PRODUCT MONOGRAPH
INCLUDING THE PATIENT MEDICATION INFORMATION

PrVALISONE-G®

Betamethasone 17-Valerate and Gentamicin Sulfate
Cream and Ointment
0.1% w/w

Topical Corticosteroid and Antibiotic

Bausch Health, Canada Inc.
2150 St-Elzear Blvd. West
Laval, Quebec
H7L 4A8

Date of Revision:
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Control #: 248385

NAME OF DRUG

PrVALISONE-G®
Betamethasone 17-Valerate and Gentamicin Sulfate
Cream and Ointment
0.1% w/w

THERAPEUTIC OR PHARMACOLOGICAL CLASSIFICATION

VALISONE-G is a combination of betamethasone as 17-valerate, an active ester of betamethasone for the topical treatment of allergic and inflammatory dermatoses and of the wide-spectrum antibiotic gentamicin (as gentamicin sulfate).

STRUCTURAL FORMULA AND CHEMISTRY

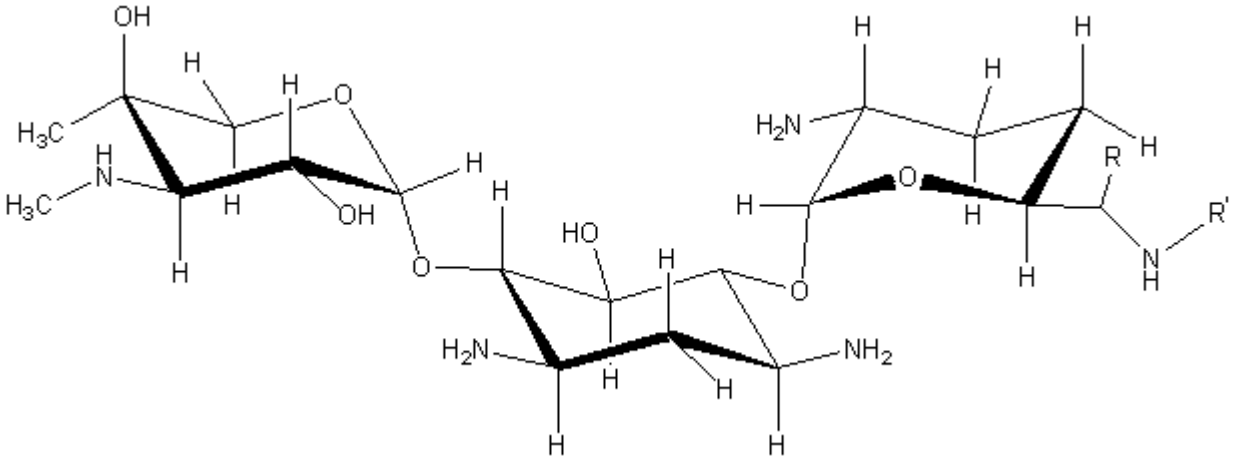
Gentamicin Sulfate

Gentamicin is derived from *Micromonospora purpurea* of the Actinomycetes group and is a heat-stable white powder that is soluble in water.

Gentamicin is a mixture of three components, namely,

Gentamicin C_1 R=R'=CH_3
Gentamicin C_2 R=CH_3; R'=H
Gentamicin C_{1a} R=R'=H

It has the following structural formula:

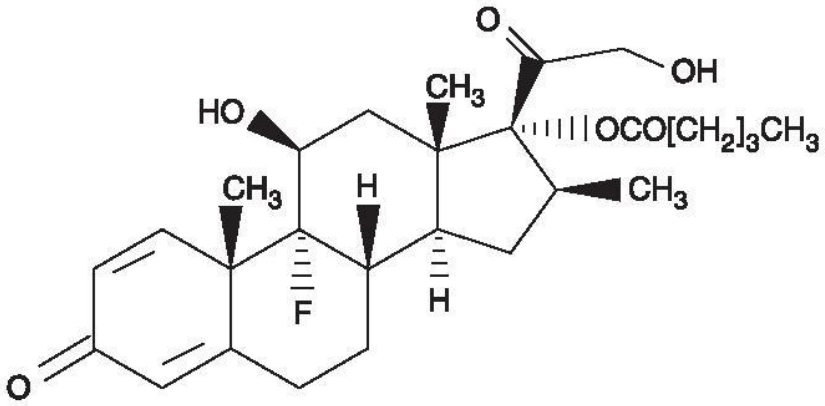


Betamethasone Valerate

Betamethasone 17-valerate is:

