Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Polyfax 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

Ointment
Off-white translucent ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Polyfax Ointment is indicated in conditions where superficial skin infection is present or likely to occur. These include:-

Prophylaxis in minor and/or partial thickness burns, graft donor sites, surgical incisions, accidental cuts, scratches and abrasions.

Therapeutic use in primary infected dermatoses, such as impetigo, bacterial otitis externa, ecthyma, folliculitis and paronychia; in secondarily infected dermatoses, such as infected eczema, secondarily infected lesions of infestations (e.g. scabies) and secondary bacterial infection accompanying viral infections.

Polyfax Ointment is also indicated in the treatment of infected ulcers, accidental cuts, scratches and abrasions, and superficial skin infections following surgical procedures and burns.

The use of Polyfax Ointment does not exclude concomitant systemic therapy with other antibiotics where appropriate.

4.2 Posology and method of administration

Following removal of debris, such as pus, crusts, etc., from the affected area, a thin film of the ointment should be applied, two or more times daily as directed by the physician.

Use in Children: Polyfax ointment may be used in children with dosages and administration as for adults.

Use in elderly: No specific information is available regarding the use of Polyfax Ointment 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 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 application of Polyfax Ointment to extensive areas of raw skin, the possibility of systemic absorption of the active ingredients exists. However in such cases this is unlikely to present any risk of systemic toxicity to the patient unless the applications were unreasonably excessive, e.g. more than 200 g per day in adults or proportionately less in children and in patients with compromised renal function.

Parenterally polymyxin B sulphate has a potential for nephrotoxicity and neurotoxicity and bacitracin zinc for nephrotoxicity.

Should extensive surfaces require treatment, systemic absorption should be presumed and renal function monitored.

As with all antibacterial preparations, prolonged use may result in superinfection with organisms including fungi, resistant to these anti-infectives.

4.5 Interaction with other medicinal products and other forms of interaction

Following siginificant 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 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 Ointment during pregnancy and lactation cannot be recommended in circumstances where siginificant systemic absorption of the active ingredients may occur.

No information is available regarding the excretion of the active ingredients or 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

If toxic symptoms develop following significant systemic absorption of the active ingredients of Polyfax 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: Anitbiotics for topical use
ATC Code: D06AX05

Mode of action:-

Polymyxin B sulphate and bacitracin zinc 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 Ointment is a bactericidal preparation active against all the pathogens commonly found in bacterial infections of the skin. The range of activity incudes:

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

Gram negative:
- Pseudomonas spp (including *P. aeruginosa*).
- Haemophilius spp.
- Klebsiells 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

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium collapsible tubes containing 20g of an 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

PLIVA Pharma Ltd
Ridings Point
Whistler Drive
Castleford
West Yorkshire
WF10 5HA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 585/13/1

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

July 2015