

30 Day Notice to Prior Authorize Acetasol[®] HC Otic Drops

Oklahoma Health Care Authority
May 2009

Manufacturer	Actavis Pharmaceuticals
Classification	Combination Anti-infective/Anti-inflammatory
Status	Prescription Only

Summary

Acetasol[®] HC Otic drops is a combination otic preparation consisting of acetic acid 2% and hydrocortisone 1%. Acetic acid lowers the pH of the ear canal and suppresses the growth of both bacterial and fungal organisms. The hydrocortisone reduces inflammation and irritation associated with infection. Acetasol HC is instilled topically in the ear three to four times a day for typically 5-7 days.

Acetasol[®] HC is a very commonly used treatment of acute otitis externa and has been available in both the brand and generic formulation for over a decade. Recently the number of manufacturers of this product has dwindled. As of April 2009, the estimated acquisition price of this product rose from approximately \$14.00 to around \$200.00 per 10mL bottle.

Recommendations

The College of Pharmacy recommends prior authorization of Acetasol[®] HC. The approval criteria is as follows:

1. Diagnosis of acute otitis externa
2. Recent (within 6 months) trials with all other commonly used topical otic anti-infectives that has failed to resolve infection.

Common Otic Topical Antibiotic Preparation and Estimated Price

Acetasol[®] (Acetic Acid 2%) Otic Solution - \$27
Cortisporin[®] HC (Neomycin/PolymyxinB/hydrocortisone) Otic Solution and Suspension - \$12
Floxin[®] Otic (Ofloxacin 3%) Drops - \$12 to \$24, dropperette \$80
Cipro[®] HC (Ciprofloxacin 0.2%/hydrocortisone 1%) Otic Suspension - \$106
Ciprodex[®] (Ciproflaxacin 0.3%/dexamethasone 0.1%) Otic Suspension - \$106

Product Details

Indication

Acetasol[®] HC Otic Drops is indicated for the treatment of infection of the external auditory canal.

Contraindications

- hypersensitivity to acetic acid, hydrocortisone, or any of the product ingredients
- perforated tympanic membrane, should not use otic solution for the outer ear canal
- herpes simplex, vaccinia, varicella

Common Adverse Effect

- irritation or sensitization; discontinue use
- when first instilled into the affected ear, stinging or burning may occur occasionally

Drug Interactions

Topical use most likely causes minimal system drug interactions.

Patient Information

- Continue using it for the full time prescribed. Stopping this medication too soon may not clear the infection and could possibly result in a reinfection.
- To avoid contamination, be careful not to touch the dropper or let it touch your ear.
- If the medication has been refrigerated, hold the bottle in your hand for a few minutes to warm it.
- To administer lie on your side or tilt the affected ear up. Place dropper directly over the ear and administer the prescribed number of drops. To help the drops roll into the ear, in adults, hold the earlobe up and back and in children, hold the earlobe down and back. Keep the head tilted for about two minutes or insert a soft cotton plug if directed to do so.
- Do not rinse the dropper.
- This medication may be administered using an ear wick. The medication is applied to the ear wick which is then gently inserted into the ear as directed. Remove the wick and instill the prescribed number of drops (usually 5) 3 to 4 times a day as prescribed.

REFERENCE

Acetasol HC Otic Drops Product Information. Micromedex Healthcare Series by Thomson Healthcare, Inc. Copyright 2009.