

Patient package insert according to Pharmacists' Regulations (Preparations), 1986.

This medicine can be sold with a physician's prescription only.

KLARIDEX, Caplets 250 mg

Each caplet contains Clarithromycin at a dosage of 250 mg.

For list of excipients and allergens - see section 6.

Read this entire leaflet carefully before taking this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to your physician or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if you think that their illness is similar.

The medicine is not recommended for use in children under 12 years.

1. What is the medicine intended for?

The medicine is used for treatment of upper and lower respiratory tract infections and infections of the skin and soft tissues.

For the treatment of MAC (Mycobacterium Avium Complex) infections in AIDS patients.

For combined treatment with other medicines for duodenal ulcer in cases of proven infection with Helicobacter pylori.

Therapeutic group: Antibiotic of the macrolide group.

2. Before use of the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see section 6) or to another antibiotic of the macrolide group such as: erythromycin or azithromycin.
- You have developed jaundice or another hepatic problem following use of clarithromycin in the past.
- You are taking additional medicines such as:
 - Astemizole or terfenadine (medicines for allergy), cisapride (a medicine for gastrointestinal disorders), pimozide (an anti-psychotic medicine) - the combination with these medicines may cause heart rate disorders.
 - Eletriptan, ergolamine or dihydroergolamine or ergolamine inhalers (for the treatment of migraine for example).
 - Eplerenone (for the treatment of heart failure).
 - Ivabradine, ranolazine or ticagrelor (for treatment of stable angina pectoris for example).
 - Medicines of the statins group such as: lovastatin, simvastatin, pravastatin, atorvastatin or rosuvastatin (for lowering cholesterol and triglycerides levels in the blood).
 - Colchicine (for treatment of gout).
- You suffer from low potassium levels in the blood (hypokalaemia).
- You suffer from liver and/or kidney problems.
- You or any member of your family suffers or has suffered in the past from heart rate problems (such as ventricular arrhythmias including "torsades de pointes") or an ECG abnormality called "long QT syndrome".

Special warnings about the use of this medicine:

•Before treatment with Klaridex tell your physician if you:

- Have heart problems.
- Have suffered in the past from liver and/or kidney dysfunction.
- Suffer or have the tendency towards fungal infections.
- Are taking theophylline (for asthma), carbamazepine, phenytoin (for epilepsy and convulsions), digoxin (for heart problems). In combined treatment with these medicines their plasma concentration must be monitored.
- Suffer of myasthenia gravis (a disorder that causes muscle weakness).
- Are sensitive to any type of food or medicine.
- If the symptoms do not improve within a few days or if they worsen, consult your physician.
- Prolonged use of this medicine may cause a resistant microbial/fungal infection.
- If you are about to undergo surgery or another procedure under anesthesia, inform your physician beforehand regarding use of this medicine.
- Klaridex may cause an arrhythmia (disturbance called "long QT syndrome"). This disturbance may be severe (and in rare cases even lethal) and manifested as rapid/irregular heart rate and other signs (such as: acute dizziness, fainting, which require immediate medical intervention. The risk of this arrhythmia may increase if you suffer from certain background diseases, low potassium or magnesium levels in the blood, medical conditions such as: acute sweating,

diarrhea, vomiting, taking diuretics or other medicines which may affect the heart rate (see sections "Do not use this medicine if" and "Drug interactions").

- If you develop acute or prolonged diarrhea during or after treatment with Klaridex tell your physician immediately since this may be a symptom of severe intestinal infection.
- If you develop any symptoms that may indicate impaired function of the liver such as loss of appetite, yellowing of the skin or whites of the eyes, dark urine, itch or stomach tenderness, stop taking the medicine and inform your physician immediately.
- Though most antibiotics probably do not affect hormonal contraceptives (such as the pill), certain antibiotics may reduce their contraceptive efficacy. Consult your physician or pharmacist if you should use other contraceptives while using this medicine.

If you are taking or have recently taken other medicines including non-prescription medicines and nutrition supplements, consult your physician or pharmacist, especially if you are taking one of the following:

