

Dexaltin Oral Paste

— Dexamethasone Paste —

A Therapeutic Agent for Diseases of the Oral Mucosa

COMPOSITION

Dexaltin Oral Paste contains the following components.

Active ingredient and content	Dexamethasone 1.0 mg/g
Inactive ingredient	Liquid paraffin, sodium polyacrylate, hydrocarbon gel

EFFICACY AND INDICATIONS

Intractable stomatitis or glossitis associated with erosion or ulceration.

DOSAGE

Usually apply an adequate amount of Dexaltin Oral Paste to the affected area 1 to several times daily. The dose may be increased or decreased depending on the condition of the patient.

CONTRAINDICATIONS

Dexaltin Oral Paste should not be used on the following patients:

- (1) Patients with tuberculous, viral or other purulent infections of the oral cavity.
- (2) Patients with a past history of hypersensitivity to Dexaltin Oral Paste.

SIDE EFFECTS

No severe side effects of Dexaltin Oral Paste have been reported except for the withdrawal of the drug from one patient for a complaint of numbness at the site of application.

Adverse reactions

- (1) Infection of the oral cavity: Fungal or bacterial infection of the oral cavity may occur in the course of treatment with Dexaltin Oral Paste. In case that any symptom or sign of such an infection has appeared, an appropriate antifungal or antibacterial treatment should concomitantly be instituted. In cases where the symptoms or signs of the infection fail to subside rapidly, withdraw Dexaltin Oral Paste.
- (2) Hypersensitivity: On manifestation of any allergic reaction, withdraw Dexaltin Oral Paste.
- (3) Function of the pituitary-adrenocortical system: The prolonged use of Dexaltin Oral Paste may be associated with hypofunction of the pituitary-adrenocortical system.
- (4) Vision, blurred

PREGNANCY AND LACTATION

The safety of Dexaltin Oral Paste when used during pregnancy has not yet been established. Its prolonged use on pregnant women or women suspected of pregnancy should be avoided.

ADMINISTRATION TO INFANTS AND CHILDREN

The prolonged use of Dexaltin Oral Paste may be associated with growth and development disturbances.

WARNING AND PRECAUTIONS

- (1) No food or fluid should be ingested for a short time after application of Dexaltin Oral Paste.
- (2) Dexaltin Oral Paste should by no means be applied to the eye.
- (3) 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.

PHARMACODYNAMICS

Dexamethasone is a synthetic adrenocortical steroid and exerts anti-inflammatory effects by the same mechanism of action as naturally occurring glucocorticoids, but the mineralocorticoid action of dexamethasone is weaker than those of naturally occurring glucocorticoids.

PHARMACOKINETICS

Dexamethasone is readily absorbed from the gastro-intestinal tract. Its biological half-life in plasma is about 190 minutes. Binding of dexamethasone to plasma proteins is about 77%, which is less than for most other corticosteroids. Up to 65% of a dose is excreted in urine within 24 hours. Clearance in premature neonates is reported to be proportional to gestational age, with a reduced elimination rate in the most premature. It readily crosses the placenta with minimal inactivation.

CLINICAL APPLICATION

The results of clinical trials of Dexaltin Oral Paste including double-blind controlled trials on a total of 49 patients mostly with radiation stomatitis at 8 medical institutions in Japan are given in summary form below.

Number of patients by response					
Marked improvement	Moderate improvement	Slight improvement	No change	Aggravation	Total
3	13	23	8	2	49

Number of patients by patient's impression of medication					
Good	Fair	Ordinary	Slightly poor	Poor	Total
11	21	10	5	2	49

Number of patients by utility rating					
Very useful	Moderately useful	Slightly useful	Unuseful	Unusable	Total
1	22	22	4	0	49

DESCRIPTION

Description of Oral Paste

Dexaltin Oral Paste is a white, smooth Oral Paste. It is practically odorless.

Physicochemical properties of active Ingredient

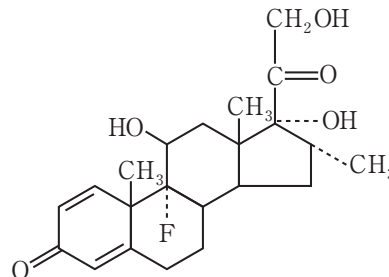
Nonproprietary name: Dexamethasone.

Chemical name: 9-Fluoro-11 β ,17,21-trihydroxy-16 α -methylpregna-1,4-diene-3,20-dione

Molecular formula: C₂₂H₂₉FO₅

Molecular weight: 392.46

Chemical structure:



Description: Dexamethasone occurs as white to light yellow crystals or a crystalline powder. It is odorless. It is sparingly soluble in methanol, in ethanol, in acetone or in dioxane, slightly soluble in chloroform, and practically insoluble in ether.

CAUTION FOR HANDLING

Storage

Keep in a tight container below 30°C.

PACKING

Dexaltin Oral Paste

1 tube of 2 g

50 tubes of 2 g

MANUFACTURER

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DATE OF REVISION

3rd August 2020