

Flumetanol

Flumetasone Pivalate BP 0.02%
& Clioquinol BP 1%

Composition:

Flumetanol Ear Drops: Each ml contains Flumetasone Pivalate BP 0.2 mg and Clioquinol BP 10 mg.

Preservative: Nil

Vehicle: Polyethylene Glycol USP

Pharmacology:

Flumetasone Pivalate is a potent difluorinated glucocorticoid designed for local application. It exerts an anti-inflammatory, anti-allergic, vasoconstrictive and anti-proliferative effect. In inflammatory skin diseases of the external auditory meatus it affords prompt relief and eliminates symptoms such as pruritus and also reduces swelling. Clioquinol is a halogenated hydroxyquinoline derivative which exerts bacteriostatic action. It is active against a broad spectrum of microorganisms including fungi (e.g., *Candida*, *Microsporum*, *Trichophyton*) and Gram-positive bacteria (e.g. *Staphylococci*). It is also effective against Gram-negative bacteria.

Indications:

Flumetanol Ear Drops is indicated for the treatment of eczema of the external auditory meatus in which secondary infection has occurred, such as otitis externa & otomycosis.

Dosage & application:

Instill 2-3 drops of **Flumetanol Ear Drops** into the auditory meatus twice daily for 7-10 days.

Contraindications:

Contraindicated in perforation of the ear-drum (suspected or verified); application to the eye; viral infections of the skin; known hypersensitivity to iodine, Flumetasone Pivalate, Clioquinol, hydroxyquinolines and other quinoline derivatives or to any other component of this product.

Side effects:

Occasionally burning sensation, itching or skin rash may occur. Treatment should be discontinued if severe irritation or sensitization develops.

Precautions:

- Prior to the beginning of therapy, the ear-drum should be examined by the physician. If there is a risk that perforation of the ear-drum may occur, this product should not be used.
- Should not be allowed to come into contact with the conjunctiva.

Drug interactions:

Topical use of Clioquinol-containing preparations may lead to a marked increase in protein-bound iodine (PBI).

Use in special group:

Use in pregnancy: No reports of adverse effects in human pregnancy have been received to date. However, when using this product in pregnancy, the risk-benefit relationship should be carefully considered.

Use in lactation: It is not known whether Flumetasone Pivalate or Clioquinol passes into breast milk. Caution should be exercised when **Flumetanol** is administered to a nursing mother.

Use in children: Safety and effectiveness in children below the age of 2 years have not been established.

Storage:

- Store below 30° C, keep in dry place & protect from light.
- Do not use longer than 30 days after the first opening.
- Keep out of the reach of the children.

Packing:

Flumetanol Ear Drops: Each LDPE dropper bottle contains 5 ml ear drops.

Manufactured by:
 **ARISTOPHARMA LTD.**
Shampur-Kadamtali I/A, Dhaka-Bangladesh