Package leaflet: Information for the user

Dexalfen 25 mg/ml, solution for intravenous and intramuscular injection

Active substance: 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dexalfen is and what it is used for

Dexalfen is an analgesic, anti-inflammatory and antipyretic drug that belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Indications for use
It is used to treat acute pain, moderate to severe, when tablets cannot be used, such as postoperative pain, renal colic (severe pain in the kidney area), and back pain.

If there is no improvement or if you feel worse, ask your doctor.

2. What you need to know before you take Dexalfen

Contraindications
Do not take Dexalfen:

- 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 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 or other non-steroidal anti-inflammatory medicines;
- 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 (a non-steroidal anti-inflammatory drug) or fibrates (drugs used to lower the level of fats in the blood);

- if you have a peptic ulcer/stomach or bowel bleeding or if you have suffered in the past from stomach or bowel bleeding, ulceration or perforation;
- if you 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 severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhoea or insufficient intake of fluids;
- if you are pregnant or breast feeding;

Warnings and precautions
Talk to your doctor or pharmacist before taking Dexalfen.
Tell your doctor if any of the following apply to you:

- if you have bowel disease with chronic inflammation (Crohn's disease or ulcerative colitis);
- 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 ulcers or bleeding, such as oral steroids, some antidepressants (such as selective serotonin reuptake inhibitors), agents that prevent blood clots (aspirin), or anticoagulants (warfarin). In such cases, consult your doctor before taking Dexalfen: 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);
- 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 Dexalfen 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;
- 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 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 are a woman with fertility problems (Dexalfen 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 chickenpox, because in exceptional cases NSAIDs can make the infection worse;
- if you 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
Dexalfen has not been studied in children and adolescent. Therefore, safety and efficacy have not been established and the product should not be used in children and adolescents.

Other medicines and Dexalfen
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 Dexalfen:

Inadvisable combinations:

- Acetylsalicylic acid, corticosteroids or other anti-inflammatory drugs;
- Warfarin, heparin or other medicines used to prevent blood clots;
- Lithium, used to treat certain mood disorders;
- Methotrexate (anti-cancer medicine or immunosuppressant), used at high doses of 15 mg/week;
- Hydantoins and phenytoin, used for epilepsy;
- Sulphametoxazole, used for bacterial infections;

Combinations requiring precautions:

- ACE inhibitors, diuretics and angiotensin II antagonists, used for high blood pressure and heart problems;
- Pentoxifylline and oxpentifylline, used to treat chronic venous ulcers;
- Zidovudine, used to treat viral infections;
- Aminoglycosides antibiotics, used to treat bacterial infections;
- Sulfonylureas (e.g. chlorpropamide and glibenclamide), used for diabetes;
- Methotrexate, used at low doses, less than 15 mg/week;

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;
- Beta-blockers, used for high blood pressure and heart problems

- Tenofovir, deferasirox, pemetrexed

If you have any doubt about taking other medicines with Dexalfen, consult your doctor or pharmacist.

Pregnancy, breast-feeding and fertility

Do not use Dexalfen during pregnancy or when breast feeding.
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as Dexalfen may not be right for you.
The use of Dexalfen is not recommended while attempting to conceive or during investigation of infertility.
With regard to potential effects on female fertility, see also section 2, "Warnings and precautions".

Driving and using machines

Dexalfen 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.

Dexalfen contains ethanol, sodium and sodium metabisulphite

One ampoule of Dexalfen contains 12.35 vol.% ethanol, i.e. 200 mg per dose, which is equivalent to 5 ml of beer or 2.08 ml of wine per dose.
Contraindicated in alcoholism.
Consideration should be given to pregnant and breastfeeding women, children, and high-risk patients such as those with liver disease or epilepsy.

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

This medicine contains sodium metabisulphite, which can cause serious allergic reactions and bronchospasm.

