

PATIENT INFORMATION LEAFLET

BERKO-FIZ 0.9% single-use vials containing nasal 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. 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/ml sodium chloride and marketed in low-density polyethylene vials.

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 – Before you use *BERKO-FIZ*

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

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

TAKE SPECIAL CARE WITH *BERKO-FIZ* in the following conditions

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.

“Please consult your doctor, even if these statements were applicable to you at any time in the past.”

Using BERKO-FIZ with food and drink:

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

Pregnancy:

Ask your doctor or pharmacist for advice before taking the 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

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding

Ask your doctor or pharmacist for advice before taking the 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.

Effects on ability to drive and use machines

No negative effect on ability to drive and use machines has been reported.

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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3 - How to use BERKO-FIZ?**Instructions for appropriate method and dose/frequency of administration:**

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

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

Route and method of administration:

BERKO-FIZ is only for nasal use.

Different age groups:**Use in children:**

Use in children is 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 populations**Kidney/Liver failure:**

There are no specific conditions for use in patients with kidney/liver insufficiency.

If you have the impression that the effect of BERKO-FIZ is too strong or too weak, talk to your doctor or pharmacist.

If you have used more BERKO-FIZ than you should:

If you may have taken more BERKO-FIZ than you should, talk to a doctor or pharmacist.

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

If you forget to use BERKO-FIZ:

Use the missed dose as soon as you remember.

If you stop using BERKO-FIZ:

None.

4 - Possible side effects?

Like all medicines, side effects can occur in people sensitive to the contents of BERKO-FIZ.

If any of the following occur stop using 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.

The side effects are listed as follows according to their frequency:

Very common: may be seen at least 1 in 10 patients

Common: may be seen less than one in 10 patients but more than one in 100 patients

Uncommon: may be seen less than one in 100 patients but more than one in 1000 patients

Rare: may be seen less than one in 1000 patients but more than one in 10.000 patients

Very rare: may be seen less than one in 10000 patients

Unknown: it cannot be estimated from the available data

Rare:

- Local irritation, dryness and stinging in the nasal mucosa

If you notice any side effects not mentioned in this leaflet 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-FIZ

*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 BERKO-FIZ after the expiry date which is stated on the label or package.

Do not use BERKO-FIZ if you notice any damage to the product and/or package.

Marketing Authorization holder:

Berko İlaç ve Kimya San.A.Ş.
Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul
0216 456 65 70 (Pbx)
0216 456 65 79 (Fax)
info@berko.com.tr

Manufacturer:

Mefar İlaç San. A.Ş.
Ramazanoğlu Mahallesi Ensar Caddesi No: 20 Kurtköy Pendik/İstanbul
0216 378 44 00
0216 378 44 11

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