SUMMARY PRODUCT CHARACTERISTICS (SPC)

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product

BUDEXA (Budesonide Nebuliser Suspension BP)

1.2 Strength

0.5mg/2 ml

1.3 Pharmaceutical form

Nebuliser Suspension

2. Qualitative and quantitative composition.

A) Qualitative declaration

Each 2 ml Respule contains

Budesonide BP..... 0.5mg

Sterile Aqueous Vehicle .....q.s

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Nebuliser Suspension

4. Clinical particulars

4.1 Therapeutic indications

Seasonal and perennial allergic rhinitis and vasomotor rhinitis. Prophylactically in Patients with nasal polyps following polypectomy. Symptomatic treatment in nasal polyposis

4.2 Posology and method of administration

Method of Administration: Nasal Route

Seasonal and perennial allergic rhinitis, vasomotor rhinitis. Adults and children over 6 year's two modes of administration may be proposed:

- Once daily scheme: Start with one daily morning administration of Budesonide into each nostril. As soon as a good effect has been achieved, the dose may be reduced on a trial basis to into each nostril in the morning.

- Twice daily scheme: Start treatment by administration of Budesonide into each nostril twice daily (morning and evening). As soon as a good effect has been achieved, the dose may be

reduced on a trial basis to 50 µg into each nostril twice daily (morning and evening).

Maintenance dose: When a satisfactory effect has been achieved, budesonide dose should be reduced to the minimum effective dose. The maximal daily dosage should not exceed 400 µg. The patient should be advised that the clinical response will be delayed (some days or up to 2 weeks) before achieving clinical improvement. Concomitant treatment to control eye symptoms and nasal obstruction may be required during the initial days of treatment. Treatment of nasal polyps. The recommended dose is twice daily 200 micrograms, to be administered as 2 puffs into each nostril. When using for the first time Budesonide nasal suspension, the bottle should be put under pressure by: − removing the dust-proof stopper and shaking Budesonide nasal spray, − afterwards putting the index and middle fingers onto the wings of the spray, − supporting the bottom with the thumb (keeping the bottle in a vertical position), − then pressing downwards several times the wings until the product is visible.

4.3 Contraindications

Hypersensitivity to budesonide or to any of the excipients.

4.4 Special warnings and precautions for use

The use of budesonide nasal suspension is not recommended in patients with infections of the airways. Clinical monitoring of infections such as tuberculosis and neurotropic viral infections (zona, herpes) should be considered. A specific therapy should be adopted for any bacterial, viral or fungal infection of upper respiratory airways, mouth or/and eyes. Patients should be informed that the full effect of budesonide nasal suspension is achieved only after few days of treatment.

Treatment of allergic rhinitis should start before the patient is exposed to allergens. Concomitant treatment to counteract eye symptoms caused by allergy may sometimes be required. The nasal mucosa of patients receiving long-term treatment should be examined by a physician at least once a year. If there is no clinical response after three months of treatment, budesonide nasal spray should be stopped. 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 be given to referring the patient to a paediatric specialist. Treatment with higher than recommended doses of nasal corticosteroids 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. Careful attention must be given when shifting from a systemic treatment with corticosteroids to a local treatment with budesonide nasal spray (risk of

reduction of the function of adrenal glands). Withdrawal should be done with graded reduced doses until the hypothalamic-pituitaryadrenal (HPA) axis function has returned to normal. During dose reduction some patients may experience symptoms of systemic corticosteroid withdrawal, e.g. joint and/or muscular pain, lassitude and depression. If evidence of adrenal insufficiency occurs, increase the systemic corticosteroid doses temporarily and thereafter continue withdrawal more slowly

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. On the basis of the current experience, no interactions between budesonide nasal spray and other medicinal products are known.

