Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betnesol 0.1% w/v Eye, Ear and Nasal Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 0.1% w/v betamethasone sodium phosphate.

Excipients with known effect

Each ml contains 0.2 mg benzalkonium chloride and 1.6 mg phosphates
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye, ear and nasal drops, solution (eye, ear and nasal drops).
A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Topical short-term treatment of corticosteroid responsive inflammation of the eye, ear and nose in the absence of local infection.

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. After more prolonged treatment (over 6 to 8 weeks), the drops should be withdrawn slowly to avoid relapse.

Eyes

1 or 2 drops instilled into the eye every one or two hours until control is achieved, when the frequency may be reduced.

Ears

2 or 3 drops instilled into the ear every two or three hours until control is achieved, when the frequency may be reduced.

Nose

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

4.3 Contraindications

Untreated bacterial, fungal, and viral infections. Use is contraindicated if glaucoma is present or herpetic keratitis (e.g. dendritic ulcer) is considered a possibility.

Use in the ear in the presence of a known or suspected perforated ear drum.

Hypersensitivity to any component at the preparation.

4.4 Special warnings and precautions for use

A patient information leaflet should be supplied with this product.

Steroids should not be administered to "red eyes" until a definitive diagnosis has been made.

Topical corticosteroids should not be used in the eye for longer than one week except under the direction and supervision of an ophthalmologist in the management of certain specific eye disorder, after the diagnosis has been made. Prolonged, continuous use should be avoided.

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).

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

Excipients

This medicinal product contains benzalkonium chloride.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Contact with soft contact lenses should be avoided. Patients must be instructed to remove contact lenses before using the medicine and wait reinserted 15 minutes before reinsertion.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Long-term use may cause oedema of the nasal mucosa.

This medicine contains 16 mg phosphates in each 10 ml bottle which is equivalent to 1.6 mg/ml.

4.5 Interaction with other medicinal products and other forms of interactions

Co-treatment with CYP3A inhibitors,including cobicistat-containing products,is expected to increase the risk ofsystemic side-effects. The combination
should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, 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

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

Cataract is reported to have occurred after unduly prolonged treatment of eye conditions with topical corticosteroids.

Prolonged use may induce corneal ulceration, increased intra-ocular pressure, corneal thinning and perforation and subcapsular lenticular opacities.

Mydriasis, ptosis and 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 nasal septum, anosmia, parosmia and disturbance 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 corticosteroids, 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.

Vision, blurred (see also section 4.4)

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.

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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Oral ingestion of the contents of one bottle (up to 10ml) of drops, or one tube (3g) of ointment is unlikely to lead to any serious adverse effects. Long-term intensive topical use may lead to systemic 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: S03B A

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution
Disodium Phosphate Anhydrous
Sodium Chloride
Disodium Edetate
Sodium Hydroxide (for pH adjustment)
Phosphoric Acid (for pH adjustment)
Water for Injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years
Once opened: Discard 28 days after first opening

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Keep the bottle in the outer carton to protect from light.

6.5 Nature and contents of container

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

Not all pack sizes may be marketed.

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

RPH Pharmaceuticals AB
Box 603
101 32 Stockholm
Sweden

8 MARKETING AUTHORISATION NUMBER

PA1638/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 13 August 2008

10 DATE OF REVISION OF THE TEXT

April 2022