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VENTACORT NASAL SPRAY 64 mcg

VIVENxx-0

1 cm
Barcode

Description
White aqueous suspension

Composition
Each actuation contains Budesonide 64 mcg.

Pharmacodynamics
Budesonide is a non-halogenated glucocorticoid with a high local anti-inflammatory action within the respiratory tract.

Budesonide is a glucocorticoid that administered by nasal route exert its anti-inflammatory action at local level. The mechanism of action glucocorticoids is not known in the treatment of rhinitis. The anti-inflammatory activity is important, such as the inhibition of liberation of inflammatory mediator and the inhibition of the response by the cytokine. The intrinsic potency of budesonide, measured like the affinity to receptor of glucocorticoids, is approximately 15 times greater than prednisolone.

The prophylactic administration of budesonide has demonstrated to have protector effects in front of hyper-response and the eosynophil induced by nasal stimulation.

Pharmacokinetics
Absorption
The systemic availabillity of budesonide from Ventacort Nasal Spray 64 mcg with reference to the metered dose is 33 %. In adults, the maximal plasma concentration after administration of 256 micrograms budesonide 64 mcg is 0.64 nM (nmol/L) and is reached within 0.7 hours. The AUC after administration of 256 micrograms budesonide 64 mcg is 2.7 nmol x h/L in adults.

Distribution
The volume of distribution of budesonide is approximately 3 L/Kg. The plasma protein binding is 85-90%.

Biotransformation
Budesonide undergoes an extensive degree (~90%) of biotransformation in the liver, to metabolites of low corticosteroid activity. The glucocorticoid activity of the main metabolites, 6β-hydroxybudesonide and 16α-hydroxyprednisolone, is less than 1% of that of budesonide. The metabolism of budesonide is mainly mediated by CYP3A4, a subfamily of Cytochrome P450. Budesonide is not metabolized in the nasal mucous.

Elimination
The metabolites are excreted as conjugated form, mainly by nasal route. Although with a glucocorticoid activity reduced in comparison with the original compound, budesonide has not been detected intact in urine. It is not, therefore, considered necessary to do and adjust doses in patients with insufficiency renal. The budesonide has a high systemic clearance (approximately 1.2 L/min) and the plasmatic semi-life after an intravenous dose has an average of 2-3 hours.

Linearity
The kinetic of the budesonide is proportional to the dose within the dose range of 64 to 256 micrograms daily.

Indications
Ventacort Nasal Spray 64 mcg is used for the relief of seasonal and perennial allergic rhinitis and vasomotor rhinitis. It is also indicated for the treatment of nasal polyps and for the prevention after a polypectomy in adult patients.

Contraindications
Hypersensitivity to the active substance (budesonide) or to any of the excipients.

Pregnancy and Lactation
Administration during pregnancy should be avoided unless there are compelling reasons. Results from prospective epidemiological studies and from worldwide post marketing experience indicate no increased risk for overall congenital malformations from the use of inhaled or intranasal budesonide during early pregnancy.

Budesonide is excreted in breast milk. However, at therapeutic doses, no effects on the breast fed child are anticipated. It can be used during breastfeeding.

Precaution
Pneumonia in patients with COPD
An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies.

There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products.

Physicians should remain vigilant for the possible development of pneumonia in patient with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.

Risk factors for pneumonia in patients with COPD include current smoking status, older age, low body mass index (BMI) and severe COPD.

Special care is demanded in treatment of patients transferred from oral steroids to Ventacort Nasal Spray where disturbances of the hypothalamic-pituitary-adrenal (HPA) axis could be expected.

Special care is needed in patients with fungal and viral infections of the airways and in patients with lung tuberculosis.

The patient should be informed that the full effect of Ventacort Nasal Spray is not achieved until after a few days treatment. Treatment of seasonal rhinitis should, if possible, start before exposure to the allergens. Concomitant treatment may sometimes be necessary to counteract eye symptoms caused by the allergy. In continuous long-term treatment, the nasal mucosa should be inspected regularly e.g. every 6 months.

