

PRODUCT NAME
CLONEOCOL CREAM

(Clobetasole Propionate ,Neomycin Sulphate &
Nystatin Cream)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

GENERIC NAME: - Clobetasole Propionate ,Neomycin Sulphate & Nystatin Cream

BRAND NAME - CLONEOCOL

2. Qualitative and quantitative composition

Composition

Each gram Contains:

Clobetasol Propionate	USP	0.5mg
Neomycin Sulphate	USP	
Eq. to Neomycin		3.5gm
Nystatin BP		100000 units
Cream Base		Qs.

3. Pharmaceutical form

Cream

A smooth white cream.

4. Clinical particulars

4.1 Therapeutic indications

Clobetasol/neomycin/nystatin Cream is indicated in more resistant dermatoses such as recalcitrant eczemas and psoriasis (excluding widespread plaque psoriasis) where secondary bacterial or candidal infection is present, suspected or likely to occur, as when using occlusive dressings.

4.2 Posology and method of administration

Posology

There is no separate dosage schedule for the young or elderly.

Method of administration

Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days.

4.3 Contraindications

if you are allergic to clobetasol propionate, neomycin sulfate, nystatin or any of the other ingredients of this medicine (listed in section 6) - on a child under 2 years old - to treat any of the following skin problems, it could make them worse: - acne - severe flushing of skin on and around your nose .

4.4 Special warnings and precautions for use

CLOBETASOL PROPIONATE+NEOMYCIN should be used with proper caution and consultation of doctor if have any fungal infections (candida infections, ringworm or athlete's foot) or any viral infections (herpes or chickenpox), acne, rosacea (redness of the skin with small, red, pus-filled bumps on the face), and psoriasis.

4.5 Interaction with other medicinal products and other forms of interaction

CLOBETASOL PROPIONATE+NEOMYCIN may interact with water pills (furosemide), antibiotics (bacitracin, polymyxin b), corticosteroids (prednisone), and drugs that lower the immune system (cyclosporine)

4.6 Fertility, pregnancy and lactation

Pregnancy:

Clobetasol Propionate Neomycin Sulphate and Miconazole Nitrate Cream **belongs to a pregnancy category C**. In short, it can be harmful to an unborn baby. So, consult with the doctor before using this medicine in case of pregnancy.

Lactation:

If your doctor says you need to, **you can use clobetasol products while you are breastfeeding**. It is not known how much passes into breast milk but it's likely to be a tiny amount.

Fertility:

Clobetasol Propionate Neomycin Sulphate and Miconazole Nitrate Cream is not usually recommended for use when pregnant. A dermatologist (skin care specialist) may prescribe it if they feel the benefits outweigh the risks. Small amounts used on small areas of skin are unlikely to cause any problems in pregnancy.

4.7 Effects on ability to drive and use machines

Clobetasol Propionate Neomycin Sulphate and Nystatin Cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Your doctor may want your eyes be checked by an ophthalmologist (eye doctor). Check with your doctor right away if you have a skin rash, blistering, burning, crusting, dryness, flaking of the skin, itching, scaling, severe redness, stinging, swelling, or irritation on the skin.

Reporting of suspected adverse reactions

Clobetasol Propionate Neomycin Sulphate and Nystatin Cream include burning, tingling, rash, swelling, and infections. These are not all the possible side effects of clotrimazole and betamethasone dipropionate cream.

4.9 Overdose

Burning, itching, irritation, or dryness at the application site may occur when this medication is first applied to the skin. This should disappear in a few days as your body adjusts to the medication. If any of these effects last or get worse, notify your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: stretch marks, skin thinning/discoloration, acne, extreme/unwanted hair growth, small red bumps on the skin (folliculitis). Skin infections can become worse when this medication is used. Tell your doctor if redness, swelling, or irritation does not improve. Rarely, it is possible this medication will be absorbed from the skin into the bloodstream. This can lead to side effects of too much corticosteroid. These side effects are more likely in children, and in people who use this medication for a long time or over large areas of the skin. Tell your doctor right away if any of the following side effects occur: unusual/extreme tiredness, weight loss, headache, swelling ankles/feet, increased thirst/urination, vision problems.

Clobetasol Propionate

Acute overdose is very unlikely to occur, however, in the case of chronic overdose or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

Neomycin Sulphate

If systemic absorption of neomycin sulphate is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored. Blood levels of neomycin sulphate should also be determined. Haemodialysis may reduce the serum level of neomycin sulphate.

Nystatin

However, do not use this medicine more often or for a longer time than your doctor ordered. To do so may increase absorption through your skin and the chance of side effects.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action

The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis. The use of nystatin in the local treatment of candidal infections of the skin and of neomycin as a broad-spectrum antibiotic is well known.

Pharmacodynamic Effects

Corticosteroids bind to the glucocorticoid receptor inhibiting pro-inflammatory signals, while promoting anti-inflammatory signals. Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces.

5.2 Pharmacokinetic properties

May cause atrophic changes in the skin e.g. skin thinning, striae and dilatation of superficial blood vessels. Pigmentation and hypertrichosis. If there is substantial systemic absorption, neomycin may prolong and intensify respiratory depressant effects of neuromuscular blockers.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clobetasol Propionate Neomycin Sulphate and Nystatin Cream was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats Clobetasol Propionate Neomycin Sulphate and Nystatin Cream and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical particulars

6.1 List of excipients

Cetostearyl Alcohol, CM 1000, Propyl Glycol Plain, LLP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dark place .

6.5 Nature and contents of container

Lami tube with cap.

Pack sizes: 25GM

6.6 Special precautions for disposal and other handling

No special requirements

7.0 EXPORTER

TRIOPLUS PHARMACEUTICALS PVT. LTD.
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8.0 MANUFACTURER

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B-75, Roop Nagar Industrial Area, Loni,
Ghaziabad (UP)- 201102

9.0 MARKETING AUTHORITY

SUITELIFE PHARMACEUTICAL LTD.
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Surulere, Lagos, Nigeria..