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

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

ZARIDEX®

Zaridex 150, Tablets
Each tablet contains 150 mg of Ranitidine (as hydrochloride).

Zaridex 300, Caplets
Each caplet contains 300 mg of Ranitidine (as hydrochloride).

For full list of excipients – please see section 6 "Additional information". See also 'Important information about some of the ingredients of the medicine'.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine used for?

Adults:
ZARIDEX is indicated for the treatment of duodenal ulcer and benign gastric ulcer, including that associated with non-steroidal anti-inflammatory agents. Zaridex is also indicated for the treatment of post-operative ulcer, Zollinger-Ellison Syndrome and oesophageal reflux disease including long term management of healed oesophagitis.
ZARIDEX is indicated for the following conditions where reduction of gastric secretion is desirable; the prophylaxis of gastro-intestinal haemorrhage from stress ulceration in seriously ill patients and before general anaesthesia in patients considered to be at risk of acid aspiration (Mendelson's Syndrome), particularly obstetric patients during labour.
Children (6 to 18 years):
Short term treatment of peptic ulcer. Treatment of gastro-oesophageal reflux, including reflux oesophagitis and symptomatic relief of gastro-oesophageal reflux disease.

Therapeutic group: Belongs to the group of medicines called H_2-receptor antagonists.

2. Before using this medicine

Do not use the medicine if:

You are hypersensitive (allergic) to the active ingredients (ranitidine) or to any of the other additional ingredients that the medicine contains (see section 6).

Special warnings regarding the use of this medicine:

■ **Before the treatment with Zaridex, tell the physician if:**
- You suffer or have suffered in the past from impaired function of the liver, kidney.
- You suffer or have suffered in the past from a gastric ulcer and you are taking non-steroidal anti-inflammatory drugs (NASAIDs).
- You are suffering from acute porphyria, stomach cancer, lung disease, diabetes.
- You suffer from any immune system problems.
- You are above 65 years old.

If you are taking or if you have recently taken any other medicines, including non-prescription drugs and nutritional supplements, please tell your doctor or pharmacist. This is because Zaridex can affect the way some other medicines work. Also some other medicines can affect the way Zaridex works.
Especially, if you are taking:
- Medicines affecting the central nervous system e.g.: diazepam (a sedative), triazolam (for insomnia), phenytoin (for epilepsy).
- Anticoagulants e.g.: warfarin.
- Theophylline (for asthma).
- Lidocaine (a local anesthetic).
- Propranolol, procainamide or N-acetylprocaineamide (for heart problems).
- Non-steroidal anti-inflammatory drugs (NSAIDs), for pain relief and inflammation.
- Glipizide (for diabetes).
- Atazanavir or delavirdine (for treatment of the HIV virus).
- Gefitinib (for cancer treatment).
- Ketoconazole (antifungal).
- Sucralfate (for treating stomach ulcers).

Midazolam is a medicine that may be given to you just before you have an operation. Tell your doctor you are taking Zaridex before your operation in case he or she wants to give you midazolam.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Zaridex.

Taking this medicine with food
You may take this medicine with or without food.

Pregnancy and breastfeeding
If you are pregnant, might be pregnant, planning a pregnancy or if you are breastfeeding, consult the physician before commencing treatment.

Smoking
If you are a smoker – inform the physician before commencing treatment with this medicine.

Important information about some of the ingredients of this medicine
- This medicine contains lactose. If you have been told by a physician in the past that you have intolerance to certain sugars, consult the physician before starting treatment with this medicine.
- This medicine contains the material sunset yellow, which can cause to allergic reactions.
- Zaridex 150 tablet contains about 1.1 mg sodium and each Zaridex 300 caplet contains about 2.2 mg sodium. This must be taken into account if you are on a low-sodium diet.

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 treatment will be determined by the physician only.
The usual recommended dosage for adults (including the elderly) is: one 150 mg tablet, twice a day, in the morning and in the evening, or alternatively, one 300 mg caplet or two 150 mg tablets before bedtime.

Your exact dose will depend on your particular stomach condition, your doctor will tell you what dose you should take.