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.

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

In vivo studies have shown that oral administration of itraconazole and ketoconazole may cause an increase in the systemic exposure to budesonide. This is of limited clinical importance for short-term (1- 2 weeks) treatment with itraconazole or ketoconazole, but should be taken into consideration during long-term treatment.

Interaction with Other Medicaments and Other Forms of Interaction

The metabolism of budesonide is primarily mediated by CYP3A4, a subfamily of cytochrome P450. Inhibitors of this enzyme, e.g. itraconazole and ketoconazole, can therefore increase systemic exposure to budesonide. However, the use of itraconazole or ketoconazole concomitant with Ventacort Nasal Spray for shorter periods is of limited importance.

Main Side/Adverse Effects

Common adverse effects : Haemorrhagic secretion and epistaxis, nasal irritation (sneezing, stinging and dryness), Pneumonia (in COPD patients)

Uncommon adverse effects : Immediate and delayed hypersensitivity reactions including urticaria, rash, dermatitis angioedema and pruritus

Rare adverse effects : Raised intraocular pressure or glaucoma

Very rare adverse effects : Nasal septum perforation, ulceration of mucus membrane

Not known adverse effects : Anaphylactic reaction

Overdose

Acute overdose should not present clicinal problems.
Inhalation of high doses of corticosteroids may lead to suppression of the hypothalamic-pituitary- adrenal (HPA) axis function.

Dosage and Administration

Route of administration: For nasal inhalation only.

Treatment should be individualised. The dosage should always be reduced to the minimum needed to achieve the effective control of symptoms.

Seasonal or perennial allergic rhinitis, non-perennial allergic rhinitis
Adults, elderly and children older than 6 years: The recommended initial dose is 256 micrograms daily. This dose can be administered in two applications (2 x 64 micrograms) into each nostril once a day (morning) or one application (1 x 64 micrograms) into each nostril morning and evening.

Once the dose achieves the clinical effect (1-2 weeks), the dose should be reduced to the minimun needed to control the symptoms.

Treatment of seasonal rhinitis should, if possible, start before exposure to the allergens. Concomitant treatment may sometimes be necessary to counteract eye symptoms caused by the allergy.

Patients could feel relief since first day of treatment. However it can be necessary some days of treatment in order to achieve the full effect (sometimes up to 2 weeks).

Treatment of the nasal polyposis / prevention after polypectomy
The recommended dose is 256 micrograms daily. The dosage can be administered as two applications (2 x 64 micrograms) into each nostril (morning) or one application (1 x 64 micrograms) into each nostril morning and evening.

Once the dose achieves the clinical effect, the dose should be reduced to the minimum needed to control the symptoms.

Renal insufficiency and/or hepatic
It is not necessary to make dose adjustment.

Children under 6 years
There are insufficient data to recommend the use of Ventacort Nasal Spray 64 mcg in this age range.

Instructions for use:







Before first application:
- Remove the protection cap
- Shake the bottle
- Actuate the applicator as many times as necessary to fill in the mechanism of the pump in order to perform a correct pulverization.

If it is not used daily, it is necessary to make an actuation to the air before using it again.

How to use. Each application:
- Blow your nose gently
- Remove the protection cap
- Shake the bottle.
- Introduce the applicator into a nostril and administer the prescribed dose.
- Repeat the same process into the other nostril in the same way.
- Replace the protection cap after its use.

Cleaning:
It is advisable to clean the protection cap and the nasal applicator regularly, washing them with warm water. Allow drying and replace them again correctly.

Storage : Do not store above 30ºC. Protect from direct sunlight and do not freeze. It should not be perforated, broken or burnt even when it is apparently empty.

Presentation/ packing : 6 ml aqueous suspension for 120 actuations

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Information date: August 2025