BUDENIDE NASAL SPRAY

NAME AND STRENGTH OF ACTIVE SUBSTANCE: Budesonide 0.128% w/v.
PRODUCT DESCRIPTION: A white to off-white suspension. Other ingredients are Dextrose, Potassium Sorbate, Disodium Edetate, Microcrystalline Cellulose, Carboxymethyl Cellulose Sodium, Polysorbate 80, Hydrochloric acid and Purified Water.

ROUTE OF ADMINISTRATION: Nasal

PHARMACODYNAMICS: In the treatment of nasal symptoms, the primary action of nasally applied corticosteroids is anti-inflammatory. Nasal corticosteroids inhibit the IgE- and mast cell-mediated early-phase allergic reaction. They also inhibit the migration of inflammatory cells into the nasal tissue (the late phase or late-onset allergic reaction) which may play a significant role in the pathology of chronic rhinitis.

PHARMACOKINETICS: Budesonide is a glucocorticosteroid with a high local anti-inflammatory effect. The exact mechanism of action of glucocorticosteroids in the treatment of rhinitis is not fully understood. Anti-inflammatory actions, such as an inhibition of inflammatory mediator release and inhibition of cytokine-mediated immune responses, are probably important. The intrinsic potency of budesonide, measured as the affinity to glucocorticoid receptor, is about 15 times higher than that of prednisolone.
Budesonide is rapidly and almost completely absorbed following administration by mouth, but has poor systemic availability due to extensive first-pass metabolism in the liver. The major metabolites, 6-β-hydroxybudesonide and 16-α-hydroxyprednisolone have less than 1% of the glucocorticoid activity of unchanged budesonide. Budesonide is reported to have a terminal half-life of about 4 hours.

INDICATION: Seasonal allergic and allergic/non-allergic perennial rhinitis. Treatment of nasal polyps. Prevention of nasal polyps after polypectomy.

CONTRAINDICATION: Hypersensitivity to any of the ingredients of this preparation.

DRUG INTERACTIONS: Budesonide has not been observed to interact with any drug used for the treatment of rhinitis.

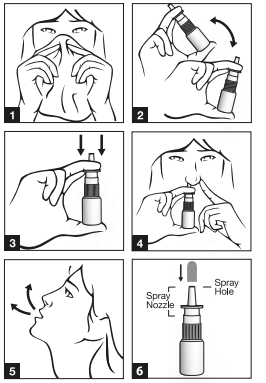
ADVERSE EFFECT: The following adverse drug reactions may occur: local symptoms such as dry nose, sneezing and nasal stinging immediately after the use of the nasal spray, slight haemorrhagic secretion and epistaxis and skin reactions (urticaria, rash, dermatitis, angioedema). Other most frequently reported cases are throat irritations and increased cough. Extremely rare cases of ulcerations of the mucous membrane and nasal septal perforation have been reported following use of intranasal glucocorticosteroids.

PRECAUTION/ WARNING: Use of excessive doses of, or long-term treatment with glucocorticosteroids may lead to signs or symptoms of hypercorticism, suppression of HPA function and/or suppression of growth in children. The long-term effects of nasal steroids in children are not fully known. Physicians should closely follow the growth of the children taking glucocorticosteroids for longer term by any route, and weigh the benefits of the glucocorticosteroids therapy against the possibility of growth suppression. Reduced liver function may affect the elimination of corticosteroids. Special consideration may be needed in patients with pulmonary tuberculosis.

Pregnancy and lactation: Budenide should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known whether Budenide is excreted in human milk. Because other glucocorticosteroids are excreted in human milk, caution should be exercised when Budenide is administered to nursing women.

RECOMMENDED DOSAGE: Adults and children > 6 years of age: The recommended starting dose i.e. 256µg daily (2 sprays into each nostril). The dose can be administered once daily in the morning or divided into two administrations morning and evening. After the desired clinical effect is obtained, usually within 1-2 weeks, the maintenance dose should be tapered to the smallest amount necessary to control the symptoms. Treatment of seasonal rhinitis should, if possible, be before exposure to the allergens. Concomitant treatment may sometimes be necessary to control eye symptoms caused by the allergy.

HOW TO USE THE SPRAY:



1. Blow the nose gently to clear nostrils.
2. Shake the bottle gently.
3. For first time use, hold the bottle upright and fill the pump by pressing the nozzle downwards and releasing it 5 times, until a fine spray is produced.
4. Close one nostril with finger. Hold the bottle upright and insert the nozzle into the nostril as far as is comfortable. Whilst breathing in gently through the nose with the mouth closed, press the bottle upwards once to deliver one spray.
5. Breathe out through the mouth.
6. Repeat steps 4 and 5 for the other nostril.
7. For patients aged > 6 years and older, steps 4, 5 and 6 should be repeated once more to achieve the recommended dosage of 2 sprays into each nostril.
8. To keep the spray nozzle clean, wipe it carefully with a clean tissue after each use and replace back the cap.

If the nasal spray has not been used for 2 weeks or more, it needs to be sprayed once into the air before use. The nozzle should be pointed away while doing this.

Always shake the bottle gently before use.

If the spray does not work and it may be blocked, clean it as follows. (See HOW TO CLEAN THE SPRAY). NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

The nasal spray should be cleaned at least once a week or more often if it gets blocked.

HOW TO CLEAN THE SPRAY:

1. Remove the cap and pull off the spray nozzle only.
2. Soak the dust-cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.
3. Shake or tap off the excess water and allow to air-dry.
4. Re-fit the spray nozzle.
5. Prime the unit as necessary until a fine mist is produced and use as normal.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE (S): If symptoms of chronic overdose occur, nasal corticosteroids should be discontinued slowly.

PACKING: 10ml, 15ml plastic spray bottle.

STORAGE: Keep containers well closed. Protect from light. Store below 30°C. For external use only. Keep out of reach of children.

RECOMMENDED SHELF LIFE: 3 years.

Manufactured by :
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