Summary of Product Characteristics

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

Dermal Ointment.

While-yellowish homogenous 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

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), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo).

Use is not indicated in treatment of primary or secondary infections due to yeast; or 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 ointment should not be applied in the external auditory canal of patients with perforated eardrum.

4.4 Special warnings and precautions for 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.

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.

Hycomycin Skin Ointment is not intended for ophthalmic use.

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.

Fire hazard in contact with dressings, clothing and bedding
Product contains paraffin. Instruct patients not to smoke or go near naked 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.

Excipient with known effect
Hycomycin 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 of interaction

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

4.6 Fertility, pregnancy and lactation

Pregnancy
There is inadequate evidence of safety with topical hydrocortisone in human pregnancy.
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 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 machines

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

4.8 Undesirable effects

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 of hydrocortisone. 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

4.9 Overdose

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

Pharmacotherapeutic group: Corticosteroids, weak, combinations with antibiotics , ATC code: D07CA01

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. 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.

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

5.2 Pharmacokinetic properties

Absorption
Hydrocortisone is absorbed through the skin particularly in denuded areas.

Biotransformation
Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol.

Elimination
Metabolites are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

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

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a dry place below 25°C.

6.5 Nature and contents of container

Each pack contains a tube of 15 gram ointment.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Manufacturer and License Holder

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

8. Registration Number

051.45.24387

This leaflet was revised in March 2023 according to MoH guidelines.