

Package leaflet: Information for the patient

Dexketoprofen Rowex 25mg 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 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 Dexketoprofen Rowex is and what it is used for
2. What you need to know before you take Dexketoprofen Rowex
3. How to take Dexketoprofen Rowex
4. Possible side effects
5. How to store Dexketoprofen Rowex
6. Contents of the pack and other information

1. What Dexketoprofen Rowex is and what it is used for

Dexketoprofen Rowex 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. What you need to know before you take Dexketoprofen Rowex

Do not take Dexketoprofen Rowex if you

- are allergic to dexketoprofen or any of the other ingredients of this medicine (listed in section 6)
- are allergic to acetylsalicylic acid or to other non-steroidal anti-inflammatory medicines
- 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
- 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 (medicines used to lower the level of fats in the blood)
- have a peptic ulcer/stomach or bowel bleeding or if you have suffered in the past from stomach or bowel bleeding, ulceration or perforation
- have chronic digestive problems (e.g. indigestion, heartburn)
- 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
- have bowel disease with chronic inflammation (Crohn's disease or ulcerative colitis)
- have severe heart failure, moderate or severe kidney problems or severe liver problems
- have a bleeding disorder or a blood clotting disorder
- are severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhoea or insufficient intake of fluids
- are in the third trimester of pregnancy or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dexketoprofen Rowex if you

- 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)
- 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 Dexketoprofen Rowex 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.
- are a woman with fertility problems (Dexketoprofen Rowex may impair your fertility, therefore you should not take it if you are planning to become pregnant or you are doing fertility tests)
- 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 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 other stomach or bowel problems
- have varicella (chickenpox), since exceptionally NSAIDs could worsen the infection
- 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 Dexketoprofen Rowex: 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).
- 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.
- had a major surgery most recently.

NSAIDs such as dexketoprofen may mask the symptoms of infection and fever.

During prolonged use of Dexketoprofen Rowex, your doctor will regularly check your liver enzymes, kidney function and the blood count.

Children and adolescents

Dexketoprofen Rowex has not been studied in children and adolescents. Therefore, safety and efficacy have not been established and the medicine should not be used in children and adolescents below 18 years of age.

Other medicines and Dexketoprofen Rowex

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Dexketoprofen Rowex:

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, used for rheumatoid arthritis and cancer
- Hydantoins and phenytoin, used for epilepsy

- Sulphametoxazole, used for bacterial infections.

Combinations requiring precautions:

- ACE inhibitors, diuretics, beta-blockers 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
- 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 Dexketoprofen Rowex, consult your doctor or pharmacist.

Dexketoprofen Rowex with food and drink

Take the film-coated 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 Dexketoprofen Rowex during the final three months of the pregnancy or when breast-feeding. Ask your doctor for advice.

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 Dexketoprofen Rowex may not be right for you. Use of Dexketoprofen Rowex should be avoided by women who are planning a pregnancy or are pregnant. Treatment at any time in pregnancy should only take place as directed by a doctor.

The use of Dexketoprofen Rowex is not recommended while attempting to conceive or during investigation of infertility.

Driving and using machines

Dexketoprofen Rowex 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.

Dexketoprofen Rowex contains sodium

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

3. How to take Dexketoprofen Rowex

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

The dose of Dexketoprofen Rowex that you need depends on the type, severity and duration of your

pain. Your doctor will tell you how many film-coated tablets you must take daily, and for how long.

The recommended dose 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 Dexketoprofen Rowex has been well tolerated.

The tablet can be divided into equal doses.

If your pain is intense and you need quicker relief, take the film-coated tablets on an empty stomach (at least 30 minutes before food) because they will be more easily absorbed (see section 2 “Dexketoprofen Rowex with food and drink”).

If you take more Dexketoprofen Rowex 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 Dexketoprofen Rowex

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

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, stomach pain, diarrhoea, digestive problems (dyspepsia).

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

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 (malaise).

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

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 (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, 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 Dexketoprofen Rowex 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 Dexketoprofen Rowex may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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. You can also report side effects directly via HPRA the national reporting system: 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 Dexketoprofen Rowex

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the blister packs in the outer carton in order to protect from light.

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 Dexketoprofen Rowex contains

The active substance is dexketoprofen trometamol.

Each tablet contains (36.90 mg) of dexketoprofen trometamol, corresponding to 25 mg of dexketoprofen.

The other ingredients are maize starch, microcrystalline cellulose, sodium starch glycolate, glycerol distearate, hypromellose (E464), titanium dioxide (E171), and macrogol 400.

What Dexketoprofen Rowex looks like and contents of the pack

25 mg tablets:

White, biconvex cylindrical shaped scored tablets debossed with 'DT2' on one side.

The tablets are packed in blister packs (PVC-PVDC/aluminium blister).

Pack sizes:

10, 20, 30, 40, 50, 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Laboratorios CINFA S.A., Ctra. Olaz-Chipi, poligono Areta, 10, 31620 Huarte, Navarra, Spain.

Galenicum Health, S.L., Avda. Cornellá 144, 7º-1ª Edificio LEKLA, Esplugues de Llobregat 08950 Barcelona, Spain.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

SAG Manufacturing, S.L.U., Ctra N-I, km. 36, 28750 San Agustín del Guadalix, Madrid, Spain.

This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal: Dexketoprofen Sandoz 25 mg comprimido revestidos por película

Bulgaria: Dexketonal 25 mg - Film-Coated Tablet

Декскетонал 25 mg филмирани таблетки

Denmark: Dexketoprofen Sandoz 25 mg filmovertrukne tabletter

Ireland: Dexketoprofen Rowex 25 mg film-coated tablets

Romania: Dexketoprofen trometamol Sandoz 25 mg comprimate filmate

Spain: Dexketoprofeno Sandoz 25 mg comprimidos recubiertos con película EFG

This leaflet was last revised in 08/2020.