

# DATASHEET

## LOCACORTEN-VIOFORM<sup>®</sup>

Clioquinol 1% w/v and flumetasone pivalate 0.02% w/v eardrops

### Qualitative and quantitative composition

Locacorten-Vioform is a clear yellowish solution containing 1% clioquinol and 0.02% flumetasone pivalate in Polyethylene glycol 300. Flumetasone is a synthetic difluorinated glucocorticoid. Clioquinol is a halogenated hydroxyquinolone derivative.

### Pharmaceutical form

Ear drops

### Clinical particulars

#### *Therapeutic indications*

Eczema of the external auditory meatus in which secondary infection with micro-organisms sensitive to clioquinol has occurred.

- Otitis externa
- Otomycosis.

#### *Dosage and method of administration*

Before application, the auditory meatus should be cleansed 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 1-2 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.

#### *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 flumetasone pivalate,
- Known hypersensitivity to clioquinol, hydroxyquinolines and other quinoline derivatives
- Known hypersensitivity to iodine,

- Known hypersensitivity to macrogol.
- Use in children under 2 years of age

### ***Special warnings and special precautions for use***

Prior to the beginning of therapy, the ear-drum should be checked 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, the therapy should be discontinued. It is then advisable to identify the pathogens and to institute an 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 discolouration 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 "Overdosage").

Medicines should be kept out of the reach of children.

### ***Interaction with other medicaments and other forms of interaction***

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 T<sub>3</sub> resin sponge test or T<sub>4</sub> 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.

### ***Pregnancy and lactation***

#### **Pregnancy**

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 foetus. However, no reports on 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 whether 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 and use machines***

None known to date.

### ***Adverse effects***

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.

### ***Overdose***

Treatment with clioquinol-containing preparations applied to extensive or eroded areas of skin may lead to increased PBI values within 1 week, and to signs and symptoms resembling those of thyrotoxicosis. Elevated PBI values also occur where 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.

## **Pharmacological properties**

### ***Pharmacodynamic properties***

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.

Flumetasone 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.

### ***Pharmacokinetic properties***

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 flumetasone 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.

## **Pharmaceutical Particulars**

### ***List of excipients***

Polyethylene glycol 300

### ***Incompatibilities***

None known to date.

### ***Shelf life***

3 years

### ***Special precautions for storage***

Store below 25 °C

### ***Nature and contents of container***

Yellow coloured polyethylene 10ml bottles containing 7.5ml solution.

### ***Instructions for use/handling***

Medicines should be kept out of the reach of children.

## **Medicine classification**

Prescription Medicine

## **Name and address**

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