9α-fluoro-11β,17, 21-trihydroxy-16β-methylpregna-1,4-diene-3, 20-dione 17-valerate

It has the following structural formula:



ACTION

VALISONE-G provides the combined anti-inflammatory, anti-allergic, and anti-pruritic actions of betamethasone 17-valerate with the antibacterial topical effect of gentamicin.

INDICATIONS

VALISONE-G is indicated in the topical management of secondarily infected allergic or inflammatory dermatoses responsive to corticosteroid therapy, such as contact dermatitis, seborrheic dermatitis, neurodermatitis, intertrigo, exfoliative dermatitis, stasis dermatitis and psoriasis.

It is also indicated for the treatment of the aforementioned conditions whenever the possibility of secondary infection is present by gram-positive or gram-negative bacteria including *Streptococci, Staphylococcus* and species of *Pseudomonas, Aerobacter, Escherichia,* and *Klebsiella*, which are susceptible organisms to the topical action of gentamicin.

The VALISONE-G ointment may be preferred for the treatment of dry, scaling and fissured lesions.

VALISONE-G contains an antibacterial ingredient, gentamicin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of gentamicin, VALISONE-G should only be used for the authorized indication and clinical use.

CONTRAINDICATIONS

VALISONE-G is contraindicated in most viral diseases including chicken pox, herpes simplex and vaccinia, and in tuberculosis of the skin.

Application in or near the eyes must be avoided.

VALISONE-G is contraindicated in those patients with a history of sensitivity reactions to any of its components.

WARNINGS AND PRECAUTIONS

Susceptibility / Resistance

Development of Drug Resistant Bacteria
Prescribing VALISONE-G in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth
Use of topical antibiotics occasionally allows overgrowth of non-susceptible organisms, including fungi, yeasts or viruses. If this occurs or if irritation, sensitization or superinfection develops, treatment with VALISONE-G should be discontinued and appropriate therapy instituted.

Corticosteroids and gentamicin are known to be absorbed percutaneously in patients under prolonged treatment, with extensive body surface treatment or particularly in those using the occlusive dressing technique on large areas of the body. In such cases, it is recommended that kidney function studies such as B.U.N. be carried out prior to treatment and regularly throughout the course of the treatment.

Causal factors should be sought and eliminated whenever possible and the sensitivity of an infecting organism to gentamicin should be verified.

Percutaneous absorption of the corticosteroid can produce systemic effects such as adrenal suppression, moon facies, striae, suppression of growth in children. When long-term topical treatment under occlusive dressings is necessary, small dosages, rotation of sites and intermittent therapy should be considered.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Systemic absorption of topically applied gentamicin may be increased if extensive body surface areas are treated, especially over prolonged time periods or in the presence of dermal disruption. In these cases, the undesirable effects, which occur following systemic use of gentamicin, may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth and development of children.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

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

While no systemic effects have been observed following the topical application of gentamicin, toxic systemic concentrations can cause permanent impairment of vestibular function in the presence of renal insufficiency or existing 8th cranial nerve damage.

Caution should be exercised if gentamicin is used in individuals who are known to be sensitive to topically applied antibacterials.

The possibility of sensitivity reactions to any of the product's components should be kept in mind.

VALISONE-G cream or ointment are not for ophthalmic use.

Pregnancy and Lactation

The use of any drug during pregnancy and the lactation period or in women of childbearing age requires that the potential benefits of the drug be weighed against the possible hazards to the fetus or infant. Although topical steroids have not been reported to have had an adverse effect on the fetus, the safety of their use in pregnant patients has not been definitively established.

Accordingly, they should not be used extensively or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Children
Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

ADVERSE REACTIONS

The following local adverse reactions have been reported rarely with the use of topical corticosteroids: burning, itching, dryness, folliculitis, hypertrichosis, acneiform, eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.

The following may occur more frequently with occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae, millaria.

