

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

PrLOCACORTEN® VIOFORM® EARDROPS

Flumethasone pivalate and clioquinol drops

0.02 % / 1 % w/v

Topical corticosteroid with antibacterial and antifungal agent for
Otic use

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RECENT MAJOR LABEL CHANGES

1 INDICATION	2025-04
7 WARNINGS AND PRECAUTIONS, Sensitivity/Resistance	2025-04

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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

LOCACORTEN VIOFORM EARDROPS (flumethasone pivalate and clioquinol drops) is indicated for:

- otitis externa
- otomycosis including that due to *Aspergillus niger*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of LOCACORTEN VIOFORM EARDROPS and other antibacterial drugs, LOCACORTEN VIOFORM EARDROPS should be used only to reduce the risk of infections that are proven or strongly suspected to be caused by susceptible bacteria.

1.1 Pediatrics

Pediatrics (< 2 years of age): Health Canada has not authorized an indication in children under 2 years of age.

1.2 Geriatrics

Geriatrics (>65 years of age): LOCACORTEN VIOFORM EARDROPS should be used with caution in geriatric patients, taking into consideration the greater frequency of decreased hepatic or renal function, of cardiovascular disease, and of concomitant disease or other drug therapy in this patient population.

2 CONTRAINDICATIONS

LOCACORTEN VIOFORM EARDROPS is contraindicated in:

- patients with perforation of the eardrum (suspected or verified)
- patients with viral (e.g., chicken pox) or syphilitic skin infections, tuberculosis of the skin or skin eruptions following vaccination
- patients with known hypersensitivity to flumethasone pivalate or to corticosteroids in general, to hydroxyquinolines, clioquinol, or other quinoline derivatives, iodine, as well as to any other components of LOCACORTEN VIOFORM EARDROPS including any non-medicinal ingredient or component of the container. For a complete listing, see [6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING](#).
- application to the eye
- use in children under 2 years of age

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Thorough cleansing of the external ear is essential for successful treatment. If a large amount of discharge is present, the meatus may initially require gentle syringing. Thereafter, the passage may be kept clean by wiping as necessary.

- Free drainage of the ear encourages healing. However, in severe cases, it may be desirable to pack the ear lightly with a gauze strip moistened with the solution, replacing this dressing as necessary, at least once every 24 hours.
- Prior to beginning therapy, the eardrum should be checked by a healthcare professional. LOCACORTEN VIOFORM EARDROPS should not be used if there is a risk that perforation of the eardrum may occur or has occurred.

4.2 Recommended Dose and Dosage Adjustment

Two to three drops of LOCACORTEN VIOFORM EARDROPS should be instilled twice daily.

Treatment should normally not exceed 10 days. If no improvement occurs within 1 week, therapy should be discontinued. The pathogens should then be identified and treated.

4.4 Administration

- The solution may be warmed to body temperature prior to application by holding the bottle in the hands. Heating above body temperature should be avoided
- To ensure correct administration of the drug, the patient or another person should be instructed both on how to clean the outer ear and apply the eardrops. The patient should be either sitting or lying down with the treated ear turned upwards during application. This position should be maintained for 1-2 minutes following the application.
- To avoid contamination of the eardrops, contact of the dropper with any surface (including the ear) should be avoided.
- LOCACORTEN VIOFORM EARDROPS may turn yellow when exposed to air and may cause staining of the skin, nails, hair or fabrics.

5 OVERDOSE

Poisoning due to accidental ingestion is not expected since a bottle of LOCACORTEN VIOFORM EARDROPS contains far less active ingredients than the upper safe limit of a single oral dose for either component.

Application of clioquinol-containing preparations to extensive or eroded areas of skin may lead to increased protein-bound iodine (PBI) within 1 week, see [9.7 Drug-Laboratory Test Interaction](#).

If signs and symptoms resembling those of thyrotoxicosis occur, the preparation should be withdrawn at once.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredient
Otic	Drops 0.02% flumethasone pivalate and 1% clioquinol	polyethylene glycol

LOCACORTEM VIOFORM EARDROPS is available in plastic bottles supplied with a controlled-drop dispenser. Each bottle contains 11 mL of solution.

7 WARNINGS AND PRECAUTIONS

General

Patients should be advised to inform subsequent healthcare professionals of the prior use of corticosteroids.

Endocrine and Metabolism

Adrenal function: Clinically important effects on adrenocortical function are possible, particularly in pediatric use and in patients undergoing prolonged therapy.

Thyroid function: Topical use of clioquinol-containing preparations may lead to a marked increase in protein-bound iodine (PBI), see [5 OVERDOSAGE](#) and [9.7 Drug-Laboratory Test Interactions](#).

