

The document on the right is a patient prescription instruction, printed on poor quality paper in 5 pt. type.

It was scanned and OCR'd by the three leading AT providers and displayed in their respective Text to Speech readers.

The images are the actual screen shots of the respective readers.



Kurzweil Educational Systems



COLLIGO

Information for Patients: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered or wrapped, so as to be occlusive, unless directed by the physician.
4. Patients should report any signs of local adverse reactions to the physician.

Laboratory Tests: The following tests may be helpful in evaluating patients for HPA axis suppression:

- ACTH stimulation test
- AM plasma cortisol test
- Urinary free-cortisol test

Carotogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

Studies in the rat following oral administration of dosage levels up to 50 mg/kg per day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Clobetasol propionate was non-mutagenic in three different test systems: the Ames test, the Saybrook-mouse chromosome gene conversion assay, and the *E. coli* WMP2 fluctuation test.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Topical corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at unusually low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

Clobetasol propionate has not been tested for teratogenicity when applied topically, however, it is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rat and mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent.

Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the highest dose tested (1 mg/kg) and teratogenicity at all dose levels tested (0.03 mg/kg). These doses are approximately 0.35 and 0.57 times, respectively, the human topical dose of clobetasol propionate cream and ointment. Anomalies often included cleft palate and skeletal abnormalities. In infants, clobetasol propionate was teratogenic at doses of 3 and 10 mg/kg. These doses are approximately 0.001 and 0.003 times, respectively, the human topical dose of clobetasol propionate cream and ointment. Anomalies seen included cleft palate, craniofacial, and other skeletal abnormalities.

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. Clobetasol propionate cream and ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when other clobetasol propionate cream or ointment is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of clobetasol propionate cream and ointment in pediatric patients have

not been established. Use in children under 12 years of age is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adverse effects during or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and 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 an absence of response to ACTH stimulation. Manifestations of hypothalamic-pituitary-adrenal axis dysfunction include long-term effects, such as osteoporosis and hypotension.

ADVERSE REACTIONS

In controlled clinical trials, the most frequent adverse reactions reported for clobetasol propionate cream were burning and stinging sensation in 1% of treated patients. Less frequent adverse reactions were itching, skin atrophy, and cracking and fissuring of the skin.

In controlled clinical trials, the most frequent adverse events reported for clobetasol propionate ointment were burning sensation, irritation, and itching in 0.5% of treated patients. Less frequent adverse reactions were stinging, cracking, exchyma, folliculitis, numbness of fingers, skin atrophy, and telangiectasis.

Cushing's syndrome has been reported in infants and adults as a result of prolonged use of topical clobetasol propionate formulations.

The following additional local adverse reactions have been reported with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings or higher potency corticosteroids. These reactions are listed in an approximately decreasing order of occurrence: dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, irritation, striae, and telangi.

OVERDOSAGE

Topically applied, clobetasol propionate cream and ointment can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

INDICATIONS AND ADMINISTRATION

Apply a thin layer of clobetasol propionate cream or ointment to the affected skin areas twice daily and rub gently and completely.

Clobetasol propionate cream and ointment are super-high potency topical corticosteroids; therefore, treatment should be limited to 2 consecutive weeks, and amounts greater than 50 g per week should not be used.

As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Clobetasol propionate cream and ointment should not be used with occlusive dressings.

HOW SUPPLIED

Clobetasol Propionate Cream USP 0.05% is supplied in:

15 g (0.53 oz) tubes	30 g (1.1 oz) tubes
45 g (1.58 oz) tubes	60 g (2.2 oz) tubes

Clobetasol Propionate Ointment USP 0.05% is supplied in:

15 g (0.53 oz) tubes	30 g (1.1 oz) tubes
45 g (1.58 oz) tubes	60 g (2.2 oz) tubes

Store in controlled room temperature 15°-30°C (59°-86°F). Do not refrigerate.

Manufactured by
Alpha USP Inc.
Baltimore, MD 21244

FORM NO. 04000401

Rev. 1-10
V01039



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ReadText - [C:\Program Files\ReadText\first.txt]

File Control Edit Format Insert Website Window Help

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Speaker: ATT DTVN 1.4 Mike

Format: 48kHz 16Bit Stereo

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Platform	 Kurzweil Educational Systems 1000/3000	 OpenBook	 Scan N Talk
OCR Errors	Too Many to Count	22	Only errors were 2 punctuation marks
Price	\$995.00+ Scanner extra	\$950.00 Scanner extra	\$399.00 Scanner included
<u>Intelligent Voice Engine</u>	No	No	Yes
Scan Speed	45 seconds	47 seconds	25 seconds
Voices Used	VoiceText (\$95.00 additional)	RealSpeak at 22 kHz or ViaVoice.	AT&T Natural Voices * at 48 kHz

Conclusion: Scan N Talk... Less expensive, more features, less editing with best voices!

*Award winning technology.

