

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Pr **LOCACORTEN[®] VIOFORM[®]**

Flumethasone pivalate and clioquinol
Cream, 0.02 % / 3 % w/w, Topical

Topical corticosteroid with antibacterial and antifungal agent

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Date of Initial Authorization:
MAY 05, 2002

Distributor:
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Date of Revision:
FEB 14, 2025

Version: 4.0

Submission Control Number: 288368

RECENT MAJOR LABEL CHANGES

None at time of most recent authorization

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Sections or subsections that are not applicable at the time of authorization are not listed.

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

LOCACORTEN VIOFORM (flumethasone pivalate and clioquinol cream) is indicated:

- the initial treatment of corticosteroid-responsive inflammatory skin disorders complicated by bacterial and/or fungal infections, with appropriate systemic antibiotics if necessary, such as: seborrheic dermatitis, atopic dermatitis, localized neurodermatitis, contact dermatitis, intertrigo, superficial forms of pyoderma (e.g., impetigo).
- dermatomycosis in which acute inflammation is a prominent feature.

The cream has a slightly drying effect primarily useful for moist, weeping lesions and in intertriginous areas.

1.1 Pediatrics

Pediatrics (< 18 years old): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (>65 years old): No data are available to Health Canada.

2 CONTRAINDICATIONS

LOCACORTEN VIOFORM is contraindicated in:

- patients with viral infections of the skin (e.g., chicken pox, skin eruptions following vaccination, herpes simplex, herpes zoster), tuberculosis of the skin, syphilis, rosacea, acne vulgaris and perioral dermatitis.
- patients with known hypersensitivity to flumethasone pivalate or to corticosteroids in general, to hydroxyquinolines, clioquinol or other quinoline derivatives, to iodine as well as to any other components of LOCACORTEN VIOFORM, including any non-medical ingredient or component of the container. For a complete listing, see [6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING](#).
- application to ulcerated areas.
- application to the eye.
- children under 2 years of age.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Use of LOCACORTEN VIOFORM under occlusive dressings is not recommended as the resulting humid conditions may promote secondary infection with non-sensitive organisms and also may increase the possibility of elevated protein-bound iodine (PBI).
- If no improvement occurs within 1 week, therapy should be discontinued; it is then advisable to identify and treat the causative pathogens.

- LOCACORTEN VIOFORM may turn yellow when exposed to air and may cause staining of the skin, nails, hair or fabrics.

4.2 Recommended Dose and Dosage Adjustment

LOCACORTEN VIOFORM should be applied to the affected areas in a thin layer 2 to 3 times daily.

Pediatrics (< 18 years old): Health Canada has not authorized an indication for pediatric use (see [7.1.3 Pediatrics](#)).

5 OVERDOSAGE

Application to extensive or eroded areas of skin may lead to increased protein-bound iodine (PBI) values within 1 week. Elevated PBI values may also occur where relatively small areas of skin are treated for more than 1 week.

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

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Topical	Cream (off-white water-soluble) 0.02% flumethasone pivalate and 3% clioquinol	Cetyl alcohol, cetyl palmitate, glycerin, petrolatum, phenoxyethanol, sodium lauryl sulfate, stearyl alcohol, water

LOCACORTEN VIOFORM is available in tubes of 30 g and 50 g.

7 WARNINGS AND PRECAUTIONS

General

LOCACORTEN VIOFORM should not be used to treat bacterial or mycotic skin diseases in which acute inflammation is not present.

Patients should, as a general rule, be advised to inform subsequent physicians of the prior use of corticosteroids.

If, in exceptional cases, LOCACORTEN VIOFORM is applied in large amounts, the patient should be kept under regular medical supervision.

Ear/Nose/Throat

LOCACORTEN VIOFORM should not be used in the external auditory canal if the eardrum is perforated.

Endocrine and Metabolism

Adrenal function: Provided the preparation is used as recommended, unwanted systemic effects are unlikely to occur. On basic medical grounds, the possibility of a clinically important effect on adrenocortical function should nevertheless be borne in mind, particularly if the preparation is used under occlusion, over large areas of the body, in pediatrics and in patients undergoing prolonged therapy.

Thyroid function: Application to relatively large and/or eroded areas, treatment for longer than 1 week, as well as use under occlusive dressings may lead to a marked increase in protein-bound iodine (PBI) and should therefore be avoided.

Hepatic/Biliary/Pancreatic

Caution is indicated in patients suffering from hepatic failure.

Renal

Caution is indicated in patients suffering from renal failure.

Ophthalmologic

LOCACORTEN VIOFORM should not be allowed to come into contact with the conjunctiva.

7.1 Special Populations

7.1.1 Pregnant Women

The safety of LOCACORTEN VIOFORM during pregnancy has not been established. Animal 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 during pregnancy (particularly in the first three months) should be weighed against possible hazard to the fetus.

7.1.2 Breast-feeding

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

7.1.3 Pediatrics

Pediatrics (18 years old): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4 Geriatrics

Geriatrics (>65 years old): No data are available to Health Canada.

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.

Isolated cases: mild skin atrophy due to flumethasone pivalate.

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

Local adverse reactions reported during topical treatment with glucocorticoids include contact allergy, changes in skin pigmentation, and secondary infections. Topically applied glucocorticoids may give rise to striae rubrae distensae, telangiectasia, purpura, skin atrophy or steroid acne, especially if applied for prolonged periods of time, under occlusive dressings, to large areas or to permeable areas (e.g., face, axillae).

