Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) – 1986
The medicine is dispensed according to a physician's prescription only

Zantac Syrup

Each 10 ml of syrup contains 150 mg Ranitidine (as Hydrochloride)

For the list of inactive and allergenic ingredients, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you or for your child. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Adults:

Zantac Syrup is indicated for the treatment of duodenal ulcer and benign gastric ulcer, including ulcer that is caused by treatment with non-steroidal anti-inflammatory agents. Zantac Syrup is also indicated for the treatment of post-operative ulcer, Zollinger-Ellison Syndrome and oesophageal reflux disease including long-term management of healed oesophagitis.

Zantac Syrup is indicated for 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 in obstetric patients during labour.

Children (3 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

Zantac Syrup contains a medicine called ranitidine. This belongs to a group of medicines called H_2-receptor antagonists.

2. Before using the medicine

Do not use the medicine if:
- you or your child is sensitive (allergic) to ranitidine or to any of the other ingredients contained in the medicine as listed in section 6.

If you are not sure, talk to your or your child's physician or pharmacist before taking Zantac Syrup.

Special warnings regarding the use of the medicine

Before the treatment with Zantac Syrup, tell the physician if:
- you or your child has stomach cancer
- you or your child has kidney problems. You or your child will need to take a different amount of Zantac Syrup
- you or your child has had stomach ulcers before and you or your child is taking non-steroidal anti-inflammatory (NSAID) medicines
- you or your child has a rare disorder called acute porphyria
- you are over the age of 65 years
- you or your child has lung disease
- you or your child is diabetic
- you or your child has any problems with the immune system.

If you are not sure if any of the above apply to you or your child, talk to your or your child's physician or pharmacist before using this medicine.

Drug interactions

If you or your child is taking, or if you or your child has recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. This is because Zantac Syrup can affect the way some medicines work. Also, some medicines can affect the way Zantac Syrup works. Especially inform the physician or the pharmacist if you or your child is taking:
- Non-Steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation
- lidocaine, for local anaesthesia
- propranolol, procainamide or n-acetylprocainamide, for treating heart problems
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy
- theophylline, for breathing problems (asthma)
- warfarin, for thinning the blood
- glipizide, for lowering blood glucose
- atazanavir or delavirdine, to treat infection caused by the human immunodeficiency virus (HIV)
- triazolam, for insomnia
- gefitinib, for lung cancer
- ketoconazole, an antifungal medicine, sometimes used for treating thrush
- sucralfate for treating stomach ulcers.

Midazolam is a medicine that may be given to you or your child just before you or your child has an operation. Tell the physician that you or your child is taking Zantac Syrup before your or his operation, in case he wants to give you or him midazolam.

If you are not sure if any of these apply to you or your child, refer to your or your child's physician or pharmacist before taking Zantac Syrup.

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 physician or pharmacist for advice before taking this medicine. Do not take the medicine unless your physician advises it is essential.

Important information about some of the ingredients of the medicine
Zantac Syrup contains sodium, potassium, ethanol (alcohol), propyl parahydroxybenzoate, butyl parahydroxybenzoate and sorbitol.

Zantac Syrup contains less than 1 mmol sodium (23 mg) per 10 ml; therefore, the medicine is considered sodium-free.

Zantac Syrup contains less than 1 mmol potassium (39 mg) per 10 ml; therefore, the medicine is considered potassium-free.

Zantac Syrup contains 700 mg sorbitol in each 10 ml, which is equivalent to 70 mg/ml. Sorbitol is a source of fructose. Do not take this medicine if the physician told you that you or your child has an intolerance to certain sugars or if you or your child was diagnosed with hereditary fructose intolerance (HFI), a rare hereditary disorder that causes the body to be unable to break down fructose. Talk to your or your child's physician before you or your child takes the medicine.

Zantac Syrup contains ethanol 96% (alcohol).
- The amount of ethanol per bottle (300 ml): 24 grams
- The amount of ethanol in 10 ml: 800 mg
- The concentration of ethanol in the product: approximately 7.5% w/v
i.e., Zantac Syrup contains up to 405 mg ethanol per 5 ml spoonful, which is equivalent to about 11 ml of beer or 5 ml of wine.

Zantac Syrup is harmful to those suffering from alcoholism. The ethanol content should also be taken into account if Zantac Syrup is to be given to pregnant or breast-feeding women, children and patients in high-risk groups such as those suffering from:
• alcoholism
• liver disease
• epilepsy
• brain injury or disease.

Zantac Syrup may modify or increase the effect of other medicines.

Refer to your or your child's physician or pharmacist if you are concerned. He may be able to suggest an alternative formulation.

This medicine also contains propyl parahydroxybenzoate and butyl parahydroxybenzoate, that may cause allergic reactions (which may be delayed).

3. How should you use the medicine?

Always use the product according to the physician’s instructions.

