Package leaflet: Information for the user

Morsadex 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 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 Morsadex is and what it is used for

Morsadex is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
Morsadex is used to treat acute moderate to severe pain, when taking tablets is not appropriate, such as post-operative pain, renal colic (severe kidney pain) and low back pain.

2. What you need to know before you use Morsadex

Do not use Morsadex <u>and tell the doctor:</u>
- if you are allergic to dexketoprofen or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to acetylsalicylic acid or to other NSAIDs;
- 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 aspirin or other NSAIDs;
- if you have suffered from photoallergic or phototoxic reactions (a particular form of reddening and/or blistering of the skin exposed to sunlight) while taking ketoprofen (NSAIDs) or fibrates (medicines used to lower the level of fats in the blood);
- if you have a peptic ulcer/stomach and bowel bleeding or if you have suffered in the past from stomach or bowel bleeding, ulceration or perforation;
- if you have or have suffered in the past from stomach or bowel bleeding or perforation, due to previous use of NSAIDs;
- if you have chronic digestive problems (e.g. indigestion, heartburn);
- 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 severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhoea or insufficient intake of fluids;
- if you are in third trimester of pregnancy or breast feeding.

Warnings and precautions
Talk to your doctor before using Morsadex 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 Morsadex - he 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 Morsadex may be associated with a small increased risk of heart attack (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;
- 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 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);
- have varicella (chickenpox), since exceptionally NSAIDs could worsen the infection;
- suffer from asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis as you have a higher risk of allergy to acetylsalicylic acid and/or NSAIDs than the rest of the population. Administration of this medicine can cause asthma attacks or bronchospasm, particularly in patients allergic to acetylsalicylic acid or NSAIDs.

Children and adolescents
Morsadex 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.

Other medicines and Morsadex
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 Morsadex.

Inadvisable combinations:
- Acetylsalicylic acid (aspirin), corticosteroids or other anti-inflammatory medicines;
- 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 using other medicines with Morsadex, 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 or pharmacist for advice before this medicine is administered to you.

You must not be given this medicine during the final three months of the pregnancy or when breast feeding.

You must not be given Morsadex 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 dexketoprofen 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, dexketoprofen 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.

Dexketoprofen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines
Morsadex 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.

Morsadex contains ethanol and sodium
Each ampoule of Morsadex contains 200 mg of ethanol, 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 (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Morsadex

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

Your doctor will tell you what dose of Morsadex that you need, according to the type, severity and duration of your symptoms. The recommended dose is 1 ampoule (50 mg) of Morsadex 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 Morsadex (3 ampoules) in any case.

Use the injection treatment only in the acute period (i.e. no longer than two days). Switch to an oral pain killer when possible.

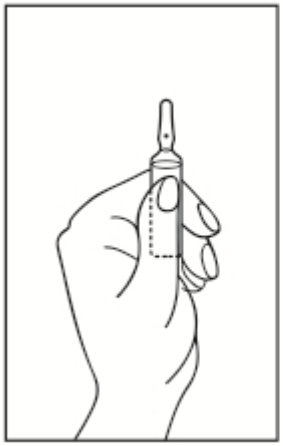
The elderly with renal dysfunction and patients with kidney or liver problems should not exceed a total daily dose of 50 mg of Morsadex (1 ampoule).

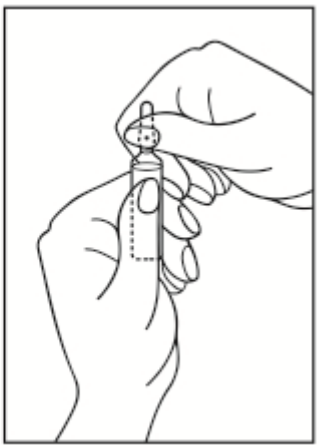
Method of administration
Morsadex can be administered either by intramuscular or by intravenous route (technical details for the intravenous injection are given in the section for health care professionals).

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

Only a clear and colourless solution should be used.

Instruction of ampoule opening:
1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).





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

If you use more Morsadex 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 use Morsadex
Do not use a double dose to make up for a forgotten dose. Use the next regular dose when it is due (according to section 3 “How to use Morsadex”).

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.

Possible side effects are listed below according to how likely they are to occur.

Common side effects: may affect up to 1 in 10 people
Nausea and/or vomiting, injection site pain, injection site reactions, e.g. inflammation, bruising or haemorrhage.

Uncommon side effects: may affect up to 1 in 100 people
Vomiting blood, low blood pressure, fever, blurred vision, dizziness, sleepiness, sleep disturbances, headache, anaemia, abdominal pain, constipation, digestive problems, diarrhoea, dry mouth, flushing, rash, dermatitis, itching, sweating increased, tiredness, pain, feeling cold.

