Prescribing Information

1. NAME OF THE MEDICINAL PRODUCT

POLYCUTAN®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole 1% w/w
Neomycin sulfate 0.645% w/w
Dexamethasone acetate 0.044% w/w

Excipients with known effect:
Polycutan contains Cetostearyl alcohol and Benzyl alcohol.

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Dermal white cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of dermatitis involving also a bacterial and/or fungal infection.

4.2 Posology and method of administration

Polycutan is for external topical use only.
Apply a thin layer of the cream twice daily (morning and evening) on the affected area and massage into the skin. If there is no improvement within a few days or if there is worsening, the condition should be assessed.

4.3 Contraindications

- Hypersensitivity to the active substances , to other aminoglycoside antibiotics or to any of the excipients listed in section 6.1.
- Skin lesions, caused by infection with viruses (e.g. herpes simplex, chicken pox), or bacteria (e.g. impetigo).
- Use is not indicated in treatment of secondary infections due to *Pseudomonas* or *Proteus* species.
- Due to the known ototoxic and nephrotoxic potential of neomycin sulfate, the use of this medicine in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.
- The cream should not be applied in the external auditory canal of patients with perforated eardrum.
- Do not use the cream to treat nail or scalp infections

4.4 Special warnings and precautions for use

Polycutan is not intended for ophthalmic use.

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

Visual disturbance
Visual disturbance may be reported with systemic 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 if systemic and topical corticosteroids.

Paediatric population
A possibility of increased absorption exists in very young children: in neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature.

In infants and children, long-term continuous topical therapy should be avoided where possible, as adrenal suppression can occur even without occlusion. In infants, the napkin may act as an occlusive dressing, and increase absorption.

Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents.

As with all corticosteroids prolonged application to the face is undesirable.

Extended or recurrent application may increase the risk of contact sensitisation.

Extension of infection may occur due to the masking effect of the steroid.

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; and neomycin has nephrotoxic potential.

In renal impairment the plasma clearance of neomycin is reduced.

Products which contain antimicrobial agents should not be diluted.

Excipient with known effect
This product contains Cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). The cream also contains Benzyl alcohol which may cause allergic reactions and mild local irritation.

Instruct patients not to smoke or go near flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

- Following significant systemic absorption, neomycin can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

- Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Fertility, Pregnancy and lactation

Fertility:

Clotrimazole
No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

Neomycin sulfate and Dexamethasone acetate
No data available.

Pregnancy and Lactation:

Clotrimazole
There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses (see section 5.3). At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician.
There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. Clotrimazole may be used during lactation.

Dexamethasone acetate
Topical application of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. There may, therefore, be a very small risk of such effects in the human fetus.
There is inadequate evidence of safety with topical corticosteroids in human pregnancy.

Neomycin sulfate
There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of this medicinal product is not recommended in pregnancy or lactation

4.7 Effects on ability to drive and use machinery

There is no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Clotrimazole

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.

Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity.

Vascular disorders: syncope, hypotension.

Respiratory, thoracic and mediastinal disorders: dyspnoea.

Skin and subcutaneous tissue disorders: blisters, contact dermatitis, erythema, paraesthesia, skin exfoliation, pruritus, rash, urticaria, stinging/burning sensation of the skin.

General disorders and administration site conditions: application site irritation, application site reaction, oedema, pain.

Corticosteroids

Eye disorders
Not known (cannot be estimated from the available data): Vision, blurred (see also section 4.4).

Skin and Subcutaneous Tissue Disorders
Not known (cannot be estimated from available data): Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

If signs of hypersensitivity appear, application should be stopped immediately.

Exacerbation of symptoms may occur.

Local atrophic changes may occur where skin folds are involved, or in areas such as the nappy area in small children, where constant moist conditions favour the absorption. Sufficient systemic absorption may also occur in such sites to produce the features of hypercorticism and suppression of the HPA axis after prolonged treatment. The effect is more likely to occur in infants and children, and if occlusive dressings are used.

There are reports of pigmentation changes and hypertrichosis with topical steroids.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

In additionally, you can report to Padagis via the following address: padagis.co.il

4.9 Overdose

Clotrimazole
No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

Neomycin sulfate and Dexamethasone acetate
Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.
Also, consideration should be given to significant systemic absorption of neomycin sulfate (see 4.4 Special Warnings and Precautions for Use). If this 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 sulfate should also be determined. Haemodialysis may reduce the serum level of neomycin sulfate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code:

Clotrimazole D01AC01
Dexamethasone D07AB19, D07CB04
Neomycin D06AX04

Mechanism of action

Clotrimazole
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane. Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.
Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.
In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram- negative microorganisms (Bacteroides).
In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.
Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

Neomycin sulfate
Broad-spectrum bactericidal antibiotic effective against the majority of bacteria commonly associated with skin infections..

Dexamethasone acetate
Anti-inflammatory and anti-allergic glucocorticoid. It is used topically for its anti-inflammatory effects which suppress the clinical manifestations of the disease in a wide range of disorders where inflammation is a prominent feature.

5.2 Pharmacokinetic properties

Clotrimazole
Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

Dexamethasone
Distribution
Dexamethasone is about 77% bound to human plasma proteins in vitro.
Elimination
The mean plasma half-life of dexamethasone is about 4 hours
Metabolism
Dexamethasone is metabolized mainly in the liver but also in the kidney.
Excretion
Dexamethasone and its metabolites are excreted in the urine.

5.3 Preclinical safety data

Clotrimazole
Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity. Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced foetal weights and decreased pup survival. In rats clotrimazole 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.

Neomycin sulfate and Dexamethasone
There are no preclinical data of relevance to the prescriber which are additional to that in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
2-Octyldodecanol
Cetostearyl alcohol
Cetyl Esters wax
Sorbitan monostearate
Polysorbate 60
Benzyl alcohol

Purified water

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

After first opening: 6 months.

6.4 Special precautions for storage

Store in a cool place below 25°C.
Caution! Inflammable material, keep away from fire!
Do not light a cigarette or expose to fire before the medicine has fully dried.

6.5 Nature and contents of container

An aluminum tube containing 15 or 30 grams of a cream

7 Manufacturer and Registration Holder

Padagis Israel Pharmaceuticals, 1 Rakefet St., Shoham, Israel

8 Registration Number

048-52-23172

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