In patients with dermatoses treated with gentamicin, mild irritation (erythema and pruritus) that did not usually require discontinuance of treatment, has been reported in a small percentage of cases. There was no evidence of irritation or sensitization, however, in any of these patients patch tested subsequently with gentamicin or normal skin.

Possible photosensitization has been reported in several patients but could not be elicited in these patients by reapplication of gentamicin followed by exposure to UV radiation.

OVERDOSE: SYMPTOMS AND TREATMENT

Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

A single overdose of gentamicin would not be expected to produce symptoms.

Excessive prolonged use of topical gentamicin may lead to overgrowth of lesions by fungi or non-susceptible bacteria.

Treatment of accidental ingestion: there is no known antidote, but gastric lavage should be performed.

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

Appropriate antifungal or antibacterial therapy is indicated if overgrowth occurs.

PHARMACOLOGY

Betamethasone 17-valerate

Clinical trials and extensive experience now available have established the effective activity of betamethasone 17-valerate in the suppression of inflammatory reactions, prompt and prolonged control of pruritus, erythema, swelling, and infiltration, which are common manifestations of allergic conditions. Reduction of scratching decreases the like hood of exacerbating the lesions of producing secondary infection. Clinical trials by numerous dermatologists who have used betamethasone 17-valerate in various localized and generalized corticosteroid-responsive diseases, indicated a high incidence of good to excellent results, either by inunction or under occlusive dressings.

Gentamicin sulfate

This wide spectrum antibiotic was developed in the Research Laboratories of Schering Corporation. It has proven to be very effective in the topical treatment of primary and secondary bacterial infections of the skin. In vitro, antibacterial activity of gentamicin shows this antibiotic to be bactericidal against a wide variety of gram-positive and gram-negative bacteria. At concentrations of 4 mcg/mL or less, gentamicin inhibited 95% of the strains of *Staphylococcus aureus* and 70 to 90% of the strains of *Escherichia coli* and *Aerobacter aerogenes*.

Bacteria sensitive to gentamicin include *Streptococci* (group A beta hemolytic, alpha hemolytic) *Staphylococcus aureus* (coagulase postitive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria *Pseudomonas aeruginosa*, *Aerobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris,* and *Klebsiella pneumoniae*.

Clinically, gentamicin has proven to be effective in the treatment of Impetigo contagiosa, superficial folliculitis, ecthyma, furunculosis, sycosis barbae, and pyoderma gangrenosum; also secondary skin infections such as eczematoid dermatitis, pustular acne, pustular psoriasis, infected seborrheic dermatitis, infected contact dermatitis (including poison Ivy), infected excoriations, and bacterial superinfections of fungal or viral infections. Results of cutaneous patch tests in 100 patients demonstrated that the antibiotic was not a primary irritant.

DOSAGE AND ADMINISTRATION

A thin film of VALISONE-G cream or ointment should be applied to cover completely the affected area two or three times daily.

Refractory lesions of psoriasis and deep-seated dermatoses which have been secondarily infected may respond better to topical corticosteroids and antibiotics when used with the hydration technique or occlusive dressing described below.

Occlusive Dressing Technique

1. Apply a thick layer of medication over the entire surface of the lesion under a light gauze dressing and cover it with a pliable, transparent, impermeable, plastic material well beyond the edges of the treated area.
2. Seal the edges to the normal skin by adhesive tape or other means.
3. Leave the dressing in place one to three days and repeat the procedure three or four time as needed.

With this method of treatment, marked improvement often is seen in a few days. However, this technique requires closer supervision of the patient since occasionally miliary eruptions of folliculitis develop in the skin under and occlusive dressing, requiring removal of the plastic cover and/or discontinuance of this method of treatment.

AVAILABILITY

Cream

Each g of cream contains: Betamethasone Valerate USP equivalent to 1.0 mg (0.1%) Betamethasone Alcohol and Gentamicin Sulfate USP equivalent to 1.0 mg (0.1%) of gentamicin base.

The microdispersion of these active ingredients in a greaseless, odorless, non-staining, washable and cosmetically pleasing cream insures effective contact with the skin and rapid onset of action of the steroid and the antibiotic.