You should check with the physician or the pharmacist if you are unsure about the product dosage and treatment regimen.

- Take or give this medicine by mouth.
- Use the spoon provided to carefully measure the dose needed.
- Do not mix Zantac Syrup with anything (not even water) before swallowing it.

The dosage and treatment regimen will be determined only by the physician.

Your or your child's exact dose will depend on your or your child's particular stomach condition; your or your child's physician will tell you the dose you should take or give him.

Use in children aged 12 years and over:
The adult dose is given.

Use in children from 3 to 11 years:
The physician will work out the right dose in milliliters based on your child’s weight. Make sure you follow his instructions.

Do not exceed the recommended dose.

Opening and closing instructions for the child-resistant pack:

Instructions for opening the bottle package: To remove the cap, press down, while simultaneously twisting to the left (turning counterclockwise).

Instructions for closing the bottle package: Place cap on top of open end and twist to the right (turning clockwise) until it locks.

If you have accidentally taken or given to your child a higher dosage
Zantac Syrup is not normally harmful if you or your child takes more than you or he needs, unless you or he takes a large amount of Zantac Syrup at once. If you took or gave your child an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take or give your child the medicine
- If you forgot to take or give a dose, take or give it as soon as you remember it, unless it is nearly time for your or your child's next dose.
- Do not take or give a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the physician.

Even if there is an improvement in your or your child's health, do not stop the treatment with the medicine without consulting the physician.

If you stop taking or giving the medicine
After a few days of taking Zantac Syrup, you or your child should start to feel much better. Do not stop taking or giving Zantac Syrup without talking to your or your child's physician or pharmacist first, otherwise your or your child's original pain and discomfort may come back.

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

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

4. Side effects

As with any medicine, use of Zantac Syrup may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You or your child may not suffer from any of them.

The following side effects may happen when taking this medicine:

Stop treatment and refer immediately to the physician if you notice any of the following serious side effects, you or your child may need urgent medical treatment:

- allergic reactions, the signs may include:
  - rash, itching or hives on the skin
  - swelling of the face, lips, tongue or other parts of the body
  - chest pain, shortness of breath, wheezing or breathing difficulties
  - unexplained fever and feeling faint, especially when standing up.
- kidney problems, which can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood tests
- severe stomach pain; this may be a sign of a problem called "pancreatitis"
- a slow or irregular heartbeat.

Additional side effects

Check with your or your child's physician **at your next visit** if you notice any of the following side effects:

Uncommon (may affect up to 1 in 100 people)
- stomach pain
- constipation
- nausea.

Rare (may affect up to 1 in 1,000 people)
- skin rash.

Rare side effects that may show up in blood tests:
• increase of serum creatinine in the blood (kidney function test)
• changes to liver function.

Refer to the physician **as soon as possible** if you notice any of the following:
Very rare (may affect up to 1 in 10,000 people)
• there can be changes in the level of certain substances in your or your child's blood. This can lead you or your child feeling unusually tired or short of breath and increase the likelihood of bruising or getting an infection
• feeling depressed, confused, seeing or hearing unexplained things (hallucinations)
• headache (sometimes severe)
• feeling dizzy or having blurred vision
• your or your child's joints or muscles are painful or swollen or you or your child cannot control their movement
• your or your child's small blood vessels can become swollen (known as "vasculitis"). Signs of this can include: a rash, swollen joints or kidney problems
• your or your child's liver can become swollen. This can lead to nausea or vomiting, loss of appetite or generally unwell feeling, itching, fever, yellowing of the skin and eyes or dark-coloured urine
• flushing or marks on your skin
• unexplained hair loss
• diarrhoea
• impotence
• breast tenderness and/or breast enlargement
• breast discharge
• awareness of the heartbeat and/or increased heart rate.

Not known (frequency cannot be estimated from the available data)
• shortness of breath.

If a side effect has appeared, if any of the side effects get worse or when you or your child suffers from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the 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 any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

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

Store below 25°C.

After first opening can be used within 28 days.

6. Additional information

- In addition to the active ingredient the medicine also contains -
  sorbitol solution, ethanol, mint flavour, hydroxypropyl methylcellulose, disodium hydrogen orthophosphate anhydrous, sodium chloride, potassium dihydrogen orthophosphate, saccharin sodium, propyl parahydroxybenzoate, butyl parahydroxybenzoate, purified water.
- **Each 10 ml dose contains approximately 7.5% w/v ethanol (alcohol), i.e., up to 800 mg per 10 ml.**
- What does the medicine look like and what is the content of the package –

  The bottle pack is child-resistant.
  Zantac Syrup is a clear, pale yellow liquid that smells of mint.
  300 ml amber glass bottle.
  The package contains a measuring spoon.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva
- Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany
- The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in November 2016, and was updated in accordance with the Ministry of Health guidelines in March 2019
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 061-99-27406