

LOCACORTEN-VIOFORM Ear Drops

DESCRIPTION

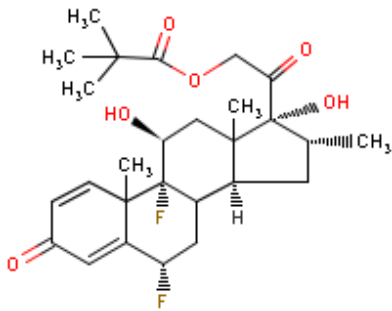
Locacorten-Vioform ear drops are presented in polyethylene bottles containing 7.5 mL solution containing 0.02% Flumethasone pivalate and 1% Clioquinol.

There are two active components

Active 1: Flumethasone pivalate

Chemical Formula: $C_{27}H_{36}F_2O_6$ (6 α , 9-Difluoro-11 β ,17,21-trihydroxy-16 α -methylpregna-1,4-diene-3,20-dione 21-pivalate)

MW: 494.571



CAS Number: 2002-29-1

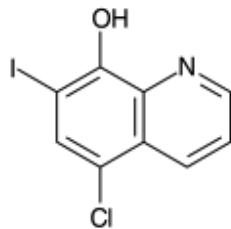
Flumethasone is a synthetic difluorinated glucocorticoid.

Active 2: Clioquinol

Chemical Formula: C_9H_5ClINO
(5-chloro-7-iodo -8-quinolinol)

MW: 305.5

CAS Number: 130-26-7



Clioquinol is an halogenated hydroxyquinoline derivative.

In-active:

Polyethylene glycol 300

ACTIONS

Pharmacology

Flumethasone pivalate is a moderately potent 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 while at the same time reducing swelling.

Clioquinol, the antimicrobial component of Locacorten-Vioform ear drops, is active against a broad spectrum of pathogenic micro-organisms, including fungi (e.g. *Candida*, *Microsporum*, *Trichophyton*) and Gram-positive bacteria (e.g. staphylococci). Clioquinol has only a moderate inhibitory effect on Gram-negative bacteria.

Clioquinol exerts a bacteriostatic, rather than a bactericidal action.

Pharmacokinetics

No pharmacokinetic data on Locacorten-Vioform ear-drops are available.

Trials (including treatment under occlusive dressings) with different formulations of Locacorten-Vioform for topical application have shown that no demonstrable percutaneous absorption of flumethasone pivalate occurs, while clioquinol was absorbed to an extent of about 1.5% to 4%, as judged by the urinary excretion.

Clioquinol is excreted in the urine mainly in glucuronide form and to a smaller extent as sulphate, whereas unchanged clioquinol is found in traces only.

Properties of the ear drops

Locacorten-Vioform is dissolved in a polyethylene glycol vehicle which forms an inert, non-irritant, rather viscous medium. This medium has a softening effect on the cerumen and ensures prolonged contact of the active ingredients with the surface of the ear canal.

INDICATIONS

Eczema of the external auditory meatus in which secondary infection with microorganisms sensitive to clioquinol has occurred

Otitis externa

Otomycosis

CONTRAINDICATIONS

Perforation of the ear-drum (suspected or verified), application to the eye. Viral infections of the skin, syphilitic skin affections, tuberculosis of the skin, known hypersensitivity to flumethasone pivalate, known hypersensitivity to clioquinol, hydroxyquinolines and other quinoline derivatives, to iodine, as well as to other components contained in Locacorten-Vioform ear drops.

Use in children under 2 years of age.

PRECAUTIONS/WARNINGS

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, Locacorten-Vioform ear drops should not be used.

If no improvement occurs within about 1 week, therapy should be discontinued. It is then advisable to identify the pathogens and to institute appropriate treatment.

Locacorten-Vioform ear drops should not be allowed to come into contact with the conjunctiva.

Contact with Locacorten-Vioform ear drops may cause discoloration of the hair and of clothing and bed-linen.

Topical use of clioquinol-containing preparations may lead to a marked increase in protein-bound iodine (PBI) (see also under "Overdosage").

Pregnancy: (Risk Category "A")

Animal experiments relevant to the safety assessment of corticosteroids, although not specifically conducted with Locacorten-Vioform ear drops, have shown either teratogenic potential or other adverse effects on the embryo and/or the fetus. However, no reports of adverse effects with Locacorten-Vioform ear drops in human pregnancy have been received to date.

When using Locacorten-Vioform ear drops in pregnancy, the risk-benefit relationship must be carefully considered.

Lactation:

It is not known if the active substances of Locacorten-Vioform ear drops and/or their metabolite(s) pass into the breast milk when the preparation is applied topically. For safety reasons caution is indicated.

Effects on ability to drive or use machines:

None known to date

ADVERSE REACTIONS

Occasionally: at the site of application signs of irritation such as a burning sensation, itching, or skin rash; hypersensitivity reactions.

Treatment should be discontinued if severe irritation or sensitisation develops.

INTERACTIONS

Topical use of clioquinol-containing preparations may increase the amount of protein-bound iodine (PBI) in patients with normal thyroid function and therefore may interfere with tests of thyroid function (such as PBI, radioactive iodine and butanol-extractable iodine). Other thyroid function tests, such as the T₃ resin sponge test or T₄ determination, are unaffected.

The ferric chloride test for phenylketonuria may yield a false-positive result when clioquinol is present in the urine.

However, no similar reports with Locacorten-Vioform ear drops have been received to date.

OVERDOSAGE

Treatment with clioquinol-containing preparations applied to extensive or eroded areas of skin may lead within 1 week to increased PBI values. Elevated PBI values also occur when relatively small areas of skin are treated for more than 1 week.

However, no similar reports with Locacorten-Vioform ear drops have been received to date.

DOSAGE AND METHOD OF ADMINISTRATION

Before application, the auditory meatus should be cleaned and dried carefully.

Instil 2 or 3 drops twice daily into the auditory meatus by gently squeezing the plastic bottle. The patient should be either sitting or lying down with the treated ear turned upwards during application.

This position should be maintained for at least 1 or 2 minutes following the application.

Alternatively, a gauze or cotton wick saturated with the solution may be inserted into the ear canal.

Keep the wick moistened by adding further solution. It should be replaced at least once every 24 hours.

The solution may be warmed to body temperature prior to each application (e.g. by holding the bottle in the hands). Heating above body temperature should be avoided. Contamination of the dropper with material from the ear, fingers, or other sources should be avoided.

Treatment should normally not exceed 10 days.

PRESENTATION

Polyethylene bottle containing 7.5mL solution

Storage:

Store below 25°C. Medicines should be kept out of reach of children.

Poison Schedule: S4

Sponsor:

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