

Preparation Strength	Fucithalmic	Supplier / Place of production	Ireland		
Comments:	Page 1 of 2 Pharma Code XX Mock-up for reg. purpose				

Fucithalmic[®]

Viscous eye-drops

Fucithalmic[®] is a sterile 1% aqueous sustained-release formulation of fusidic acid, preserved with benzalkonium chloride.

Properties:

Fucithalmic[®] is active against Staphylococci, Streptococci, Neisseria, Haemophilus, Moraxella and Corynebacteria. The sustained-release formulation of Fucithalmic[®] ensures a prolonged contact with the conjunctival sac. A twice-daily application provides sufficient concentrations in all relevant tissues of the eye. Fucithalmic[®] penetrates well into the aqueous humour.

Indications:

Bacterial eye infections caused by susceptible organisms in conjunctivitis, blepharitis, sty, keratitis, dacryocystitis and in connection with removal of foreign bodies.

Dosage:

One drop to be instilled into the eye twice daily. Treatment should be continued for at least two days after the eye appears normal.

Contra-indications:

Hypersensitivity to any component.

Precautions:

Should not be used when contact lenses are being worn.

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Item-number:
See details below

8. PROOF FROM OMA		Mock-up Approval Stamp (MAS)					
Date	13/03/15	Graphic Design		Editorial Proof		Second Approver	
New proof requested <input type="checkbox"/> Sign.:		According to: Instruction For Use, Mock-up Approval Stamp (MAS) SOP_000647 and SOP_000962 <input type="checkbox"/>		According to: Instruction For Use, Mock-up Approval Stamp (MAS) SOP_000647 and SOP_000962 <input type="checkbox"/>		Product name <input type="checkbox"/>	
						Dosage form <input type="checkbox"/>	
Date:						Strength/Stripes <input type="checkbox"/>	
						Pack size <input type="checkbox"/>	
						Prompts <input type="checkbox"/>	
						Item No./Reg. No. <input type="checkbox"/>	
						Barcode <input type="checkbox"/>	
						Sign.: Date:	



Scale 100%	Get-up SG	Item No. 008024	Rev. No. YY	Sent by e-mail ▼	
Subject INS 145 x 148 mm			Date 28/09/11	Date	Date
Colour Black			Sign. OMA	Sign.	Sign.

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145 mm		80 mm	
148 mm	<p>Pregnancy and lactation: There is inadequate evidence of safety in human pregnancy. Animal studies and many years of clinical experience have suggested that fusidic acid is devoid of teratogenic effects. Safety in nursing mothers has not been established.</p> <p>Side-effects: Transient stinging may occur. Fucithalmic® has a very low allergenic potential.</p> <p>Drug interaction: Not relevant.</p> <p>Incompatibilities: Fucithalmic® is a ready-for-use preparation and should, therefore not be mixed with other ingredients or preparations.</p> <p>Storage: Do not store above 30°C. Discard 28 days after opening (Do not store above 25°C).</p> <p>List of excipients: Benzalkonium chloride, Disodium edetate, Mannitol, Carbomer, Sodium hydroxide, Water for injections.</p> <p>Packaging available: 5g per tube</p> <p>Date of last revision of the package insert: February 2015</p> <p>MAH: Amdipharm Limited Temple Chambers 3 Burlington Road, Dublin 4, Ireland</p> <p>102645/008024-YY8/LF/0.4</p>	008024-YY	000000-00
		Item-number: See details below	