Ophthalmologic

LOCACORTEN VIOFORM EARDROPS should not come into contact with the conjunctiva, see [2 CONTRAINDICATIONS](#).

Sensitivity/Resistance

Development of Drug Resistant Bacteria: Prescribing LOCACORTEN VIOFORM EARDROPS in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

7.1 Special Populations

7.1.1 Pregnancy

There are no adequate data to establish the safety of LOCACORTEN VIOFORM EARDROPS during pregnancy. Studies have shown that corticosteroids may induce fetal abnormalities in pregnant animals. The relevance of this finding to human use has not been elucidated.

The potential benefit of LOCACORTEN VIOFORM EARDROPS during pregnancy (particularly during the first three months) should be weighed against possible hazard to the fetus.

7.1.2 Breastfeeding

The safety of LOCACORTEN VIOFORM EARDROPS during lactation has not been established. It is not known whether flumethasone pivalate and/or clioquinol pass into breast milk when applied in the ear. The potential benefit of LOCACORTEN VIOFORM EARDROPS during lactation should be weighed against possible hazard to the nursing infant.

7.1.3 Pediatrics

Pediatrics (<2 years of age): Health Canada has not authorized an indication in children under 2 years of age.

7.1.4 Geriatrics

Geriatrics (>65 years of age): LOCACORTEN VIOFORM EARDROPS should be used with caution in geriatric patients, taking into consideration the greater frequency of decreased hepatic or renal function, of cardiovascular disease, and of concomitant disease or other drug therapy in this patient population.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

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

If an exacerbation or allergic type reaction occurs, treatment with LOCACORTEN VIOFORM EARDROPS should be discontinued.

8.2 Clinical Trial Adverse Reactions

In human toxicity and absorption studies no systemic or pituitary-adrenal effects were noted. The only significant abnormalities found were elevated 17-ketosteroid levels and elevated serum protein-bound iodine (PBI) levels following topical administration.

No systemic toxic effects due to absorption of LOCACORTEN VIOFORM EARDROPS from the auditory canal were reported in clinical trials. However, transient reversible adrenocortical suppression occurred in three patients while using large amounts of 0.03% flumethasone pivalate cream, i.e., 90 g per day for 7 days over the entire body with about half the skin occluded at all times.

9 DRUG INTERACTIONS

9.3 Drug-Behavioural Interactions

Interactions with individual behaviour risks such as alcohol consumption, sexual activity and smoking have not been established.

9.4 Drug-Drug Interactions

Interactions with other drugs have not been established.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Thyroid function test: Topical use of clioquinol, as well as other iodine-containing compounds, may increase the amount of protein-bound iodine (PBI) in patients with normal thyroid function and therefore may interfere with some thyroid function tests (such as PBI, radioactive iodine and butanol-extractable iodine). These tests should not be performed within 1 month of LOCACORTEN VIOFORM EARDROPS use.

Other thyroid function tests, such as the T₃ resin sponge test or the T₄ determination, are unaffected by clioquinol.

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

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Flumethasone pivalate is a moderately potent difluorinated glucocorticoid with anti-inflammatory, antipruritic, and vasoconstrictive properties. As it is a pivalate, its action is concentrated at the site of application. This local effect on diseased areas results in a decrease in inflammation, exudation and itching.

Clioquinol, the antimicrobial component of LOCACORTEN VIOFORM EARDROPS, is active against a broad spectrum of pathogenic microorganisms, including fungi (e.g., *Candida*, *Microsporum*, *Trichophyton*) and gram-positive bacteria (e.g., *Staphylococci*). Clioquinol has only a slight inhibitory effect on gram-negative bacteria. Clioquinol exerts a bacteriostatic rather than a bactericidal action.

The polyethylene glycol vehicle is inert, non-irritant and viscous. This vehicle softens the cerumen and ensures prolonged contact of the active ingredients with the surface of the ear canal.

10.2 Pharmacodynamics

Flumethasone pivalate has marked local anti-inflammatory activity. Activity was quantified by comparing the degree of foreign body granuloma formation caused by implantation of a sterile cotton pellet versus a sterile cotton pellet impregnated with flumethasone pivalate or other corticoids, for 6 days under the skin of the back of male rats.

Flumethasone pivalate was more than 800 times as active as cortisol acetate, about 70 times as active as prednisolone trimethylacetate and about 10 times as active as dexamethasone trimethylacetate. In doses with an optimal local effect, flumethasone pivalate did not exert any remarkable effect on the contralateral control granuloma, and produced only insignificant changes of body weight, thymus and adrenal weight. This demonstrates the absence of systemic effects.