- Anticoagulants (warfarin or any other blood thinning medicine) - you may need to undergo blood clotting tests.
- Zidovudine, delamanvir, nevirapine, efavirenz, efavirenz, protease inhibitors such as: ritonavir, alazanavir, saquinavir (medicines for the treatment of the AIDS virus).
- Digoxin (see section "Before treatment with Klaridex tell your physician if you"), disopyramide, quinidine, amiodarone, dofetilide, sotalol, procainamide, propafenone (for heart problems) you may have to undergo blood tests and tests for monitoring the function of the heart.
- Thioridazine (anti-psychotic).
- Rifabutin, rifampicin, rifapentine, fluconazole or itraconazole (for the treatment of various infections).
- Aprepitant (for the prevention of vomiting during chemotherapy treatment).
- Theophylline, aminophylline (medicines for lung diseases such as asthma, and breathing difficulties - see section "Before treatment with Klaridex tell your physician if you").
- Carbamazepine, phenobarbital, phenytoin or valproic acid (for epilepsy - see section "Before treatment with Klaridex tell your physician if you").
- Triazolam, alprazolam, midazolam (sedatives and/or hypnotics).
- Colchicine (for the treatment of gout, see section "Do not use the medicine if").
- Cyclosporine, tacrolimus, or sirolimus (immunosuppressants used for example for prevention of transplant rejection).
- Sildenafil, vardenafil and tadalafil (for impotence or pulmonary hypertension).
- Vinorelbine (for the treatment of cancer).
- Corticosteroids such as methylprednisolone.
- Tolterodine (for the treatment of irritable bladder).
- Medicines of the calcium channel blockers group such as: verapamil, amlodipine, diltiazem, nifedipine (such as for the treatment of hypertension).
- Cimetazone (for blood flow problems).
- Omegazole (for heartburns and gastric ulcer, unless prescribed for the treatment of helicobacter pylori).
- Medicines for lowering blood glucose levels such as: repaglinide, rosiglitazone, pioglitazone, nateglinide and insulin.
- Hypericum (St. John's wort - a herbal remedy for the treatment of depression).
- Cimetidine (for gastrointestinal disorders).
- Antibiotics of the aminoglycoside group (such as: gentamicin, streptomycin, tobramycin, amikacin, netilmicin), of the macrolide group (such as: erythromycin); moxifloxacin and gatifloxacin.

- Bromopride.
- Hexobarbital.
- Alfentanil and fentanyl (narcotic pain relievers).
- Live bacterial vaccines.

- Astemizole, terfenadine, cisapride, pimozide, ergolamine or ergolamine inhalers, dihydroergolamine, eletriptan, eplerenone, ivabradine, ranolazine, ticagrelor - see also section "Do not use the medicine if".
- Lovastatin, simvastatin, atorvastatin, rosuvastatin, pravastatin - see also section "Do not use the medicine if". Statins can cause rhabdomyolysis (a condition that causes breakdown of muscle tissue and may cause kidney damage) and signs of myopathy (muscle pain or muscle weakness) that should be monitored.

Use of the medicine and food:

The medicine can be taken with or without food.

Pregnancy and breast feeding: If you are pregnant, are planning on getting pregnant, think you are pregnant or breastfeeding, inform your physician before commencing treatment.

Driving and operating machinery:

Use of this medicine may cause dizziness, vertigo, confusion, disorientation, drowsiness or impaired alertness, and therefore caution should be exercised when driving a car, operating dangerous machinery and in any other activity requiring alertness. As for children - they should be warned against riding a bicycle or playing near roads, etc.

Important information on some of the medicine's ingredients:

Each caplet contains approximately 3 mg of sodium. If you keep on a low sodium diet take this into consideration.

3. How to use this medicine?

Always use according to your physician's instructions. Check with your physician or pharmacist if you are not sure.

Dosage and administration will be determined by the physician only.

Use this medicine at regular intervals as determined by the attending physician.

For the treatment of duodenal ulcer caused by helicobacter pylori, you should take other medicines concomitantly - the physician will recommend.

In elders with severe kidney failure the physician may perform dosage adjustment.

Do not exceed the recommended dose. Do not halve! You may crush. There is no information about chewing. The medicine should be taken with at least half a glass of water.

If you have taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you. Possible side effects of the digestive system may appear such as diarrhea, nausea, vomiting and stomach pain.

If you forget to take this medicine do not take a double dose. Take a dose as soon as you remember, unless the time for the next dose is close. Take the next dose at the usual time and consult your physician. Continue with the treatment as recommended by your physician.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your physician. If you stop taking this medicine before the time the physician instructed, your problem may recur.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a physician or a pharmacist.

