

Composition

Active ingredient: Budesonide

Excipients: Cellulose microcrystalline & Carmellose sodium, Glucose anhydrous, Polysorbate 80, Edetate disodium, Potassium sorbate, Hydrochloric acid, Purified water.

Pharmaceutical Form: Metered dose nasal spray

Strength: 1 ml contains 1.0 mg Budesonide (50 mcg budesonide per actuation) or 2.0 mg Budesonide (100 mcg budesonide per actuation)

Presentation - Packaging

White suspension in glass transparent, dark bottles closed with special metered dose caps, with a label printed with the product and batch characteristics. Each bottle contains 10 ml of suspension (200 doses). In each box there is one bottle and a patient information leaflet.

Therapeutic category:

Glycocorticosteroid - Treatment of allergy

The information of this leaflet refers only to the product prescribed by your Physician: ESONIDE®. Please read it carefully. It provides important information but it does not explain everything. If you need more information ask your Pharmacist or your Physician.

General information

Pharmacodynamic properties

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

Pharmacokinetic properties

Bioavailability of oral budesonide in man is low (11-13%) due to an extensive first pass metabolism in the liver. After nasal administration of a large dose (1mg) from the metered dose inhaler the systemically available fraction is about 14%. After application of budesonide in solution directly on the nasal mucosa, all the dose is systemically available. This indicates that budesonide does not undergo local metabolism in the nose. Maximal plasma concentration after nasal application of 100 mcg budesonide is less than 1nmol/L and is reached within 45 minutes.

Indications:

ESONIDE® is indicated for:

- Treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children (over 6 years old) and for the treatment of the perennial non allergic rhinitis only in adults.
- Treatment of nasal polyps.

Contra-indications:

Drugs can cure, but can also create problems when are not taken as prescribed by Physicians.

ESONIDE® is contra-indicated to patients who have shown hypersensitivity to budesonide or to any other ingredient of the drug.

Precautions:

1. General

This drug is indicated only for your disease. Do not use it for any other situation, except if recommended by your Physician.

Do not give your drug to anybody else.

Unreasonable dosage or long-term therapy with glucocorticosteroids, may lead to the appearance of symptoms or signs of corticosteroids overdose, suppression of HPA axis and/or growth delay in children.

Physicians should regularly monitor the growth rate of children using any kind of corticosteroids for long-term treatment, and they should evaluate the benefits of the therapy against the growth delay risk.

Reduced hepatic function affects the corticosteroid elimination. You should inform your physician if you have any hepatic dysfunction. Caution in the use of corticosteroids is recommended in case of patients that suffer of pulmonary tuberculosis. Also, caution is recommended in case of patients with nasal diseases caused by fungi and virus or bacterial antritis, which should be treated adequately. Children under immunosuppressant therapy are more susceptible compared with the healthy ones, i.e. diseases as chickenpox or morbilli could be expressed with more severe forms in children that are under glucocorticosteroid treatment. Children or adults that are not immune to these diseases, should avoid to be exposed and if exposed they should seek urgently a medical advice. Special care is demanded in treatment of patients transferred from oral steroids to ESONDE® nasal spray. In case that an inhaler corticosteroid is used, the sum of the nasal and inhaler dosage should be adjusted, in order that possible side-effects of corticosteroids should be avoided, especially for children. In case of long-term treatment, the nasal mucosa should be examined every 6 months. Long - term therapy in children is not recommended at least until to obtain more experience in this sector.

Moreover during ESONIDE® treatment the general precautions of all corticosteroids should be taken into consideration: Long-term therapy with corticosteroids leads, as already mentioned, to HPA axis suppression. The rate of this suppression depends on the dose, strength, frequency and time of administration during 24 hours of the corticosteroid drug as well as on the half-life of the drug in the tissues and the whole duration of the therapy. The dose is adjusted according to the disease exacerbation or suppression, the individual patient response to the therapy and his exposition to emotional or physical stress (diseases, operations, trauma etc.).

2. Elderly patients: there are not any particular instructions. Dosage is adjusted in each case separately.

3. Pregnancy: Administration during pregnancy is not recommended unless, according to physician's evaluation, the benefits for the pregnant woman compensate the risks for the foetus.

4. Lactation: ESONDE® nasal spray could be administrated during lactation only, according to physician's evaluation, when the benefits for the pregnant woman compensate the risks for the foetus. In case of unexpected pregnancy while you are under corticosteroid therapy, you should contact your physician the soonest possible.

5. Children: the results of the long-term use of corticosteroids for nasal use are not completely known. Read carefully the paragraph of the dosage for children.

6. Affects in driving ability and in ability to operating machines: ESONIDE® nasal does not affect the ability to drive and operate machinery.

7. Special warnings for the excipients: There are not any special warnings for the excipients.

8. Visual disturbance

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.

Adverse Reactions

Vision, blurred

Drug interactions:

Before using this medicine please inform your Physician about all medicines you may use, especially for antifungal drugs (ketoconazole), including these you have bought without prescription.

