

PACKAGE LEAFLET: INFORMATION FOR THE USER

Polyfax Ointment, 10,000 IU Polymyxin B Sulphate + 500 IU Bacitracin Zinc
(polymyxin B sulphate and bacitracin zinc)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you.
- Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Polyfax Ointment is and what it is used for

Polyfax Ointment is a skin ointment, which contains the active ingredients polymyxin B sulphate and bacitracin zinc. Polymyxin B sulphate and bacitracin zinc are antibacterials.

Polyfax Ointment is used to help prevent infection of the skin following:

- minor burns
- a skin graft being taken
- surgery
- accidental cuts, scratches or scrapes.

Polyfax Ointment is used for the treatment of:

- infected accidental wounds
- infected burns
- infected skin grafts
- infected ulcers (on the skin)
- infected surgical cut.

It is also used to treat infected skin caused by skin diseases such as:

- impetigo (itchy skin blisters)
- bacterial otitis external (infection of the outer ear)
- ecthyma (bacterial infection that affects the deep layers of the skin)
- folliculitis (infection of the hair roots)
- paronychia (infection of the nail bed)
- eczema (skin condition with itching, redness and a burning feeling)
- scabies (infestation of the skin caused by a mite).

2 Before you use Polyfax Ointment

Do not use Polyfax Ointment if you:

- Are allergic (hypersensitive) to polymyxin B sulphate, bacitracin zinc, other similar antibiotics, or any of the other ingredients of Polyfax Ointment (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Take special care with Polyfax Ointment (and speak to your doctor) if you:

- are an adult using more than 200g of Polyfax Ointment per day
- have a child using large amounts
- have a kidney disorder

If a large amount of Polyfax Ointment is absorbed into the body it may cause damage to the nerves and kidneys. Therefore, if a large area of your skin is treated with Polyfax Ointment your doctor should monitor your kidney function.

Long-term use may cause an increased growth of micro-organisms (germs) that are not affected by Polyfax Ointment, such as fungi, and this could lead to an infection.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. This is especially important of the following substances as they may interact with your Polyfax Ointment:

- neuromuscular blocking drugs (sometimes used during surgery) – if you have absorbed a lot of Polyfax Ointment, these drugs will have a greater effect on depressing breathing.

It may still be all right for you to be given Polyfax Ointment and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or breast-feeding. Polyfax Ointment is not recommended if large amounts are likely to be absorbed. Ask your doctor or pharmacist before taking any medicines.

Driving and using machines

There are no known effects on driving or using machines.

3 How you use Polyfax Ointment

Dosage

Always use Polyfax Ointment exactly as your doctor has told you. You should check with your doctor if you are unsure.

Adults and children

Following removal of debris, such as pus, crusts etc. Polyfax Ointment should be applied thinly over the affected area, which is left uncovered. Two or more applications a day may be necessary, depending on how severe the infection is.

Elderly

The doctor should reduce the maximum dosage if there is decreased kidney function in an elderly patient.

If you use more Polyfax Ointment than you should

If you think you have used more than 200g of Polyfax Ointment per day, contact your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Polyfax Ointment can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported rarely:

- allergic reactions
- anaphylactic reaction (severe allergic reaction)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Polyfax Ointment

Keep Polyfax Ointment out of the reach and sight of children.

Do not use Polyfax ointment after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25 °C

6 Further information**What Polyfax Ointment contains:**

The active substances are polymyxin B sulphate 10,000 IU and bacitracin zinc 500 IU per gram of ointment. The other ingredient is white petrolatum.

What Polyfax Ointment looks like and contents of the pack

Aluminium tubes with screw caps.

Pack sizes: 20g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

PLIVA Pharma Ltd.

Ridings Point, Whistler Drive,

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Manufacturer

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