (e.g. of the oral mucosa) or other signs of an allergic reaction.

Water retention and swelling (especially in the ankles and legs), an increase in blood pressure and heart failure have been reported in connection with treatment with NSAIDs.

Medicines such as Dolodex may be associated with a slightly increased risk of heart attacks ("myocardial infarction") or strokes.

In patients with systemic lupus erythematosus or mixed connective tissue diseases (diseases of the immune system that affect the connective tissue), NSAIDs can, in rare cases, cause fever, headaches and neck stiffness.

Inform your doctor immediately if, during the use of Dolodex signs of infection appear or worsen.

If you notice any side effects, contact your doctor, pharmacist or healthcare professional. This also applies to side effects that are not listed in this package leaflet.

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 to the Pharmacovigilance Department of the National Agency of Drugs and Medical Devices at the email address farmakovigjilenca@akbpm.gov.al or via the website www.akbpm.gov.al/formulari-raportimi. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOLODEX

Keep out of the sight and reach of children.
Do not store above 25°C. Store in the original packaging to protect the contents from light. Do not freeze.

Do not use this medicine after the expiry date which is stated on the package.
You must not use this medicinal product if you notice the solution is not clear and colorless, and if it shows signs of deterioration (e.g. suspended particles).
Dolodex is for single use only; any residues must be discarded.
From a microbiological point of view, the ready-to-use preparation should be used immediately unless the opening/dilution procedure eliminates the risk of microbial contamination. If the ready-to-use preparation is not used immediately, the user is responsible for the duration and conditions of storage.

6. FURTHER INFORMATION

What Dolodex 50 mg / 2 ml solution for injection / infusion contains:

The **active substance** is Dexketoprofen.

1 ampoule of 2 ml contains 50 mg dexketoprofen, equivalent to 73.80 dexketoprofen trometamol.

The **excipients** of the solution are ethanol 96%, sodium chloride , sodium hydroxide, water for injection.

Content of the pack

Carton box with 6 amber glass ampoules of 2 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,
St. "Skënder Vila",
Tirana, Albania.
Tel.: +355 4 23 89 602

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The following information is intended for healthcare professionals:

Intravenous use

Intravenous infusion: The contents of one ampoule (2 ml) of Dolodex, are mixed with 30 to 100 ml of an isotonic sodium chloride solution 9 mg/ml (0.9%), glucose solution 50 mg/ml (5 %) or Ringer's lactate solution. The diluted solution is administered as a slow intravenous infusion over a period of 10 to 30 minutes.
The solution must be protected from natural daylight at all times.

Intravenous bolus: If necessary, the contents of one ampoule (2 ml) of Dolodex can be injected as a slow intravenous bolus over at least 15 seconds.

Dolodex must not be administered neuraxially (intrathecally or epidurally) due to the ethanol content.

Instructions for handling the medicinal product
If Dolodex is administered as an intravenous bolus, the solution should be injected immediately after removal from the ampoule.
For use as an intravenous infusion, the solution should be diluted aseptically and protected from natural daylight.
Use only a clear, colorless solution.

Compatibility
When mixed in small volumes (e.g. in a syringe), Dolodex is compatible with injection solutions of heparin, lidocaine, morphine and theophylline.

The solution for injection diluted according to the instructions is a clear solution.

Dolodex diluted with 100 ml sodium chloride solution 9 mg/ml (0.9%) or glucose solution 50 mg/ml (5%), has been proven to be compatible with the following medicinal products: Dopamine, heparin, hydroxyzine, lidocaine, morphine, pethidine and theophylline.

The active substance is not adsorbed when diluted infusion solutions of Dolodex are packaged in plastic bags or application aids made of ethylene vinyl acetate (EVA), cellulose propionate (CP), low-density polyethylene (LDPE) or polyvinyl chloride (PVC).