

Prescribing Information

VIOFORM® HYDROCORTISONE

(clioquinol 3% - hydrocortisone 1%)

Cream

Antibacterial - Antifungal Agent with Topical Corticosteroid

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Antibacterial - Antifungal Agent with Topical Corticosteroid

Actions and Clinical Pharmacology

Clioquinol, the antimicrobial component of VIOFORM HYDROCORTISONE (clioquinol/hydrocortisone), 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.

Hydrocortisone is a mild glucocorticoid with an anti-inflammatory, anti-allergic and vasoconstrictive effect. In inflammatory skin diseases of widely varying type and origin it affords prompt relief and eliminates symptoms such as pruritus.

VIOFORM HYDROCORTISONE combines the antifungal and antibacterial actions of clioquinol with the anti-inflammatory and antipruritic effects of hydrocortisone for broad control of acute and chronic dermatologic disorders.

Indications and Clinical Use

Anti-inflammatory, antibacterial, antifungal, anti-pruritic, anti-itch.

For temporary relief of:

- minor skin irritations associated with redness, itching, dryness and scaling
- minor skin irritations, rashes, itching and redness due to eczema, insect bites, poison ivy, poison oak, poison sumac, contact dermatitis (e.g. caused by soaps, detergents, cosmetics and/or jewellery), seborrheic dermatitis, psoriasis.

Contraindications

Viral infections of the skin (e.g., chicken pox, skin eruptions following vaccination, herpes simplex, herpes zoster), tuberculosis of the skin, syphilitic skin infections.

Known hypersensitivity to hydrocortisone or to corticosteroids in general, to hydroxyquinolines, clioquinol, or other quinoline derivatives, to iodine, as well as to any other components of VIOFORM HYDROCORTISONE (clioquinol/hydrocortisone) (see **Composition in Pharmaceutical Information section**).

Application to ulcerated areas.

Do not use in or around the eye.

Do not apply to large areas.

Do not use for the treatment of diaper rash, except on the advice of a health care practitioner.

Use in children under 2 years of age, except on the advice of a health care practitioner.

Warnings

For external use only.

If symptoms worsen or persist more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless directed by a health care practitioner.

Use in Pregnancy and Lactation:

The safety of VIOFORM HYDROCORTISONE (clioquinol/hydrocortisone) during pregnancy or lactation has not been established. Studies have shown that corticosteroids may induce fetal abnormalities in pregnant animals. The relevance of this finding to human use has not been elucidated. It is not known whether the active substances pass into breast milk when applied topically. Therefore, the potential benefit of VIOFORM HYDROCORTISONE, if used during pregnancy (particularly in the first three months) or lactation, should be weighed against possible hazard to the fetus or the nursing infant.

Precautions

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 be avoided.

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.

If no improvement occurs within 1 week, therapy should be discontinued; it is then advisable to identify and treat the causative pathogens.

VIOFORM HYDROCORTISONE (clioquinol/hydrocortisone) should not be used to treat bacterial or mycotic skin diseases in which acute inflammation is not present.

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

As a general rule, advise patients to inform physicians that they have been using corticosteroids.

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

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

In patients suffering from hepatic and/or renal failure, caution is indicated.

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

Interactions:

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

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

Adverse Reactions

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

If an exacerbation or an allergic type reaction occurs, treatment with VIOFORM HYDROCORTISONE (clioquinol/hydrocortisone) should be discontinued.

Local adverse reactions reported during topical treatment with glucocorticoids (predominantly with glucocorticoids more potent than hydrocortisone) include contact allergy, changes in skin pigmentation, 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). However, serious side effects caused by topically applied hydrocortisone are rare unless it is used excessively.

Symptoms and Treatment of Overdosage

Application to extensive and/or eroded areas of skin may lead to increased 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.

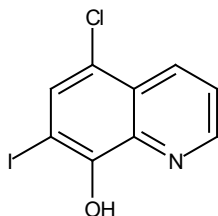
Dosage and Administration

Apply VIOFORM HYDROCORTISONE (clioquinol/hydrocortisone) to the affected area in a thin layer 2 to 3 times daily.

Use of VIOFORM HYDROCORTISONE under occlusive dressings is not recommended as the resulting humid conditions may promote secondary infections with non-sensitive organisms and also may increase the possibility of elevated PBI.

