SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Betnesol-N Eye, Ear and Nose Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone sodium phosphate PhEur (equivalent to 0.1% w/v betamethasone)	0.105% w/v.
Neomycin sulphate PhEur (equivalent to 0.385% w/v neomycin base)	0.5% w/v.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ear/Eye/Nose Drops, Solution

A colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Eye

Short-term treatment of steroid responsive inflammatory conditions of the eye when prophylactic antibiotic treatment is also required, after excluding the presence of viral and fungal disease.

Ear

Otitis externa or other steroid responsive conditions where prophylactic antibiotic treatment is also required.

Nose

Steroid responsive inflammatory conditions where prophylactic antibiotic treatment is also required.

4.2 Posology and method of administration

The frequency of dosing depends on the clinical response. If there is no clinical response within 7 days of treatment, the drops should be discontinued.

Treatment should be the lowest effective dose for the shortest possible time. Normally, Betnesol-N Drops should not be given for more than 7 days, unless under expert supervision. After more prolonged treatment (over 6 to 8 weeks), the drops should be withdrawn slowly to avoid relapse.

Eyes

1 or 2 drops applied to each affected eye up to six times daily depending on clinical response.

Ears

2 or 3 drops instilled into the ear three or four times daily.

Nose

2 or 3 drops instilled into each nostril two or three times daily.

4.3 Contraindications

Viral, fungal, tuberculous or purulent conditions of the eye. Fungal infections of the nose or ear. Use is contra-indicated if glaucoma is present or herpetic keratitis (e.g. dendritic ulcer) is considered a possibility. Use of topical steroids in the latter condition can lead to an extension of the ulcer and marked visual deterioration.

Otitis externa should not be treated when the eardrum is perforated because of the risk of ototoxicity.

Corticosteroids should not be used in patients with a perforated tympanic membrane.

Hypersensitivity to any component of the preparation.

4.4 Special warnings and precautions for use

A patient information leaflet should be supplied with this product.

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding.

Treatment with corticosteroid/antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infection due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation and the emergence of resistant organisms.

Ophthalmological treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular pressure, cataract formation or unsuspected infections.

Aminoglycoside antibiotics may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment. Although this effect has not been reported following topical ocular use, the possibility should be considered when high dose topical treatment is given to small children or infants.

Nasal administration of corticosteroids is not advised if an untreated nasal infection is present or if the patient has pulmonary tuberculosis or following nasal surgery (until healing has occurred).

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

4.5 Interaction with other medicinal products and other forms of interaction

Betnesol-N Drops contain benzalkonium chloride as a preservative and therefore should not be used as eye drops to treat patients who wear soft contact lenses.

4.6 Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

There is a risk of foetal ototoxicity if aminoglycoside antibiotic preparations are administered during pregnancy.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Patients should be warned not to drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

Hypersensitivity reactions, usually of the delayed type, may occur leading to irritation, burning, stinging, itching and dermatitis.

Topical corticosteroid use may result in corneal ulceration, increased intraocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects.

Intensive or prolonged use of topical corticosteroids may lead to formation of posterior subcapsular cataracts.

In those diseases causing thinning of the cornea or sclera, corticosteroid therapy may result in thinning of the globe leading to perforation.

Mydriasis, ptosis, epithelial punctate keratitis and glaucoma have also been reported following ophthalmic use of corticosteroids.

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Following nasal administration, the most common effects are nasal irritation and dryness, although sneezing, headache, lightheadedness, urticaria, nausea, epistaxis, rebound congestion, bronchial asthma, perforation of the nasal septum, ulceration of the nasal septum, anosmia, parosmia and disturbance to sense of taste have also been reported.

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses.

It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid, if possible, to the

lowest dose at which effective control of symptoms is maintained. In addition, consideration should also be given to referring the patient to a paediatric specialist.

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme on the MHRA website (www.mhra.gov.uk/yellowcard).

4.9 Overdose

Long-term intensive topical use may lead to systemic effects.

Oral ingestion of the contents of one bottle (up to 10ml) is unlikely to lead to any serious adverse effects.

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence of higher than recommended doses being used then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: S03C A

Betamethasone has topical corticosteroid activity. The presence of neomycin should prevent the development of bacterial infection.

5.2 Pharmacokinetic properties

Not applicable as the drops are applied topically.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride (anhydrous equivalent)
Disodium edetate
Polyethylene glycol 300
Sodium formate
Anhydrous sodium sulphate
Disodium hydrogen phosphate anhydrous
Sodium acid phosphate
Sodium hydroxide or
Phosphoric acid
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened:	18 months
Opened:	4 weeks

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C. Avoid freezing. Always replace the bottle back in the carton after use to protect its contents from light. The sterility of the drops is assured until the cap seal is broken.

6.5 Nature and contents of container

5 and 10ml bottles with nozzle insert moulded in natural low density polyethylene closed with a tamper evident high density polyethylene cap.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

RPH Pharmaceuticals AB,
Lagervägen 7,
136 50 Haninge,
Sweden

8 MARKETING AUTHORISATION NUMBER(S)

PL 36301/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3 December 1992

10 DATE OF REVISION OF THE TEXT

31/03/2015