SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Locorten Vioform Ear Drops
Flumetasone/Clioquinol 0.02% w/v / 1% w/v Ear Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Flumetasone Pivalate 0.02% w/v

Clioquinol 1.0% w/v

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ear drops, solution

Clear, yellowish to brownish-yellow solution

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Inflammatory conditions of the external ear where a secondary infection is suspected.
Otorrhoea.

4.2. Posology and method of administration

Posology

Instill 2 or 3 drops twice daily directly into the auditory canal of the affected ear. Treatment should be limited to 7-10 days.

If there is little improvement after 7 days treatment with this medicine, appropriate microbiological investigations should be carried out and local or systemic antibiotic treatment given.

Elderly

There is no evidence to suggest that dosage should be different in the elderly.

Paediatric population

This medicine is contra-indicated in children below the age of two years.

Method of administration

Auricular use

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Primary bacterial, viral or fungal infections of the outer ear. Perforation of the tympanic membrane. Use in children below the age of two years.

4.4 Special warnings and precautions for use

Long-term continuous topical therapy should be avoided since this can lead to adrenal suppression.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid

side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Topical application of clioquinol-containing preparations may lead to a marked increase in protein-bound iodine (PBI). The results of thyroid function tests, such as PBI, radioactive iodine and butanol extractable iodine, may be affected. However, other thyroid function tests, such as the T_3 resin sponge test or T_4 determination, are unaffected.

The ferric chloride test of phenylketonuria may yield a false-positive result when clioquinol is present in the urine. This medicine should not be allowed to come into contact with the conjunctiva.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None known via this topical route.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intra-uterine growth retardation. There may, therefore, be a very small risk of such effects in the human foetus.

Breast-feeding

It is not known whether the active substances of this medicine and/or their metabolite(s) pass into breast milk after topical administration. Use in lactating mothers should only be at the doctor’s discretion.

Fertility

No data available

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The adverse drug reactions are listed according to system organ classes in MedDRA. Within each system organ class, ADRs are presented in order of decreasing seriousness.

The names used to describe each of the frequency groupings should follow standard terms established in each official language using the following convention:

Not known (cannot be estimated from the available data)

System Organ Class	**Undesirable effect**
Immune system disorders	Hypersensitivity reactions.
Eye disorders	Not known: Vision blurred (see also section 4.4)
Skin and subcutaneous tissue disorders	Hair discoloration
General disorders and administration site conditions	*Irritation, burning, pruritus and rash in the application site.

*This medicine is generally well tolerated, but occasionally at the site of application, there may be signs of irritation such as a burning sensation, itching or skin rash.

Treatment should be discontinued if patients experience severe irritation or sensitization.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9. Overdose

This medicine is for topical (external) use only. If accidental ingestion of large quantities occurs, there is no specific antidote and general measures to eliminate the drug and reduce its absorption should be undertaken. Symptomatic treatment should be administered as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Otologicals corticosteroids and anti-infectives in combination, ATC code: SO2CA02

This medicine combine the anti-fungal and anti-bacterial properties of clioquinol with the anti-inflammatory activity of Flumetasone pivalate.

5.2. Pharmacokinetic Properties

No pharmacokinetic data on this medicine is available.

5.3. Preclinical Safety Data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Polyethylene Glycol

6.2. Incompatibilities

Not applicable

6.3. Shelf life

18 months

6.4. Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Plastic dropper bottle containing 7.5ml or 10ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Keep out of the sight and reach of children.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Amdipharm UK Limited,

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8. MARKETING AUTHORIZATION NUMBER(S)

PL 20072/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/07/2006

10 DATE OF REVISION OF THE TEXT

27/03/2024