Like side effects

Use any medicine, the use of Klaridex may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop use and refer to your physician immediately if you experience:

- Severe and/or prolonged diarrhea accompanied by cramps or stomach pain which may be bloody or with mucus and may appear during or even months after treatment cessation (may be a symptom of severe bacterial infection). Do not take anti diarrhea medicine or narcotic pain relievers as they may worsen the situation.
- An allergic reaction (such as: rash, difficulty breathing, fainting, swelling of the face and throat).
- Symptoms which may indicate liver problem such as: yellowing of the skin and/or eyes, skin irritation, bright stools, dark urine, itch or abdominal tenderness or loss of appetite.
- DRESS Syndrome (a severe illness accompanied by rash, fever and internal organ inflammations).
- A severe skin reaction such as Stevens Johnson syndrome or Toxic Epidermal Necrolysis (a severe illness accompanied by blisters on the skin, mouth, lips, eyes and genitals).
- Purple spots on the skin, joint pain, digestive system problems and kidney problems (which may indicate of a disease called Henoch-Schönlein purpura).
- Muscle pain or weakness, which may indicate on rhabdomyolysis (a condition that causes the breakdown of muscle tissue and may cause kidney damage).

Refer to your physician immediately if you experience:

- Hearing loss (uncommon), changes in mood or mental state.
- Acute dizziness, fainting, rapid/irregular heart rate.
- New signs of infection (such as: fever, prolonged throat pain), muscle weakness, nausea or continuous vomiting, acute abdominal pain, changes in the amount of urine.

Refer to your physician if you notice:

- White spots in the mouth, changes in vaginal discharge or other new symptoms that may indicate mouth or vaginal fungal infection (since prolonged or recurring use of the medicine may increase the risk for such infections) - uncommon.

Additional side effects:

Common side effects (appear in 1-10 users out of 100):

Sleeping difficulties, headaches, diarrhea, nausea, vomiting, abdominal pain, indigestion, changes in liver function, changes in sense of taste, increased sweating, rash, flushing.

Uncommon side effects (appear in 1-10 users out of 1000):

Skin fungal infections, decrease in white blood cells count (may increase the risk of infections), changes in the blood platelets level (may increase the risk of bruising, bleeding or blood clots), loss or decrease in appetite, anorexia, anxiety, nervousness, screaming, fainting, loss of consciousness, drowsiness, tiredness, dizziness or tremor, movement difficulties, involuntary movements of the tongue, face, lips or limbs, vertigo, hearing ringing/buzzing, changes in heart rate, rapid heartbeats (palpitations), cardiac arrest, breathing difficulties (asthma), nose bleed, pulmonary blood clot, stomach bloating, constipation, flatulence, belching, heartburn, rectal pain, inflammation of the stomach wall or esophagus, mouth or throat inflammation, dry mouth, mouth pain, liver inflammation or biliary tract obstruction (yellowing of the skin, dark urine, bright stools, skin irritation is possible), increase in liver enzymes, bloating, itching or skin redness, brown scales, skin inflammation, hives, joint or muscle pain, loss of muscle mass (if you suffer of myasthenia gravis these symptoms may worsen), muscle stiffness or cramps, impaired function of the kidney such as increase of protein discharge by the kidney or increase in kidney enzymes, increase in blood creatinine and urea levels, fever, shivers, weakness, chest pain or general feeling of discomfort, abnormal blood test results.

Side effects with unknown frequency (frequency that has not yet been determined): Colon infection, skin or skin folds infections, low blood sugar levels which may cause fainting, psychotic disorders, mania, confusion, hallucinations, changes in reality perception, loss of orientation ability, panic or depression, nightmares (bad dreams), convulsions, loss or change in the sense of taste and/or smell, paraesthesia, deafness, hemorrhage, pancreatitis, change of the color of the tongue and teeth, liver failure, jaundice, acne, muscle diseases, impaired function of the kidney, kidney inflammation (manifested by: tiredness, swelling of the face, stomach, thighs and ankles, problems passing urine or hypertension), presence of blood in urine or kidney failure, agranulocytosis.

If a side effect appears, if one of the side effects worsens, if you experience side effects not listed in this leaflet, or if there is a change in your general feeling, consult your physician.

5. How to store the medicine?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Do not store different medicines in the same package. Store in the original package.

Store at a temperature below 25°C.

6. Additional Information

In addition to the active ingredient, this medicine also contains:

Cellulose microcrystalline, starch pregelatinised, croscarmellose sodium, povidone, talc, hypromellose, stearic acid, propylene glycol, magnesium stearate, silica colloidal anhydrous, titanium dioxide, yellow lake E-104, hydroxypropylcellulose, sorbic acid, vanillin, sorbitan stearate, carnauba wax.

Each caplet contains approximately 3 mg sodium.

What does the medicine look like and what does the package contain:

Klaridex caplets: yellow, coated caplets with a score line on one side.

Each pack contains 7, 10, 14, 20, 28, 30, 100 caplets. Not all pack sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health: 113-95-29599-00

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Manufacturer and registration holder: **Dexel® Ltd**

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