

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed without a doctor's prescription

Babyzim Drops

Composition:

Every 5 ml contain:

pepsin 1:10,000	30 mg
sodium glycerophosphate	40 mg
nicotinic acid	10 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information.

When treating constipation: Consult your doctor if symptoms of illness get worse or do not improve within 7 days.

1. What is this medicine intended for?

This medicine is intended to treat constipation and flatulence.

Therapeutic group: digestive enzymes.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Before using Babyzim Drops, tell your doctor if:

- you have or have ever had impaired function of the heart and/or blood vessels, kidneys/urinary tract.
- Do not use this medicine often or for a long time without consulting a doctor.

Interactions with other medicines:

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food

Take this medicine with a meal.

Important information about some of this medicine's ingredients

This medicine contains about 0.3 grams alcohol (ethanol) per 5 ml, which are equivalent to a concentration of 6% w/v.

The amount of alcohol in 5 ml of this medicine is equivalent to 7.5 ml of beer or 3 ml of wine. This small amount of alcohol in the medicine will not have a noticeable effect.

This medicine contains less than 1 millimole (23 mg) of sodium per dose, so it is considered 'sodium free'.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

In the absence of other instructions from your doctor, the recommended dose is:

Babies up to one year old: 5 drops before eating and 5 drops after eating, at each feeding (up to 50 drops per day).

Babies of 1 to 2 years old: 20 to 40 drops after each meal.

Children of 2 to 5 years old: 40 to 60 drops after each meal.

Children of 5 to 14 years old: 1/2 to 1 teaspoon (5 ml teaspoon) after each meal.

Measure the drops into a teaspoon and not directly into the baby's mouth.

Do not exceed the recommended dose.

Treatment duration

When treating constipation, if there is no improvement within one week, consult your doctor.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Babyzim Drops may cause side effects in some users.

Side effects and interactions with other medicines in children and babies:

Parents should report any side effect to their doctor as well as all other medicines given to their child!

If a side effect appears or if any side effect gets worse, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.
- Use within 12 months of opening.

6. Additional information

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

Glycerin, alcohol 95%, glycine, calcium chloride dihydrate, sodium Nipagin, lactic acid 90%, Tutti Frutti, hydrochloric acid conc. 33%, purified water.

What the medicine looks like and contents of the pack:

Colorless to yellowish solution. Each carton contains a bottle with 40 ml of solution.

Registration holder and manufacturer: Sam-On Ltd., 25 Ehad Kinnamon (HaAvoda) street, Bat-Yam.

Revised in June 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 25-17-21245