Use in children 12 years and over: The adult dose is given.
Use in children from 6 to 11 years and over 30kg of weight: your doctor will work out the right dose for you based on your child's weight.
The medicine is not intended for children who cannot swallow tablets/caplets in their entirety, i.e., under 6 years of age.
In patients with kidney problems, dosage adjustment may be required, according to the physician's instructions.

Do not exceed the recommended dose.

Do not chew/halve/crush since the medicine has a protective coating. Swallow the medicine whole with a small amount of water.

Attention! Allow a lapse of at least 2 hours between taking this medicine and taking sucralfate.

If you accidently took an overdose, or if a **child accidently swallowed** this medicine, proceed immediately to a physician or hospital emergency room and bring the medicine package with you.

If you forget to take this medicine, do not take a double dose. Take the dose as soon as you remember, unless it is almost time for the next dose; Take the next dose at the specified time and consult a physician.

Persist the treatment as recommended by the physician. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the physician.

If you stop using this medicine, the pain and discomfort may return.

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

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

4. Side effects

Like all medicines, the use of **Zaridex** can 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 of this medicine and refer to the physician immediately with the appearance of:
- An allergic reaction which may manifest by the following symptoms:
  - Wheezing while breathing or breathing difficulties, shortness of breath, chest pains or tightness.
  - Swelling of the eyelids, face, lips, mouth, tongue or other parts of the body.
  - Rash, tingling, itching or hives on the skin.
  - Unexplained fever, feeling faint, especially when shifting from lying down or sitting position to standing.
- Kidney problems, that may manifest by back pain, fever, pain when passing urine, blood in the urine and changes in blood tests.
- Severe stomach pain (may be a sign of pancreatitis).
- Slow, fast or irregular heartbeat.

Refer to the physician as soon as possible with the appearance of:
very rare side effects (effects that appear in less than one user out of 10,000):
- Changes in the levels of certain substances in the blood, may be manifested by: unusual tiredness, shortness of breath, tendency towards bruising or infection.
- Depression, confusion, hallucinations (visual or auditory).
- Headache (sometimes severe), dizziness or blurred vision.
- Pain or swelling of the muscles or joints or inability to control their movement.
- Swelling of blood vessels, (vasculitis, blood vessel inflammation) which may be manifested by: rash, swollen joints, kidney problems.
- Flushing or marks on your skin, unexplained hair loss, diarrhea, impotence, breast tenderness and/or breast enlargement, breast discharge.
- Enlarged liver that may be manifested by: nausea, vomiting, loss of appetite, feeling unwell, fever, itching, yellowing of the skin and eyes, dark urine.
- Awareness of the heart beat and/or increased heart rate.

Additional Side Effects:
Uncommon side effects (effects that appear in 1-10 users out of 1000):
stomach pain, constipation, nausea, vomiting.

Rare side effects (effects that appear in 1-10 users out of 10,000):
rash.

Rare side effects that may appear in blood tests:
kidney function test – increase of serum creatinine in the blood, changes in liver functions.

Side effects with unknown frequency (frequency which cannot be estimated):
shortness of breath.

If a side affect appears, if one of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet, consult the physician.

Side effects can be reported to the Ministry of Health using the online form for reporting side effects found on the home page of the Ministry of Health's website (www.health.gov.il) or via the following link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

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 a physician!
Do not use this 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 above a temperature of 25°C.
Do not store different medicines in the same container.
Store in the original package.

6. Additional information

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

Microcrystalline cellulose, Croscarmellose sodium, Lactose monohydrate, Magnesium stearate, Hypromellose, Basic butylated methacrylate copolymer, Quinoline yellow Al Lake (E104), Triacetin, Titanium dioxide (E171), Iron oxide yellow (E172), Sunset yellow FCF Al lake (E110), Carnauba wax.

What the medicine looks like and contents of the pack:
Zaridex 150 mg tablets: yellow, round, coated tablets.
Zaridex 300 mg caplets: yellow, coated caplets with a score line on one side.

Authorized pack sizes: 10, 20, 30, 100. Not all package sizes may be marketed.

This leaflet was checked and approved by the Ministry of health on: 04.2017.

Drug registration number at the national medicines registry of the Ministry of Health:

Zaridex 150 mg tablets - 109282927200
Zaridex 300 mg caplets -109452927300

Zaridex PIL PB0617-04

Manufacturer and registration holder: Dexcel® Ltd.
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