Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betnovate-N Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone	0.1 %w/w (as Betamethasone Valerate).
Neomycin Sulphate	0.5 %w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment
An off-white, homogenous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Betnovate-N skin preparations are indicated in the management of corticosteroid sensitive dermatoses actually or potentially complicated by infection due to micro-organisms sensitive to the anti-infective contained therein. Betnovate-N preparations are indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected or likely to occur: eczema, including atopic, infantile, discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses, including lichen simplex; lichen planus; seborrhoeic dermatitis; contact sensitivity reactions, insect bite reactions, prickly heat, anal and genital intertrigo, and otitis externa (see *Contraindications*).

4.2 Posology and method of administration

A small quantity should be applied to the affected area one to three times daily until improvement occurs or as directed by a physician. It may then be possible to maintain improvement by applying once a day or even less often.

Betnovate-N Ointment is especially appropriate for dry, lichenified or scaly lesions, but this is not invariably so.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betnovate-N can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions, thereafter improvement can usually be maintained by regular application without occlusion.

Treatment should not be continued for more than 7 days without medical supervision.

Betnovate-N is suitable for use in children (2 years and over) at the same dose as in adults. A possibility of increased absorption exists in very young children, thus Betnovate-N is not recommended for use in neonates and infants (<2 years) (see 4.3 Contraindications and 4.4 Special Warnings and Precautions for Use).

Use in the elderly:
Betnovate-N is suitable for use in the elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur (see 4.4 Special Warnings and Special Precautions for use).

Dosage in renal impairment:
Dosage should be reduced in patients with reduced renal function (see 4.4 Special Warnings and Special Precautions for Use).

4.3 Contraindications

Rosacea.
Acne vulgaris.
Perioral dermatoses.
Perianal and genital pruritus.
Primary cutaneous viral infections (e.g., herpes simplex, chickenpox).
Hypersensitivity to any component of the preparation.

Use of Betnovate-N skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria, primary or secondary infections due to yeast; secondary infections due to Pseudomonas or Proteus species; dermatoses in children under two years of age, including dermatitis and nappy eruptions.

Preparations containing neomycin should not be used for the treatment of otitis externa when the ear-drum is perforated, because of the risk of ototoxicity.

Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, the use of Betnovate-N in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur. A possibility exists in very young children, thus Betnovate-N is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced and renal function may be immature.

4.4 Special warnings and precautions for use

Prolonged use of an anti-infective may result in the development of superinfection due to organisms, including fungi, resistant to that anti-infective.

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion.

The anti-infective present may be toxic if absorbed from open surfaces.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus, erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.

If bacterial infection persists, systemic chemotherapy is required.

Any spread of infection requires withdrawal of topical corticosteroid therapy.

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

Products which contain antimicrobial agents should not be diluted.

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

Topical steroids may be hazardous in psoriasis for a number of reasons, including rebound relapses, development of tolerance, risk of generalized pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis, careful patient supervision is important.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied.

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 (see 4.2 Dosage in Renal Impairment).

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and lactation

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 Betnovate-N is not recommended in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

There are reports of pigmentation changes and hypertrichosis with topical steroids. Exacerbation of symptoms may occur.

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercorticism. This effect is more likely to occur in infants and children and if occlusive dressing are used. In infants, the napkin may act as an occlusive dressing. In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

The Betnovate preparations are usually well tolerated, but if signs of hypersensitivity appear, application should stop immediately.

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 gradually. However because of the risk of acute adrenal suppression this should be done under medical supervision.

Also consideration should be given to significant systemic absorption of neomycin sulphate (See 4.4 Special Warnings and Special 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 sulphate should also be determined.
Haemodialysis may reduce the serum level of neomycin sulphate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone valerate is an active corticosteroid that produces a satisfactory response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy and is often effective in the less responsive conditions such as psoriasis.

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

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroid is determined by many factors including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily by the liver and are then excreted by the kidneys.

5.3 Preclinical safety data

No additional data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin
Liquid Paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

Betnovate-N Ointment is supplied in collapsible 30 g aluminium tubes.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 44/23/2

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