

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Polyfax Ophthalmic Ointment, 10,000 IU Polymyxin B Sulphate + 500 IU Bacitracin Zinc.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains:

Polymyxin B Sulphate	10,000	IU
Bacitracin Zinc	500	IU

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye ointment
Off-white translucent ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Polyfax Ophthalmic Ointment is indicated for the treatment of bacterial infections of the eye and its adnexa including conjunctivitis, keratitis, corneal ulceration and ulcerative blepharitis.

Polyfax Ophthalmic Ointment may be applied both pre- and post-operatively to prevent ocular infection following surgical procedures, including the removal of foreign bodies from the eye.

The use of Polyfax Ophthalmic Ointment does not exclude concomitant systemic therapy or other forms of local therapy where appropriate.

4.2 Posology and method of administration

A thin film of ointment should be applied, either directly to the affected area or inside the lower conjunctival sac twice or more times a day as directed by the physician.

Treatment should be continued for at least 48 hours after the eye has apparently returned to normal.

Use in children: Polyfax Ophthalmic Ointment may be used in children with dosages and administration regimens as for adults.

Use in the elderly: No specific information is available regarding the use of this product in the elderly, however the maximum dosage should be reduced in cases where a decrease in renal function may exist (*see Special warnings and precautions for use*)

4.3 Contraindications

The use of Polyfax Ophthalmic Ointment is contra-indicated in patients who are hypersensitive to polymyxin B sulphate, bacitracin zinc, to cross-sensitising substances or to any of the excipients.

4.4 Special warnings and precautions for use

Following significant systemic absorption polymyxin B sulphate and bacitracin zinc have nephrotoxic potential and polymyxin B sulphate has neurotoxic potential.

Ocular administration of Polyfax Ophthalmic Ointment is extremely unlikely to lead to significant adsorption of the constituents and therefore presents no risk of systemic toxicity.

As with all anti-bacterial preparations, prolonged use may result in overgrowth of non-susceptible organisms, including fungi.

4.5 Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption, polymyxin B sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

4.6 Fertility, pregnancy and lactation

The clinical benefit of the treatment to the patient must be balanced against any possible but unknown hazards to the developing foetus.

Due to lack of detailed information, the use of Polyfax Ophthalmic Ointment during pregnancy and lactation cannot be recommended in circumstances where significant systemic absorption of the active ingredients may occur.

No information is available regarding the excretion or the active ingredients of their metabolites in human milk.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders Rare ($>1/10,000$, $<1/1,000$): Allergic hypersensitivity, Anaphylactic reactions.

4.9 Overdose

If toxic symptoms develop following significant systemic absorption of the active ingredients of Polyfax Ophthalmic Ointment, treatment with the product should be stopped and the patient's general status, renal function and neuromuscular function should be monitored and blood levels of polymyxin B sulphate and bacitracin zinc determined.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmological antiinfectives
ATC Code: S01A A30

Mode of action:-

Polymyxin and bacitracin are both bactericidal antibiotics. The former exerts its action by binding with the cellular membrane and the latter by inhibiting bacterial cell wall development.

In vitro activity:-

Polyfax Ophthalmic Ointment is a bactericidal preparation active against the majority of bacterial eye pathogens including:

Gram-positive: -

- Staphylococcus spp.
- Streptococcus spp including *S. pyogenes* (β haemolytic streptococcus), *S. pneumoniae* (*pneumococcus*).
- Corynebacterium spp.

Gram-negative: -

- Pseudomonas spp (including *P aeruginosa*).
- Haemophilus spp.
- Klebsiella spp.
- Enterobacter spp.
- Escherichia spp.
- Neisseria spp.

5.2 Pharmacokinetic properties

No data.

5.3 Preclinical safety data

No data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White petrolatum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 5 years.

Once opened: Discard within one month of first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube containing 4g of a smooth off-white translucent ointment.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 585/13/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2007

10 DATE OF REVISION OF THE TEXT

May 2011