

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

VANMYCETIN EYE DROPS

Chloramphenicol Eye Drops BP 0.5% w/v

Composition:

Each ml contains
Chloramphenicol Ph. Eur.....0.5% w/v
Phenylmercuric Nitrate Ph. Eur.....0.002% w/v
(As preservative)
Aqueous buffered vehicleq.s

Dosage Form:

Eye drops for topical ophthalmic use.

Product Description:

Clear, colourless solution free of visible particulate matter, odourless.

Pharmacodynamics:

Chloramphenicol is a broad spectrum antibiotic originally isolated from Streptomyces Venezuelae. It is primarily bacteriostatic and acts by inhibition of protein synthesis by interfering with the transfer of activated amino acids from soluble RNA to ribosomes. It has been noted that chloramphenicol is found in measurable amounts in the aqueous humor following local application to the eye. Development of resistance to chloramphenicol can be regarded as minimal for staphylococci and many other species of bacteria.

Pharmacokinetics:

Following topical application to the eye, chloramphenicol may be absorbed into the aqueous humor. Studies in patients with cataracts suggest that the degree of penetration varies with the dosage form and the frequency of application. Aqueous humor concentrations of the drug are highest with frequent application of chloramphenicol eye drops. The possibility of systemic absorption following ophthalmic application should be considered.

Indications:

Vanmycetin Eye Drops (Chloramphenicol Eye Drops BP 0.5% w/v) is used for Ophthalmic infections such as Conjunctivitis, blepharitis, keratitis and trachoma.

Recommended Dose and Administration:

1 to 2 drops every one or two hours, then subsequently at longer intervals.

Route of Administration:

Ophthalmic.

Contraindications:

Vanmycetin Eye Drops (Chloramphenicol Eye Drops BP 0.5% w/v) is contraindicated in persons sensitive to any of its components.

Warnings & Precautions:

Warnings

Bone marrow hypoplasia including aplastic anemia and death has been reported following local application of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment.

Precautions:

The prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If new infections appear during medication, the drug should be discontinued and appropriate measures should be taken.

In all serious infections the topical use of chloramphenicol should be supplemented by appropriate systemic medication.

Interactions with other medicaments:

Concomitant treatment with Penicillin and Chloramphenicol reduces their antimicrobial action.

Pregnancy and Lactation:

The safety of vanmycetin eye drops (Chloramphenicol Eye Drops BP 0.5% w/v) during pregnancy and lactation has not been established. It is not recommended for use during pregnancy.

In view of the fact that chloramphenicol may appear in breast milk, use of the product during lactation should be avoided.

Side Effects:

Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis. Treatment must be discontinued immediately in such cases.

Transient burning or stinging sensations may occur with the use of vanmycetin eye drops (Chloramphenicol Eye Drops BP 0.5% w/v). Bone marrow depression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

Symptoms and Treatment of Overdose:

In view of the relatively small amount of chloramphenicol in vanmycetin eye drops (Chloramphenicol Eye Drops BP 0.5% w/v), overdosage with this product is unlikely to constitute a hazard. No specific treatment would be required.

Storage condition:

Store in a refrigerator (2°C - 8°C)

Shelf Life:

24 Months from Date of manufacture.

Discard after 28 days of opening

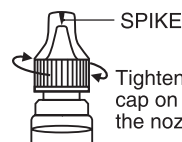
Presentation:

Pack of vial 10ml LDPE plastic bottle, closure -polystyrene spike cap.

Regn. No.: MAL 08111769AZ

Revision Date: September 2020

MODE OF USE



Tighten the cap on the nozzle



The spike in the cap will pierce the tip of the vial



Dispense drops with gentle pressure
Replace the cap after every use

Manufactured in India by:

FDC FDC Limited
B-8, MIDC Industrial Area, Waluj,
Aurangabad - 431 136, Maharashtra.

IMPORTED BY

UNIMED SDN BHD
53, Jalan Tembaga SD 5/2B
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52200 Kuala Lumpur, Malaysia.

SAP CODE (01)

 FDC Limited		LEAFLET		Mini Pharma Code No. : Front: 696/Back: 695	
Size	110(L)x144(H) mm				
Folded Size				Unfolded Size	
No. of Folds					
GSM	60 gsm				
Paper	Maplitho Paper				
Specifican No.					
Colour				■ TEXT IN BLACK	
Artwork Code: SAP CODE (01)		Supercodes A/W Code: -----			
Location : Waluj - Malaysia		Prepared On : 24-09-2021			
Reason for Change: 1) Discard within 28 days of opening line change by Discard after 28 days of opening 2) Brand name added					