Pharmaceutical Information

Drug Substances



Clioquinol

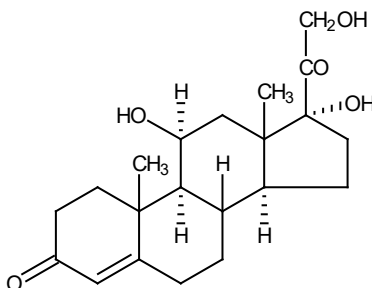
Chemical Name: 5-chloro-7-iodo-8-quinolinol

Molecular Formula: C₉H₅ClINO

Molecular Weight: 305.5

Description: Practically white to faintly yellowish powder.

Solubility: Freely soluble in pyridine, soluble in dimethylformamide and hot ethyl acetate, sparingly soluble in dioxane, slightly soluble in ethanol, practically insoluble in water.



Hydrocortisone

Chemical Name: Pregn-4-ene-3,20-dione

Empirical Formula: C₂₁H₃₀O₅

Molecular Weight: 362.47

Composition:

VIOFORM HYDROCORTISONE (clioquinol and hydrocortisone) Cream:

The cream contains the medicinal ingredients clioquinol and hydrocortisone and the non-medicinal ingredients: cetyl alcohol, cetyl palmitate, glycerin, petrolatum, phenoxyethanol, sodium lauryl sulfate, stearyl alcohol, and water.

Storage Conditions

Protect from heat (store between 15-30°C) and freezing. VIOFORM HYDROCORTISONE may turn yellow when exposed to air and may cause staining of the skin, nails, hair or fabrics.

Availability of Dosage Forms

VIOFORM HYDROCORTISONE (clioquinol and hydrocortisone) Cream:

Each tube of off-white water-soluble cream contains the medicinal ingredients clioquinol (3%) and hydrocortisone (1%). Available in 30 g tubes.

Information for the Consumer

Please read this information carefully before starting VIOFORM HYDROCORTISONE treatment.

What is VIOFORM HYDROCORTISONE?

The active ingredients of VIOFORM HYDROCORTISONE are clioquinol and hydrocortisone. Clioquinol is an anti-infective agent. Hydrocortisone belongs to a group of medicines called corticosteroids.

Non-medicinal Ingredients: Cetyl alcohol, cetyl palmitate, glycerin, petrolatum, phenoxyethanol, sodium lauryl sulfate, stearyl alcohol, water.

What does VIOFORM HYDROCORTISONE do?

Anti-inflammatory, antibacterial, antifungal, anti-itch
For temporary relief of:

- minor skin irritations associated with redness, itching, dryness and scaling;
- minor skin irritations, rashes, itching and redness due to eczema, insect bites, poison ivy, poison oak, poison sumac, contact dermatitis (e.g. caused by soaps, detergents, cosmetics and/or jewellery), seborrheic dermatitis, psoriasis.

Before starting treatment with VIOFORM HYDROCORTISONE

Be sure to tell your health care practitioner:

- if you have bleeding or blood clotting problem,
- if you have kidney or liver disease,
- if you have ever had any unusual or allergic reactions to corticosteroids, iodine or iodine - containing preparations, clioquinol or hydroxyquinolines,
- if you are pregnant or intend to become pregnant while using VIOFORM HYDROCORTISONE, or if you are breast-feeding or planning to breast-feed.

In these cases, your health care practitioner will decide whether you may apply VIOFORM HYDROCORTISONE to your skin.

How to use VIOFORM HYDROCORTISONE

For Adults and Children 2 years and older: Apply VIOFORM HYDROCORTISONE as directed in a thin layer to the affected areas only. Do not wrap or bandage the areas treated unless instructed to do so by your doctor. Do not apply to large areas or broken skin.

VIOFORM HYDROCORTISONE is for external use only. Do not take by mouth.

What side effects can VIOFORM HYDROCORTISONE have?

Like all medicines, VIOFORM HYDROCORTISONE may cause some unwanted effects in addition to the desired ones. Therefore, if redness, burning, itching or other signs not present before using VIOFORM HYDROCORTISONE occur, stop treatment and consult your doctor or pharmacist.

Other precautions

If symptoms worsen or persist more than 7 days or clear up and occur again within a few days, stop use of this product and consult a doctor. Do not begin use of any other hydrocortisone product unless directed by a health care practitioner.

Do not use VIOFORM HYDROCORTISONE 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.

Do not use for the treatment of diaper rash

Do not use if you have viral infection of the skin (e.g. chicken pox, herpes, rash following vaccination), tuberculosis of the skin, syphilitic skin infections.

Storage:

Protect from heat and freezing (store between 15-30 °C).

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

Keep out of reach of children.

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