



Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

Therapeutic Class:

Ear Preparations

Overview:

Aero Otic HC, Vosol[®] and Vosol[®] HC are all topical otic products used to treat otitis externa. They have been commercially available for decades and all have generic formulations. These products are typically used for 7-10 days of therapy and like other otic products, should not be used in patients with perforated tympanic membranes.

Aero Otic HC, is a combination of chloroxylenol; a halogenated phenol used topically for its antiseptic and germicidal properties, hydrocortisone; a topical steroid with anti-inflammatory, antipruritic, and vasoconstrictor actions, and pramoxine; a topical local anesthetic. It is indicated for use in adults and children but safety has not been established in infants. Vosol[®] contains acetic acid (glacial) which is an organic acid with bacteriostatic and fungistatic properties. Acetic acid penetrates the bacterial cell wall and disrupts the cell membrane and is considered active against the following microorganisms: *Aspergillus sp.*, *Pseudomonas sp.*, and *Candida sp.* Acetic acid (glacial)/hydrocortisone or Vosol[®] HC is a combination product with bacteriostatic, fungistatic, anti-inflammatory, and antipruritic properties. Vosol[®] is indicated for use in adults and Vosol[®] HC is indicated for use in adults and children ≥ 3 years of age.

Topical corticosteroids like hydrocortisone (contained in Aero Otic HC and Vosol[®] HC), are contraindicated in varicella infection (such as varicella zoster or herpes infection) and vaccinia infection. Long-term use (greater than 7-10 days) of acetic acid-containing preparations like Vosol[®] and Vosol[®] HC has been associated with superinfections (including fungal infections). Dosing for all products is similar, with the option to use with a cotton wick in the external ear canal initially followed by 3-5 drops instilled in the affected ear three to four times per day or every 4-6 hours while awake. These products are generally well tolerated with the most common adverse events associated with therapy being burning or stinging, pruritis, and skin irritation.

GENERIC NAME	TRADE NAME	MANUFACTURER	GENERIC
Chloroxylenol/ Hydrocortisone/ Pramoxine	Aero Otic HC	Adamis Laboratories, others	Y
Acetic Acid (glacial)	Vosol [®]	Several generic manufacturers, brand product unavailable	Y
Acetic Acid (glacial)/ Hydrocortisone	Vosol [®] HC	ECR Pharmaceuticals, others	Y

Summary:

The selected ear products, Aero Otic HC, Vosol[®], and Vosol[®] HC are all indicated for the treatment of otitis externa and have been available for decades. In general, these products should be used for only 7-10 days and should not be used in patients with perforated tympanic membranes. Prolonged use of Vosol[®] and Vosol[®] HC has been associated with superinfection, including fungal infections. These products are generally well tolerated with the most common adverse events associated with therapy being burning or stinging, pruritis, and skin irritation. All three products have generic formulations available.