In normal male rats loaded orally with 20 mg/kg of a 0.85% NaCl solution, appreciable diuresis occurred within four hours after the administration of flumethasone pivalate in doses ≥ 0.02 mg/animal. Such effect is typical for this type of compounds in rats.

Comparison to above data shows that the dose exerting a clear-cut inhibiting effect on the formation of foreign body granulomata is about 80 times smaller than that necessary to alter water and salt excretion in the same animal.

11 STORAGE, STABILITY AND DISPOSAL

Store between 15-30 °C. Protect from heat and light.

12 SPECIAL HANDLING INSTRUCTIONS

Not applicable

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

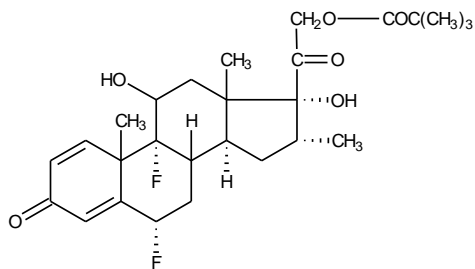
Drug Substances

Proper name: Flumethasone pivalate

Chemical name: 6 α , 9-difluoro-11 β , 17 α -dihydroxy-16 α -methyl-21-trimethylacetoxymethyl-1,4-pregnadiene-3,20-dione

Molecular formula and molecular mass: C₂₇H₃₆F₂O₆; 494.6 g/mol

Structural formula:



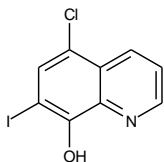
Physicochemical properties: Virtually white, odorless, fine crystalline powder. Slightly soluble in methanol and ethanol, very slightly soluble in chloroform and methylene chloride, and is insoluble in carbon tetrachloride and isooctane.

Proper name: Clioquinol

Chemical name: 5-chloro-7-iodo-8-quinolinol

Molecular formula and molecular mass: C₉H₅ClINO; 305.5 g/mol

Structural formula:



Physicochemical properties: Practically white to faintly yellowish powder. Freely soluble in pyridine, soluble in dimethylformamide and hot ethyl acetate, sparingly soluble in dioxane, slightly soluble in ethanol, practically insoluble in water.

14 CLINICAL TRIALS

The clinical trial data on which the original indication was authorized is not available.

15 MICROBIOLOGY

The antifungal and antibacterial activities of clioquinol are shown in the following tables:

Table 2 – Clioquinol antifungal activities

Antifungal Spectrum	
Fungus	Effect of clioquinol
<i>Trichophyton Quinckeanum</i>	++
<i>Epidermophyta</i>	++
<i>Scopulariopsis brevicaulis</i>	++
<i>Candida albicans</i> *	++
<i>Aspergillus niger</i> *	++

++ = considerably decreased growth rate

* = organisms commonly occurring in ear infections

Table 3 – Clioquinol antibacterial activities

Antibacterial Spectrum	
Bacterium	Effect of clioquinol
<i>Staphylococcus</i> *	+++
<i>Streptococcus</i> *	++
<i>Ps. pyocyanea</i> *	+
<i>E. Coli</i> *	++
<i>B. anthracis</i>	++
<i>Kl. pneumonia</i>	++
<i>Pneumococcus</i> *	+++
<i>Salmonella typhi</i>	+++
<i>Salmonella paratyphi</i>	+++
<i>Dysentery bacillus</i>	+++
<i>Meningococcus</i>	+++
<i>B. pseudodiphtheria</i>	++
<i>B. subtilis</i>	++
<i>Tubercle bacillus</i>	++

+++ = complete growth inhibition in appropriate concentration

++ = considerably decreased growth rate

+ = slight growth inhibition

* = organisms commonly occurring in ear infections

16 NON-CLINICAL TOXICOLOGY

General Toxicology

The LD₅₀ for flumethasone pivalate is >1000 mg/kg in the mouse, and >500 mg/kg in the rat. In dogs 0.01 mg/kg/day s.c. was well tolerated. This represents a dose 400-700 times greater than that needed to exert an optimal local effect.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr^rLOCACORTEN® VIOFORM® EARDROPS

Flumethasone pivalate and clioquinol drops

Read this carefully before you start taking **LOCACORTEN VIOFORM EARDROPS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LOCACORTEN VIOFORM EARDROPS**.

What is LOCACORTEN VIOFORM EARDROPS used for?

LOCACORTEN VIOFORM EARDROPS is used in ear infections to:

- relieve symptoms such as itching and redness.
- stop the growth of bacteria and fungi.