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 a period shorter than 1 month following the use of LOCACORTEN VIOFORM.

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

Clioquinol, the antimicrobial component of LOCACORTEN VIOFORM (flumethasone pivalate and clioquinol), 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.

LOCACORTEN VIOFORM combines the antifungal and antibacterial effects of clioquinol with the anti-inflammatory and antipruritic effects of flumethasone.

11 STORAGE, STABILITY AND DISPOSAL

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

12 SPECIAL HANDLING INSTRUCTIONS

Not Applicable

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

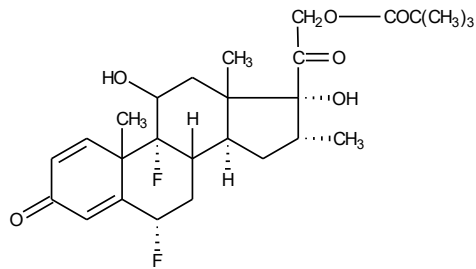
Drug Substances

Proper name: Flumethasone pivalate

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

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

Structural formula:



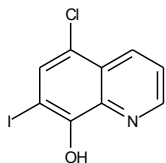
Physicochemical properties: Virtually white, odorless, fine crystalline powder. Slightly soluble in methanol and ethanol, very slightly soluble in chloroform and methylene chloride, and is insoluble in carbon tetrachloride and isooctane.

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

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

The non-clinical toxicology data, on which the original indication was authorized, is not available.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrLOCACORTEN® VIOFORM®

flumethasone pivalate and clioquinol cream

Read this carefully before you start taking **LOCACORTEN VIOFORM** 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**.

What is LOCACORTEN VIOFORM used for?

LOCACORTEN VIOFORM is used to:

- relieve symptoms such as itching and redness in infected, inflammatory skin diseases.
- stop the growth of bacteria and fungi that cause certain types of skin infections.

How does LOCACORTEN VIOFORM work?

LOCACORTEN VIOFORM contains two medicinal ingredients. Flumethasone pivalate belongs to a group of medicines called corticosteroids which fights inflammation. Clioquinol is an antibacterial and antifungal agent.

What are the ingredients in LOCACORTEN VIOFORM?

Medicinal ingredients: flumethasone pivalate and clioquinol

Non-medicinal ingredients: cetyl alcohol, cetyl palmitate atomized, glycerin, petrolatum white, phenoxyethanol, purified water, sodium lauryl sulfate, stearyl alcohol

LOCACORTEN VIOFORM comes in the following dosage forms:

Cream; 0.02% flumethasone pivalate and 3% clioquinol

Do not use LOCACORTEN VIOFORM if:

- you have skin viral infections (e.g., chicken pox, skin eruptions following vaccination, herpes), tuberculosis of the skin, syphilis, rosacea, acne, and perioral dermatitis (red rash to the skin around the mouth and nostrils).
- you are allergic to flumethasone pivalate, corticosteroids, hydroxyquinolines, clioquinol, other quinolone derivatives, iodine, or any other ingredients in LOCACORTEN VIOFORM.
- it is to be applied to ulcerated areas.
- it is to be applied 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. Talk about any health conditions or problems you may have, including if you:

- have kidney or liver problems.

- will be using LOCACORTEN VIOFORM in or around your ear and you have a ruptured ear drum.
- are pregnant or planning to become pregnant.
- are breast-feeding.

Other warnings you should know about:

- LOCACORTEN VIOFORM 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 with LOCACORTEN VIOFORM.
- You should tell any other healthcare professional that you see that you are being, or have been, treated with LOCACORTEN VIOFORM.

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:

- LOCACORTEN VIOFORM 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.
- Apply LOCACORTEN VIOFORM as directed in a thin layer to the affected areas only. Do not wrap or bandage the areas treated unless otherwise instructed by your healthcare professional.
- LOCACORTEN VIOFORM is for external use only. Do not take by mouth.
- Do not use LOCACORTEN VIOFORM in the eyes and be very cautious when using it near the eyes. If it gets in the eyes accidentally, flush them at once with plenty of water.
- If there is no improvement or if your skin condition becomes worse after you have used LOCACORTEN VIOFORM for 1 week, talk to your healthcare professional.
- LOCACORTEN VIOFORM has been prescribed for your present medical problem only. Do not use it to treat other skin conditions without checking with your healthcare professional first.
- LOCACORTEN VIOFORM may turn yellow when exposed to the air.
- LOCACORTEN VIOFORM may stain hair, fabric, skin or nails.

Usual dose:

LOCACORTEN VIOFORM should be applied to the affected areas in a thin layer 2 to 3 times daily.

Overdose:

If you think you, or a person you are caring for, have taken too much LOCACORTEN VIOFORM, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using LOCACORTEN VIOFORM?

These are not all the possible side effects you may have when taking LOCACORTEN VIOFORM. 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 site of application
- contact allergy
- changes in skin pigmentation
- secondary infections
- stretch marks, skin atrophy or acne

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 freezing.

Keep out of reach and sight of children.

If you want more information about LOCACORTEN VIOFORM:

- 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.

Last Revised: FEB 14, 2025