3. How to take Dexalfen

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor should prescribe the medicine in the dose you need, based on the symptoms, their severity and duration. As a rule, the recommended dose is 1 ampoule (50 mg) of Dexalfen with an interval of 8-12 hours. If necessary, the medicine is administered again only after 6 hours. In any case, the total daily dose should not exceed 150 mg (3 ampoules).
Use the injectable form of the medicine only during the period of acute pain (no more than two days). Switch to oral pain relievers as soon as possible.
If you are elderly, or if you suffer from kidney or liver problems, the total daily dose should not exceed 2 tablets (50 mg).

Posology

Dexalfen is administered either intramuscularly or intravenously (for more information on intravenous administration, see section 7).
When administered intramuscularly, the solution is taken from a colored ampoule and immediately slowly injected deep into the muscle.
The solution can only be used if it is clear and colorless.

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

If you use more Dexalfen 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 Dexalfen
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 Dexalfen").

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 including inflammation, bruising or bleeding.

Uncommon side effects: may affect up to 1 in 100 people
Hematemesis, decreased blood pressure, fever, blurred vision, dizziness, drowsiness, sleep disturbances, headaches, anemia, abdominal pain, constipation, indigestion, diarrhea, dry mouth, redness of the face and neck, rash, dermatitis, itching , increased sweating, fatigue, pain, shivering.

Rare side effects: may affect up to 1 in 1,000 people
Peptic ulcer, peptic ulcer perforation or bleeding, increased blood pressure, fainting, decreased breathing, inflammation of the superficial veins due to the formation of blood clots (superficial vein thrombophlebitis), extraordinary contractions of the heart (extrasystole), palpitations, peripheral edema, laryngeal edema, extraneous sensations, feeling hot and trembling, ringing in the ears (tinnitus), itchy rash, jaundice, acne, back pain, kidney pain, frequent urination, menstrual irregularities, prostate problems, muscle stiffness, joint stiffness, muscle cramps abnormal liver function tests (blood tests), high blood sugar (hyperglycemia), low blood sugar (hypoglycemia), high blood triglycerides (hypertriglyceridemia), ketone bodies in urine (ketonuria), proteins in 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 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, 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 Dexalfen as soon as you notice the appearance of a skin rash, or any lesion inside the mouth, 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 Dexalfen may be associated with a small increased risk of heart attack (myocardial infarction) or cerebrovascular accident (stroke).

In patients with systemic lupus erythematosus or mixed connective tissue disease (an immune system disorders that affect connective tissue), anti-inflammatory medicines may rarely cause fever, headache and neck stiffness.

If signs of infection appear or if the condition worsens while using Dexalfen, contact your doctor immediately.

The most commonly-observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, worsening of colitis and Crohn's disease have been reported following administration. Less frequently, inflammation of the stomach lining (gastritis) has been observed.

As with other NSAIDs haematological reactions (purpura, aplastic and haemolytic anaemia, and rarely agranulocytosis and medullar hypoplasia) may appear.

5. How to store Dexalfen

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 and on the blister. The expiry date refers to the last day of that month.
Protect from light below 25 °C.

Do not use this medicine if the solution is cloudy and colorless and shows signs of deterioration (e.g. particles). Dexalfen solution for intravenous and intramuscular **injection** is intended for single use, it should be used immediately after opening the package, and the remainder should be discarded.

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 Dexalfen contains
The active substance is dexketoprofen (as dexketoprofen trometamol).
Each 2 ml ampoule contains 50 mg dexketoprofen.
Other excipients are: ethanol, sodium chloride, sodium metabisulphite (see section 2 Dexalfen contains ethanol, sodium and sodium metabisulphite), sodium hydroxide, water for injection.

What Dexalfen looks like and contents of the pack
Solution for intravenous and intramuscular injection.
2 ml in ampoules of light-protective glass with a colored break ring or with a colored dot and a notch. One, two or three colored rings and/or two-dimensional barcode and/or alphanumeric coding or without additional color rings, two-dimensional barcode, alphanumeric coding are additionally applied to the ampoules.
5 ampoules in a blister pack made of PVC film and polymer film or without film.
1 blister pack with package leaflet in a carton.

In-use shelf life:
Use the prepared solution immediately after preparation.