The following interactions concern all corticosteroids in general:

Phenytoin, phenobarbital, ephedrine, rifampicin, alcohol, non-steroid anti-inflammatory drugs, kaliopenic diuretics, digitalis, coumarin anticoagulants, insulin or oral anti-diabetics.

Dosage and administration:

The dosage of ESONIDE® is individualised. Please follow your physician's instructions about this medicine. Before using ESONIDE® for first time you should read this leaflet carefully.

Seasonal or perennial allergic rhinitis

Adults, elder and children over 6 years old:

The recommended initial dose is 400 mcg daily. ESONIDE® may be given once daily in the morning or may be divided in two doses, in the morning and in the evening:

200 mcg (4x50 mcg or 2x 100 mcg) in each nostril every morning. It should not be administered for more than twice daily. There are no data for the drug use in children above 6 years old for this indication and therefore the drug should not be used by this patient category.

Symptomatic treatment of perennial non-allergic rhinitis only to adults:

The dosage is as reported above. It is not indicated in children, because during clinical trials, the number of children required was not fulfilled.

Treatment of nasal polyps in adults:

The recommended dose is 200 mcg twice daily, i.e. 100 mcg (2x50 mcg or 1x100 mcg) in each nostril in the morning and in the evening.

There are no data for the drug use in children for this indication and therefore ESONIDE® should be administered only in adults.

Note: The patient should be informed that full effect of ESONIDE® is not achieved until after a few days of treatment (in few cases up to 2 weeks).

After having achieved the clinical result, maintenance dosage should be limited to the possibly lowest dosage that is required for the control of the symptoms.

Treatment of seasonal rhinitis should, if possible, start before the allergy initiation.

ESONIDE® nasal spray is not indicated for the relief of the eye allergic symptoms. If you feel any kind of eye allergy, physician could prescribe to you some other medicines for the relief of those symptoms.

Children should always use nasal spray under surveillance, in order to ensure that the administration is correct and according to physician prescription.

Overdose

If a single high dose of the drug is taken, side effects would probably not occur. If you have used the drug in high dosage for a long period (months), side effects would probably occur. In this case you should contact your physician.

Side effects

Along with the benefits drugs could also promote unwanted effects. You should inform your physician if any of the side effects reported below occurs and persists:

Common side effects: irritation of nasal mucous membranes, nasal bleeding

Unusual side effects: immediate and obvious hypersensitivity reactions as skin exanthema etc. In this case you should contact your physician.

Very rare side effects: ulcerations, mycosis, and atrophy of nasal mucosa.

Topical effects, as pinches, dryness and sneezing could occur immediately after administration.

You should also contact your physician if any unusual effect occurs, while using ESONIDE® nasal spray.

Moreover during treatment with ESONIDE® the following side-effects applied for all corticosteroids in general, should be taken into consideration:

Natural corticosteroids as well as their synthetic derivatives given in equivalent doses have equal side-effects. Therefore, the long-term use could lead to severe side-effects, the most important of which are: Cushing's syndrome medicamentous, sodium and water retention, negative nitrogen and calcium balance with osteoporosis, peptic ulcer, psychotic symptoms (as nervousness, anxiety, depression), increase of intra-ocular pressure and glaucoma, cataract, increased susceptibility to infections and development of microbial inflammation, growth suppression in infancy, childhood and adolescence, increased intra-cranial pressure, increased requirement for antidiabetic therapy, hypothalamic-pituitary-adrenal (HPA) axis suppression, suppression of surgical abdomen (not known peritonitis in case of perforation)

Instructions in case you have forgotten to take one dose:

If you have omitted one dose, do not try to replace it. Just wait until the next administration, according to the prescription. Do not double the dose

Expiry date

The shelf life of the product is printed on the vial labelling and the box. Do not use after expiration.

Pharmaceutical precautions

After having used the drug replace the protective cover on the vial. ESONIDE® should be stored at room temperature (<25°C). Do not freeze the product.

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Warning!

Keep out of the reach of children.

INFORMATION FOR RATIONAL USE OF DRUGS

This drug is prescribed by your physician and is only for your medical pathology. You should not give it to others or use it for other pathology, without your physician advice.

If during therapy a problem occurs with the drug, you should inform immediately your physician or pharmacist.

If you have any queries about for your pathology do not hesitate to ask information from your doctor or your pharmacist.

You should follow the instructions for use of the drug that you have been administrated, in order to ensure drug efficacy and safety.

For your health and safety, is required to read carefully, all the information about the drug that you are taking.

Do not keep the drug in bathroom shelves, because the heating and humidity could alternate the drug and rend it noxious for your health.

Do not keep drugs that you do not need or expired ones.

For major safety, keep drugs in a safe place and keep out of reach of children.

Manufacturer

KLEVA S.A.

189, Parnithos Av. 13675, Acharnai, Greece

Tel.: +302 10 2402404-7

ESONIDE® is administered only with physician's prescription