

PACKAGE LEAFLET

BERKO-FIZ %0.9 nasal drops, solution

For nasal use.

- *Active substance(s):* Each 1 ml solution contains 9 mg sodium chloride.
- *Excipient(s):* Distilled water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

This medication is intended to treat a mild illness with the advice of your pharmacist without obtaining a prescription and without the help of a doctor. However, you still have to use BERKO-FIZ carefully so that you can get the best results.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

- 1. What *BERKO-FIZ* is and what it is used for**
- 2. What you need to know before you use *BERKO-FIZ***
- 3. How to use *BERKO-FIZ***
- 4. Possible side effects**
- 5. How to store *BERKO-FIZ***

1. What *BERKO-FIZ* is and what it is used for?

- *BERKO-FIZ* is a solution containing 9 mg sodium chloride in 1 milliliter and is marketed in low density polyethylene (LDPE) bottles with dropper containing 20 ml of solution.
- *BERKO-FIZ* is used for moisturizing of dry and uncomfortable intranasal mucosa due to various reasons, if any normalizing of the mucous membrane swelling, breathing comfortable and easy.

2. What you need to know before you use *BERKO-FIZ*

Do not use *BERKO-FIZ* in the following conditions

Do not use if you are allergic to any of the ingredients of *BERKO-FIZ*.

Warnings and precautions

Use nasally.

Do not contact the vial tip with the nasal mucosa during use.

It is sterile until it opens.

If allergic reactions occur, stop using the medication and consult a doctor.

The same vial should not be used by different people.

If these warnings apply to you, even if at any time in the past, please consult your doctor

BERKO-FIZ with food and drink

BERKO-FIZ has no known interaction with food and drink.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

There is not adequate data on the use of BERKO-FIZ in pregnant women.

It should not be used during pregnancy unless it is necessary. The benefit to the mother and the potential risks for the baby should be considered in case of use during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

There is insufficient / limited data whether sodium chloride passes into human or animal milk. A risk for the breastfeeding child is non-ignorable because of the physicochemical and available pharmacodynamic / toxicological data on passing of sodium chloride into milk. It should not be used during breastfeeding. The benefit to the mother and the potential risks for the baby should be considered in case of use during breastfeeding.

Driving and using machines

BERKO-FIZ does not have a negative effect on the ability to drive and use machines.

Important information about some of the ingredients of BERKO-FIZ

It does not contain any substance with any distinguishing characteristics requiring special warning.

Using with other medicines

It can collapse into silver chloride with colloidal silver and silver nitrate solutions.

There is no known interaction with other medicinal products.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use BERKO-FIZ?

- **Instructions for use and dosage/frequency of administration:**

In infants and children: 1-2 drops per nostril 1-2 times a day.

In adults: 1-2 drops per nostril 3-4 times a day.

- **Route of administration and method:**

BERKO-FIZ is only for nasal use.

- **Different age groups:**

- **Use in children:**

- 1-2 drops per nostril 1-2 times a day.

Use in elderly:

No specific conditions regarding use of BERKO-FIZ in patients aged 65 years and over.

• Special cases of use:**Renal/hepatic failure:**

There are no specific conditions for use in patients with renal/hepatic failure.

If you have impression that the effect of BERKO-FIZ is very strong or weak, tell a doctor or pharmacist.

If you use more BERKO-FIZ than you should:

If you take more BERKO-FIZ than you should, tell your doctor or pharmacist.

Since BERKO-FIZ is only for nasal use, overdose is not possible.

If you forget to use BERKO-FIZ:

Do not take a double dose to make up for a forgotten dose.

Use the medicine as soon as you remember the missed dose.

If you stop using BERKO-FIZ:

None.

4. Possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the followings stop taking BERKO-FIZ and immediately inform your doctor or go to the nearest emergency department:

- Allergic reactions (redness, itching/swelling (especially in the face and throat), dizziness, difficulty in breathing)

These are all very serious side effects.

If you have any of them, this means you have serious allergy to BERKO-FIZ. You may need emergency medical care or hospitalization.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

Rare:

- Local irritation, dryness and stinging in the nasal mucosa

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store BERKO-FİZ?

*Keep in the original package and out of the reach and sight of children.
Store in room temperature under 25°C.*

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the label or packaging.

Do not use this medicine if you notice any damage to the product and/or package.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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