

## REF 006 Bacterial Vaginosis treatment gel INFORMATION LEAFLET

Please read this leaflet carefully before you start using this product because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Contact your doctor if your symptoms worsen or do not improve.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Ask your doctor or pharmacist if you need more information or advice.

### What is Bacterial Vaginosis (BV)?

Bacterial vaginosis (BV) is a common cause of unusual vaginal discharge. BV isn't a sexually transmitted infection (STI),

The most common symptom of bacterial vaginosis is unusual vaginal discharge that has a strong fishy smell, particularly after sex. You may notice a change to the colour and consistency of your discharge, such as becoming greyish-white and thin and watery.

### Recurrent bacterial vaginosis

It's common for BV to recure, usually within 3-12 months. To help relieve symptoms and prevent bacterial vaginosis returning:

- use water and plain soap to wash your genital area
- have showers instead of baths
- do not use perfumed soaps in bath.
- do not use vaginal deodorants, washes or douches.

### What is <Bacterial Vaginosis treatment gel>?

The <Bacterial Vaginosis treatment gel> is a medical device for the treatment of Bacterial Vaginosis (BV).

- Strengthens and supports a healthy vaginal flora.\*
- Lowers and stabilizes the pH value in the vagina.\*
- Reduces unpleasant odor and abnormal discharge.
- Soothes itching and burning sensations.

Contains moisturizing ingredients

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\* measured in a laboratory setting.

The <Bacterial Vaginosis treatment gel> contains six pipette applicators with a clear jelly solution. The tip of the pipette assures clean, quick and easy application. The gel contains lactic acid which restores the normal pH of the vagina and is free of hormones and preservatives.

### How to use

The <Bacterial Vaginosis treatment gel> is indicated for adults (women in reproductive age).

Preferably use the <Bacterial Vaginosis treatment gel> before bedtime. A part of the content of the tube might leak out. The tube contains more gel then strictly necessary, this won't affect the treatment. If a part of the tube leaks out we advise to use a panty liner.

1. Wash your hands.
2. Shake and squeeze the contents of the applicator towards the tip.
3. Remove the cap by breaking the tip using a light forced twist (figure 1)



Figure 1

4. Then put the tube into the vagina. Best when lying or standing with one leg up (figure 2) and squeezing out the complete contents of the tube.



Figure 2

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5. Then remove the tube and dispose the tube
6. Wash your hands.

### How long can <REF 006 tradename> be used?

*Treatment of acute symptoms of Bacterial Vaginosis:*

Use <REF 006 tradename> for 6 days, 1 tube per day.

If, after 6 days of treatment, not any result is observed, consult a doctor to discuss alternative or additional treatment.

The solution acts only locally and can therefore be used during pregnancy and lactation. Contact your physician when suffering from Bacterial Vaginosis during pregnancy.

Missed a dose?

Don't take a double dose, just skip one day and continue treatment as normal.

### When should you not use this product?

If you are allergic to any of the ingredients.

### Possible Side Effects

In some patients, a mild and temporarily burning sensation may occur.

### Shelf Life and Storage

- Do not use after the expiry date shown on the tube seal.
- Do not use when tube is damaged.
- Store at room temperature, 25°C. Don't keep in fridge or freezer.

### Disposal

- Do not throw away the <REF 006 tradename> via wastewater or household waste. Ask your pharmacist how to throw away the product you no longer use. These measures will help protect the environment.
- Do not use the product if the product is not stored as specified above. If the product has been stored temporarily above 25°C (no longer than 1 month up to 40°C) then the product can be safely used.



### Warnings and Precautions

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- In case of allergic reactions consult a doctor.
- Keep out of the reach and sight of children.
- Keep away from the eyes and mucous membranes.
- Only for vaginal application.
- Single-use only .
- During fertility treatment this product may negatively influence fertilization.
- Not be used as contraceptive.
- The product is compatible with natural rubber latex condoms.

If you experience a serious incident , which leads to for example hospitalization, linked to the <REF 006 tradename> please notify the manufacturer and the local authorities.

**Content:** 6 (single-use) applicators of 5 ml per applicator

**Ingredients:** Glycerin, Lactic acid 1,64%, Propylene glycol, Sodium lactate, Hydroxyethyl cellulose, Sodium hydroxide and Water.



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006



Include full address of entity responsible for translation



(CE and number at least 5 mm)



Include full address of the distributor



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Workplace Health Promotion

## Explanation of the symbols in the instructions for use, carton box and label.

	Use-by date		Medical device
	Batch code		Caution
	Consult instruction for use		Single-use only
	Unique device identifier		Country of manufacture
	Manufacturer		Catalogue number
	Distributor		Translation
	Do not use if package is damaged.		

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