Antibiotic drugs like LOCACORTEN VIOFORM EARDROPS treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, LOCACORTEN VIOFORM EARDROPS should be used exactly as directed. Misuse or overuse of LOCACORTEN VIOFORM EARDROPS could lead to the growth of bacteria that will not be killed by LOCACORTEN VIOFORM EARDROPS (resistance). This means that LOCACORTEN VIOFORM EARDROPS may not work for you in the future. Do not share your medicine.

How does LOCACORTEN VIOFORM EARDROPS work?

LOCACORTEN VIOFORM EARDROPS contains two medicinal ingredients. Flumethasone pivalate belongs to a group of medicines called corticosteroids which fights inflammation. Clioquinol is an anti-infective agent that kills bacteria and fungus.

What are the ingredients in LOCACORTEN VIOFORM EARDROPS?

Medicinal ingredients: flumethasone pivalate and clioquinol

Non-medicinal ingredient: polyethylene glycol

LOCACORTEN VIOFORM EARDROPS comes in the following dosage forms:

Drops, 0.02 % flumethasone pivalate and 1 % clioquinol

Do not use LOCACORTEN VIOFORM EARDROPS if:

- you have, or think you have, a perforation (rupture, tear or hole) of the eardrum
- you have viral (e.g., chicken pox) or syphilitic skin infections, tuberculosis of the skin or skin eruptions following vaccination.
- you are allergic to flumethasone pivalate, hydroxyquinolines, clioquinol or other quinoline derivatives, corticosteroids, iodine or any other ingredients in LOCACORTEN VIOFORM EARDROPS.
- it is for application to the eye.
- it is for children under 2 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LOCACORTEN VIOFORM EARDROPS. Talk about any health conditions or problems you may have, including if you:

- are pregnant or planning to become pregnant while using LOCACORTEN VIOFORM EARDROPS.
- are breastfeeding.

Other warnings you should know about:

- You should tell any other healthcare professional that you see that you are being, or have been, treated with LOCACORTEN VIOFORM EARDROPS.
- LOCACORTEN VIOFORM EARDROPS may affect the results of some blood and urine tests including thyroid tests. If you need to have any blood or urine tests done tell your healthcare professional that you are being treated, or have been treated in the last month, with LOCACORTEN VIOFORM EARDROPS.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take LOCACORTEN VIOFORM EARDROPS:

- LOCACORTEN VIOFORM EARDROPS must be used as directed by your healthcare professional. Do not use more of it, do not use it more often, and do not use it for a longer period of time than your healthcare professional has specified.
- Some ear infections cause a discharge. As your ear must be clean for LOCACORTEN VIOFORM EARDROPS to work, your healthcare professional may show you how to clean your ears before instilling the drops.
- You may warm the drops to body temperature (but not warmer) before using them by holding the bottle in your hands.
- To use LOCACORTEN VIOFORM EARDROPS:
 1. lie down with the infected ear up and pull down gently on the ear lobe.
 2. instill the prescribed number of drops in the ear canal.
 3. gently push on the ear until the drops are evenly spread in the ear and wait 1-2 minutes before sitting up.If LOCACORTEN VIOFORM EARDROPS gets in the eyes accidentally, flush them at once with plenty of water.
- To avoid contamination of the drops, do not let the dropper touch any surface, including the ear.
- Keep the container tightly closed after use.
- LOCACORTEN VIOFORM EARDROPS are for external use only. Do not take by mouth.
- If there is no improvement or if your ear infection becomes worse after you have used LOCACORTEN VIOFORM EARDROPS for 1 week, talk to your healthcare professional.
- LOCACORTEN VIOFORM EARDROPS may stain hair, fabric, skin or nails yellow.

Usual dose:

Two to three drops of LOCACORTEN VIOFORM EARDROPS should be instilled twice daily.

Overdose:

If you think you, or a person you are caring for, have taken too much LOCACORTEN VIOFORM EARDROPS, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

What are possible side effects from using LOCACORTEN VIOFORM EARDROPS?

These are not all the possible side effects you may have when taking LOCACORTEN VIOFORM EARDROPS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- burning sensation, itching or skin rash at the application site

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Allergic reaction: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, rash or hives, wheezing, feeling sick to your stomach and throwing up			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15-30 °C. Protect from heat and light.

Keep out of the reach and sight of children.

If you want more information about LOCACORTEN VIOFORM EARDROPS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the distributor's website www.paladin-pharma.com, or by calling 1-888-867-7426.

This leaflet was prepared by Endo Operations Ltd.

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