Non-medicinal ingredients: Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Monobasic Sodium Phosphate, Phosphoric Acid, Polyethylene Glycol 1000 Monocetyl Ether, Purified Water, Sodium Hydroxide and White Petrolatum.

Tubes of 2 g (physician sample) and 30 g.

Ointment

Each g of ointment contains: Betamethasone Valerate USP equivalent to 1.0 mg (0.1%) Betamethasone Alcohol and Gentamicin Sulfate USP equivalent to 1.0 mg (0.1%) of gentamicin base.

The microdispersion of these active ingredients in an odorless, non-staining ointment base insures effective contact with the skin and rapid onset of action of the steroid and the antibiotic.

Non-medicinal ingredients: White Petrolatum USP.

Tubes of 30 g.

STORAGE

Store at 15 to 30˚C.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrVALISONE-G®
Betamethasone 17-Valerate and Gentamicin Sulfate
Cream and Ointment
0.1% w/w

Read this carefully before you start taking VALISONE G 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 VALISONE G.

What is VALISONE G used for?
VALISONE-G is used to treat inflamed skin (dermatosis) that may be infected by bacteria.

VALISONE-G contains an antibacterial ingredient called gentamicin, and it should be used exactly as directed by your healthcare professional.

How does VALISONE-G work?
VALISONE-G contains two medicines that work together in different ways:
- Betamethasone 17-valerate is used to relieve swelling, redness, and itching
- Gentamicin sulfate is a topical antibacterial agent to prevent and treat infection.

What are the ingredients in VALISONE-G?

Medicinal ingredients: Betamethasone Valerate USP and Gentamicin Sulfate USP.
Non-medicinal ingredients:
- **Cream:** Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Monobasic Sodium Phosphate, Phosphoric Acid, Polyethylene Glycol 1000 Monocetyl Ether, Purified Water, Sodium Hydroxide, and White Petrolatum.
- **Ointment:** White Petrolatum.

VALISONE –G comes in the following dosage forms:
Cream or ointment.

Do not use VALISONE-G:
- If you are allergic to any of the ingredients in VALISONE-G (see "What are the ingredients in VALISONE-G?") or the materials of the container.
- If you have viral diseases including chicken pox, herpes simplex, and vaccinia, and in tuberculosis of the skin.
- In or near the eyes.

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

- Your condition gets worse or you have any other skin reactions or infections.
- You use other medicines that contain steroids.
- You are pregnant or planning to get pregnant.
- You are breast-feeding or plan to breast-feed.

Other warnings you should know about:
Using too much VALISONE-G may increase your chance of experiencing side effects. See "What are possible side effects from using VALISONE-G?", below.

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

How to take VALISONE-G

- Apply a thin film of VALISONE-G (cream or ointment) to completely cover the affected area two or three times daily.
- Although you may feel better early in treatment, VALISONE-G should be used exactly as directed.
- Misuse or overuse of VALISONE-G could lead to the growth of bacteria that will not be killed by gentamicin. This means that VALISONE-G or other medicines that contain gentamicin may not work for you in the future.
- Do not share your medicine.

Usual dose:
Apply two or three times daily.

Overdose:
Using this drug for longer than recommended, can lead to medical conditions, such as Cushing's disease or adrenal suppression.

If you think you have taken too much VALISONE-G, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you forget to use VALISONE-G as directed, apply it as soon as possible, then go back to your regular schedule.

What are possible side effects from using VALISONE-G?
Common side effects when used with occlusive dressings

- softening and breaking down of skin
- secondary infection
- thinning of skin
- stretch marks

- heat rash

Less common side effects include
- burning, itching, dryness
- inflammation around hair and mouth
- excessive hair growth
- acne
- skin discoloration

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	
Allergic reaction : rash, hives			✓
Adrenal effects: Fatigue, increased urination / thirst, problems controlling blood sugar levels, weakness, weight loss.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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/adverse-reaction-reporting.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 at 15 to 30°C.
Keep out of reach and sight of children.

If you want more information about VALISONE-G:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer 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) or by calling 1-800-361-4261.

This leaflet was prepared by:

Bausch Health, Canada Inc.
2150 St-Elzear West
Laval, Quebec
H7L 4A8
www.bauschhealth.ca

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