Summary of Product Characteristics

Hycomycin

Skin Ointment

1. Name of the medicinal product

Hycomycin

2. Qualitative and quantitative composition

Active Ingredients

Hydrocortisone	2.5%
Neomycin sulfate	0.5%

For the full list of excipients see section 6.1

3. Pharmaceutical form

Ointment.

While-yellowish ointment**.**

4. Clinical particulars

4.1 Therapeutic indications

Allergic dermatoses and other corticosteroid-responsive inflammatory skin diseases, including atopic dermatitis, contact dermatitis, seborrheic dermatitis, anogenital pruritus, infantile eczema, and external otitis.

4.2 Posology and method of administration

Directions for Use:

Apply to the affected area 3-4 times daily.

4.3 Contraindications

Known hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

Topical corticosteroids are contraindicated in fungal infections, tuberculosis of the skin, varicella and herpes simplex.

The ointment should not be applied in the external auditory canal of patients with perforated eardrum.

4.4 Special warnings and precautions for use

Hycomycin Skin Ointment is not intended for ophthalmic use.

Patients and/or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids. Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure, although dose levels do not allow prediction of

the onset, type, severity or duration of reactions. Most reactions recover after either dose reduction or withdrawal, although specific treatment may be necessary. Patients/carers should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected. Patients/carers should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently.

Particular care is required when considering the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first degree relatives. These would include depressive or manic-depressive illness and previous steroid psychosis.

Ototoxicity and nephrotoxicity have been reported with the topical use of neomycin. This is especially important if the patient is also being concurrently treated with an aminoglycoside antibiotic. Therefore, caution is required when the preparation is prescribed for patients with aural or renal disease.

When using neomycin-containing preparations to control secondary infection in chronic dermatoses, it should be borne in mind that the skin is more liable to become sensitive to other substances, including neomycin.

Precautions

For Corticosteroids

If irritation, rectal bleeding or sensitization occurs, use should be discontinued.

Prolonged use of corticosteroids may produce systemic effects.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of potent steroids, use over large surface areas, prolonged use, and the use of occlusive dressings, tight-fitting diapers and plastic pants. Such patients should be periodically evaluated for evidence of HPA axis suppression. This is performed using urinary-free cortisol and adrenocorticotropic hormone (ACTH) stimulation tests. If HPA axis suppression is noted, an attempt should be made either to reduce the frequency of application, or to substitute a less potent steroid. Recovery of the HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids

If extensive areas are treated or if the occlusive technique is used, the possibility exists of increased systemic absorption and suitable precautions will be required in patients with electrolyte imbalance. gastrointestinal disturbances, diabetes, myopathy, cataract, renal or hepatic impairment, osteoporosis, and hemorrhage.

Systemic corticosteroids have also been implicated in the development, reactivation, perforation and delayed healing of peptic ulcers. In the presence of renal disease with a fixed or decreased glomerular filtration rate, systemic corticosteroids may cause edema.

Adrenocorticosteroids may promote progression of cataracts especially with the use of high- to very high-potency products in periorbital area.

Adrenocorticosteroids may cause an increase in the intraocular pressure especially with the use of high- to very high-potency products in periorbial area.

If a local infection is already present at the area of treatment an appropriate antimicrobial agent should be used concurrently since corticosteroids may cause an exacerbation of the infection while the local anesthetic effect may be decreased due to an alteration in the pH of the anesthetic agent by the local infection at the treatment site.

Corticosteroids may influence the immune system therefore caution should be exercised upon administration of these agents.

For Hycomycin Preparation

If sensitization or irritation occurs, medication should be discontinued. If the sensitivity is attributed to the antibiotic component, neomycin-containing products should be avoided by the patient in the future.

If local infection should continue or become severe, or in the presence of systemic infection, appropriate antimicrobial therapy should be instituted. If a favorable response is not obtained, this medication should be discontinued temporarily, until the infection has been controlled.

As with other antibiotic-containing preparations, prolonged use may result in overgrowth of non-susceptible organisms including fungi. Appropriate measures should be taken if this occurs.

When using neomycin-containing products to control secondary infection in chronic dermatoses, such as chronic otitis externa or stasis dermatitis, it should be borne in mind that the skin is more liable to become sensitive to other substances, including neomycin.

Because of the concern of possible nephrotoxicity and ototoxicity associated with neomycin, this preparation should not be used over a wide area or for extended periods of time.

Application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen (see Use in Pediatrics).

Laboratory Tests

The urinary free cortisol test and the ACTH stimulation test may be helpful in evaluating the HPA axis suppression.

Systemic effects of excessive levels of the cortisone component may include a reduction in the number of circulating eosinophils and a decrease in urinary excretion of 17-hydroxycorticosteroids.

Use in Pediatrics

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients, because of a larger skin surface area to body weight ratio. Therefore, application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Use in Geriatrics

For Corticosteroids

Reported clinical experience has not identified differences in responses between theelderly and younger patients. In general, dose selection for an elderly patient should be cautious using the least amount compatible with an effective therapeutic regimen and reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Excipient with known effect

This medicine contains lanolin anhydrous, that may cause local skin reactions (e.g. contact dermatitis).

This medicine contains methylparaben (Methyl p-hydroxybenzoate (E218)), that may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms ofinteraction

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

the neuromuscular blocking activity of neomycin sulfate is unlikely to present a hazard during use of this preparation.

4.6 Fertility, pregnancy and lactation

Use in Pregnancy

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. Infants born to mothers who have been treated with large amounts of corticosteroids during pregnancy, or for prolonged periods of time, should be observed carefully for signs of hypoadrenalism.

Use in Lactation

It is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, caution should be exercised when topical corticosteroids are applied to nursing mothers.

There is little information to demonstrate the possible effect of topically applied neomycin in lactation.

4.8 Undesirable effects

For Corticosteroids

The following local adverse reactions have been reported infrequently with topical corticosteroids: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations, and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults, the frequency of severe reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown.

General

Allergic cross-reactions may occur which could prevent the future use of any or all of the following antibiotics for the treatment of infections: kanamycin, paromomycin, streptomycin, gentamicin.

Signs of a sensitivity reaction to neomycin may appear, usually in the form of a low-grade reddening with swelling, dry scaling and itching, or simply as a failure to heal.

Hycomycin preparations are usually well tolerated. However, signs of sensitivity reactions to neomycin may appear. During long-term use of neomycin- containing preparation, periodic examination for such signs is recommended. If they occur, patients should be advised to discontinue treatment.

It should be noted that these adverse reactions may occur more frequently with occlusive dressings, tightfitting diapers or plastic pants.

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

5. Pharmacological properties

Mechanism of Action

Hycomycin preparations combine the potent anti-inflammatory and anti-allergic glucocorticoid hydrocortisone with the broad-spectrum antibiotic neomycin.
Hycomycin skin ointment incorporates the active ingredients hydrocortisone (alcohol-free) and neomycin sulfate, in a specially elaborated greasy base. Hydrocortisone (alcohol-free) has proved much more effective than the acetate form in the topical treatment of skin disorders.

6. Pharmaceutical particulars

List of excipients
White petrolatum, Mineral oil, Lanolin anhydrous, Paraffin hard, Super harlotan woolwax alcohols, Methylparaben, Butylparaben.

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

Special precautions for storage
Store in a dry place below 25°C.

Nature and contents of container
Each pack contains a tube of 15 gram of white-yellowish ointment.

7. Manufacturer and License Holder

Teva Israel Ltd.,
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8. Registration Number:

051.45.24387

This leaflet was revised in June 2022 according to Ministry of Health guidelines.