

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Predmycin-P Liquifilm 5mg/ml + 3.5mg/ml + 10,000U/ml Eye drops suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredients</u>	<u>Percent (w/v)</u>	<u>mg/mL</u>
Prednisolone acetate	0.50	5.0
Neomycin Sulphate (0.5% w/v) (equivalent to Neomycin base)	0.35	3.5
Polymyxin B Sulphate	10,000 units/mL	10,000 units/mL

Excipients: contains thiomersal (10 microgram/ml)

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Eye drops suspension

A white to creamy white microfine suspension.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

PREDMYCIN-P is indicated for the treatment of blepharitis and conjunctivitis including those in which the inflammation is due to micro-organisms sensitive to the anti-infective.

#### 4.2 Posology and method of administration

To Treat the Eye: 1 drop every 3 to 4 hours, or more frequently as required.

Intra-ocular instillation into conjunctival sac and topical application to eyelids.

#### 4.3 Contraindications

Use in those individuals who have shown hypersensitivity to any of the drug's ingredients.

#### 4.4 Special warnings and precautions for use

##### Warnings

Prolonged use of an anti-infective may result in the development of superinfection due to organisms, including fungi, resistant to that anti-infective.

The anti-infective present may be toxic if absorbed from open surfaces.

Prolonged use may induce increased intraocular pressure corneal thinning and perforation and subcapsular lenticular opacities.

May cause allergic reactions. Prolonged use may cause pigmentation of the lens and Keratopathy.

### Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

## **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

## **4.6 Fertility, pregnancy and lactation**

There are no adequate and well controlled studies in pregnant women. PREDMYCIN-P should be used during pregnancy only if the potential benefit outweighs the potential risk to the foetus.

Nursing mothers: It is not known whether topical administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when PREDMYCIN-P is administered to a nursing woman taking into consideration the importance of the drug to the mother.

## **4.7 Effects on ability to drive and use machines**

None known.

## **4.8 Undesirable effects**

In those diseases causing thinning of the cornea, perforation has been known to have occurred with the use of topical steroids.

Side effects include local irritation, conjunctival hyperaemia, blurred vision (see also section 4.4) and less frequently allergic reactions.

This medicinal product contains thiomersal (an organomercuric compound) as a preservative, and therefore it is possible that sensitisation reactions may occur (see Section 4.3).

### 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](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## **4.9 Overdose**

Overdosage will not ordinarily cause acute problems. If accidental overdosage occurs in the eye, flush the eye with water or normal saline. If accidentally ingested, drink fluids to dilute.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### Prednisolone Acetate

Prednisolone acetate is a glucocorticoid that has three to five times the anti-inflammatory potency of hydrocortisone without concomitant increase in mineralocorticoid activity.

#### Neomycin sulphate

Neomycin sulphate is a broad spectrum bactericidal aminoglycoside antibiotic effective against a variety of gram-positive and gram-negative organisms.

#### Polymyxin B sulphate

Polymyxin B, a cyclic lipopeptide antibiotic, is rapidly bactericidal for a variety of gram-negative organisms.

### 5.2 Pharmacokinetic properties

Refer to 5.1.

### 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Polyvinyl alcohol  
Polysorbate 80  
Propylene glycol  
Sodium acetate trihydrate  
Thiomersal  
Purified water

### 6.2 Incompatibilities

Polymyxin B sulphate: Lack of compatibility has been reported with many other antimicrobial agents including amphotericin, cephalothin sodium, cephalozin sodium, chloramphenicol, sodium succinate, and tetracycline hydrochloride; and also with magnesium salts, heparin sodium, and prednisolone sodium phosphate.

### 6.3 Shelf life

Unopened: 2 years

Once opened: Use within 28 days of opening. Any unused product should be discarded.

### 6.4 Special precautions for storage

Do not store above 25°C. Protect from freezing.

### 6.5 Nature and contents of container

Dropper container.

The product will be marketed in a 5mL fill size in a 10ml bottle with a dropper tip. All bottles and tips are made from low density polyethylene. The caps are made of polystyrene. A safety seal is placed around the bottle cap to ensure integrity of the product.

#### **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**

This product should be shaken well before using and stored in an upright position.

#### **7 MARKETING AUTHORISATION HOLDER**

Allergan Pharmaceuticals Ireland  
Castlebar Road  
Westport  
County Mayo

#### **8 MARKETING AUTHORISATION NUMBER**

PA0148/017/001

#### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> April 1978

Date of last renewal: 1<sup>st</sup> April 2008

#### **10 DATE OF REVISION OF THE TEXT**

November 2017