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4.6 Fertility, pregnancy and lactation

Pregnancy

The available data on the use of Budesonide in pregnancy in women are not sufficient to evaluate the safety of the product. Foetal malformations were observed in animal studies. The relevance of these findings to humans has not been established yet. Budesonide shouldn't be used during pregnancy unless the clinical benefits outweigh the risk.

Lactation

It is not known whether Budesonide is secreted into the human milk. Budesonide administration is not recommended during lactation.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and to use machines have been performed.

4.8 Undesirable effects

The side effects listed below may occur with the following frequencies:

Very common: > 1/10

Common: > 1/100 < 1/10

Uncommon: > 1/1,000 < 1/100

Rare: > 1/ 10,000 < 1/1,000

Very rare: < 1/10,000, including isolated reports

Respiratory, thoracic and mediastinal disorders:

Very common: irritation of nasal mucosa (similar irritation and frequency was reported in placebo-treated humans. At the beginning of the treatment, nasal dripping and crusting could occur for a short time. Nasal bleeding might also occur.

Common: sneezing might occur soon after initial administration; dyspnoea, hoarseness,

wheezing, nasal pain.

Gastrointestinal disorders: Common: dry throat.

Skin and subcutaneous disorders:

Rare: urticaria, rash, dermatitis, pruritus, angioedema

General disorders and administration site conditions:

Uncommon: Candidiasis and atrophy of the mucosa could occur, in particular after a long-term therapy.

Very rare: Ulcerations of the nasal mucosa and nasal septum perforation have been reported.

Some ENT (ear, nose, and throat) signs may be masked when administering corticoid

treatment.

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

If high-doses of budesonide are recommended by the physician, possible systemic effects including adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, signs of hypercorticism, cataracts and glaucoma cannot be excluded.

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 Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

No data are available on the symptoms that could occur in case of acute overdosing of budesonide nasal spray. However, acute overdosing effects are unlikely. If a high-dose use of Budesonide is recommended, a blocking effect on adrenal cortex cannot be excluded

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids

ATC code: R01AD05

General Properties

Budesonide is a glucocorticosteroids with a strong topical anti-inflammatory effect on the nasal mucosa and weak systemic effects after topical administration.

5.2 Pharmacokinetic properties

Budesonide is probably completely absorbed in the digestive system. After absorption, Budesonide is rapidly metabolized in the liver. After oral administration, the systemic availability of budesonide is about 10%. Budesonide metabolites have a minimal biologic activity. Following nasal application of budesonide, peak plasma concentration is achieved after about 30 minutes. Following inhalation of budesonide, peak plasma concentration is achieved after about 5- 10 minutes. Plasma half-life is about 2 hours. Budesonide does not undergo local metabolization in the nasal and pulmonary mucosae. Budesonide is highly bound to plasma proteins (86-90%), mainly to albumin

Preclinical safety data

Toxicological testing in animals shows the typical effects of glucocorticoids, such as a decrease in body weight gain, adrenal and thymus atrophy, and effects on leukocyte counts.

Teratogenicity testing in rat and rabbit showed cleft palate and skeletal abnormalities, as with other glucocorticoids.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

S. No.	Excipients Name	Specification
1.	Polysorbate-80	BP
2.	Sodium Chloride	BP
3	Citric Acid Monohydrate	BP
4.	Disodium Edetate	BP
5.	Water for Injections	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30^0C. Protect from light. Do not freeze.

6.5 Nature and contents of container

4 X 5 X 2.0 ml LDPE respule packed in unit carton along with leaflet

6.6 Special precautions for disposal

Discard product after one month of first opening.

7. Marketing authorization holder

AXA Parenterals Limited

Address : Plot No. 936, 937 & 939, Vill. Kishanpur, Jamalpur,

Roorkee-247667, Distt. Haridwar, Uttarakhand, INDIA

Country : INDIA

8. Marketing authorization number(s)

H2025/CTD7648/14673

9. Date of first authorization/ renewal of the authorization

August 2025

10. Date of revision of text

Not applicable