Rare side effects: may affect up to 1 in 1 000 people
Peptic ulcer, peptic ulcer haemorrhage or peptic ulcer perforation, high blood pressure, fainting, too-slow breathing, inflammation of a superficial vein due to a blood clot (superficial thrombophlebitis), isolated heart skip (extrasystole), fast heartbeat, peripheral oedema, laryngeal oedema, abnormal sensation, feeling feverish and shivering, ringing in the ears (tinnitus), itchy rash, jaundice, acne, back pain, renal pain, passing water frequently, menstrual disorders, prostate problems, muscle stiffness, joint stiffness, muscle cramp, abnormal liver tests (blood tests), increased blood sugar level (hyperglycaemia), decreased blood sugar level (hypoglycaemia), increased triglyceride fats concentration in blood (hypertriglyceridaemia), sensation of pins and needles, numbness or other tingling feelings (paraesthesia), ketone bodies in the urine (ketonuria), proteins in the urine (proteinuria), liver cell injury (hepatitis), acute renal failure.

Very rare: may affect up to 1 in 10 000 people
Anaphylactic reaction (hypersensitive reaction which may also lead to a collapse), ulceration of the skin, mouth, eyes and genital areas (Stevens Johnson and Lyell's syndromes), facial swelling or swelling of the lips and throat (angioedema), breathlessness due to contraction of the muscles around the airways (bronchospasm), shortness of breath, pancreatitis, skin sensitivity reactions and skin over-sensitivity to light, renal damage, reduced white blood cell count (neutropenia), reduced platelet count (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 medicines, and especially if you are elderly.

Stop using Morsadex 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 NSAIDs, fluid retention and swelling (especially in the ankles and legs), a raise in blood pressure and heart failure have been reported.

Medicines such as Morsadex may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

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 taking Morsadex.

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, Website: www.hpra.ie

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

5. How to store Morsadex

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light. Do not freeze.

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.

Morsadex is for single use only and any unused solution should be discarded.

Do not use this medicine if you notice that the solution is not clear and colourless, but shows signs of deterioration (e.g. particles).

Chemical and physical in-use stability has been demonstrated in 0.9 % sodium chloride, 5 % glucose and Ringer lactate solution for 18 hours at 25 °C and at 28 °C, provided it is adequately protected from natural daylight.
From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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 Morsadex contains
- The active substance is dexketoprofen trometamol.

1 ml of solution contains dexketoprofen trometamol corresponding to 25 mg of dexketoprofen.
One ampoule (2 ml) contains dexketoprofen trometamol corresponding to 50 mg of dexketoprofen.

- The other excipients are sodium chloride, ethanol 96 %, sodium hydroxide (for pH adjustment), water for injections.

What Morsadex looks like and contents of the pack
Clear colourless solution, free from visible particles.

Morsadex is produced in Type I amber glass ampoules of 2 ml.

Pack size: 1, 5, 6, 10, 25 or 100 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Estonia	Dexketoprofen Kalceks
Latvia	Dexketoprofen Kalceks 50 mg/2 ml šķīdums injekcijām/infūzijām
Lithuania	Dexketoprofen Kalceks 50 mg/2 ml injekcinis ar infuzinis tirpalas
Romania	Xedofen 50 mg/2 ml soluţie injectabilă/perfuzabilă
Bulgaria	Auxilen 50 mg/2 ml инжекционен/инфузионен разтвор
Ireland	Morsadex 50 mg/2 ml solution for injection/infusion
Poland	Auxilen
Austria	Auxilen 50 mg/2 ml Injektions-/Infusionslösung
Germany	Dexketoprofen Ethypharm Kalceks 50 mg Injektions-/Infusionslösung
Spain	Auxilen 50 mg/2 ml, solución inyectable y para perfusion EEG

The following information is intended for healthcare professionals only.

Intravenous use
Intravenous infusion: the content of one ampoule (2 ml) of Morsadex should be diluted in a volume of 30 to 100 ml of 0.9 % sodium chloride, 5 % glucose or Ringer lactate solution. The diluted solution should be administered as a slow intravenous infusion, lasting 10 to 30 min. The solution must always be protected from natural daylight.
Intravenous bolus: if necessary, the content of one ampoule (2 ml) of Morsadex can be administered in a slow intravenous bolus over no less than 15 seconds.

Morsadex is contraindicated for neuraxial (intrathecal or epidural) administration due to its ethanol content.

Instructions on handling the medicine
When Morsadex is administered as intravenous bolus, the solution should be injected immediately after its removal from the ampoule.

For administration as intravenous infusion, the solution should be diluted aseptically and protected from natural daylight.
Should only be administered clear and colourless solution.

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

According to the instructions diluted solution for injection is a clear solution. Morsadex, **diluted in a volume of 100 ml** of 0.9 % sodium chloride or 5 % glucose solution, has shown to be compatible with the following medicinal products: dopamine, heparin, hydroxyzine, lidocaine, morphine, pethidine and theophylline.

No sorption of the active ingredient has been found when diluted solutions of Morsadex 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).