

Sonidar

Corticosteroid Inhaler

Composition

Each metered dose (actuation) contains:

Active ingredient: Budesonide 200mcg

Excipients: Sorbitan trioleate and propellant 11,12, and 114.

Properties

Budesonide, the active ingredient of **Sonidar** inhaler, is a corticosteroid with a potent local anti-inflammatory effect. It reduces chronic inflammation and oedema in asthmatic airways as well as mucus secretion into the airways.

Budesonide also enhances the response to beta-adrenergic bronchodilators by increasing the number of beta-adrenergic-receptors and reducing down-regulation of these receptors after prolonged exposure to beta-agonists.

Budesonide has shown anti-anaphylactic effects, which is manifested as decreased bronchial obstruction in the immediate, as well as the late allergic reactions. Budesonide has also been shown to decrease airway reactivity to both direct and indirect challenges in hyperreactive patients. Therapy with inhaled budesonide has been reported to be effective when used for prevention of exercise-induced asthma.

Budesonide is rapidly absorbed from the lungs and gastrointestinal tract. Approximately 10 - 25% of the inhaled dose is deposited in the airways; the remainder is deposited in the mouth and throat, and swallowed.

Indications

Sonidar is indicated in the management of chronic asthma, which is not controlled by short-acting beta₂-stimulants.

Dosage

The dose of **Sonidar** is to be individualized according to the age of the patient and previous asthma therapy.

Adults

- Patients on bronchodilators alone
 - 1 - 2 inhalations (200 - 400mcg) twice daily.
- Patients on inhaled corticosteroids
 - 1 - 2 inhalations (200 - 400mcg) twice daily. Dosage may be increased as needed and as tolerated to a maximum of 4 inhalations (800mcg) twice daily.
- Patients on oral corticosteroids
 - 2 - 4 inhalations (400 - 800mcg) twice daily.

Maximum adult dose: 8 inhalations (1600mcg) a day for patients previously treated with inhaled or oral corticosteroids or 4 inhalations (800mcg) a day for those previously treated with bronchodilators alone.

Children

Children 6 years of age and over:

1 inhalation (200mcg) twice daily, to be increased as needed and as tolerated to a maximum of 2 inhalations (400mcg) twice daily.

Children up to 6 years: Use is not recommended.

Maximum paediatric dose: 4 inhalations (800mcg) a day.

Notes:

- In all patients it is desirable to titrate to the lowest effective dose once control of asthma is achieved.
- Once daily dosing (morning or evening) of 1 - 2 inhalations (200 - 400mcg) may be considered in patients (adults or children) with mild to moderate asthma who are well controlled on inhaled corticosteroids.
- Gargling and rinsing the mouth with water after each dose are recommended to prevent throat irritation. The rinse water should not be swallowed as this can significantly reduce the amount of inhaled corticosteroid absorbed from the gastrointestinal tract.
- If the inhaler therapy requires discontinuation, the dosage regimen should be tapered off gradually.

Directions for use

1. Remove the cover from the mouthpiece and shake the inhaler vigorously.
2. Holding the inhaler with the mouthpiece down towards your mouth and putting your thumb under the mouthpiece and your index over the bottom of the canister, breathe out gently (but not fully) and then immediately place the mouthpiece in the mouth and close your lips around it.
3. After starting to breathe in slowly and deeply through your mouth, press the inhaler firmly by using your index to release **Sonidar** and continue to breathe in.
4. Hold your breath for 10 seconds, or as long as is comfortable, before breathing out slowly.
5. Rinse your mouth out with water after inhaling your prescribed dose.
6. If you are to take a second inhalation, you should wait at least 1 minute before repeating steps 2, 3, and 4.
7. After use replace the cover on the mouthpiece.
8. **Cleaning:** Remove the canister, rinse the actuator in warm water, dry, and replace canister.

Contraindications

It should not be used in any individual with a known hypersensitivity reaction to budesonide or any other ingredient in the preparation.

Precautions

As with other inhaled corticosteroids, budesonide inhaler is not intended for rapid relief of acute episodes of asthma where an inhaled short-acting bronchodilator is required.

If a beta₂-adrenoceptor stimulant is to be used at the same time as an inhaled corticosteroid it should be used first to help increase the penetration of the inhaled corticosteroid.

Particular care is needed in patients who are transferred from oral to inhaled corticosteroids. The transfer must be done slowly and at a time when the asthma is well controlled. Gradual reduction in dose of oral corticosteroid using an alternate-day regimen is usually recommended.

Reinstatement of systemic therapy may be required during period of stress (e.g. an operation) or when increased airway obstruction or mucus (due to infection) prevents drug access to smaller airways.

The potential for paradoxical bronchospasm should be borne in mind as this may call for discontinuation of treatment and establishing an alternative therapy. However, mild cases may be prevented by inhalation of a beta₂-adrenoceptor stimulant.

As with other inhaled corticosteroids, budesonide should be used with great caution in patients with active or quiescent tuberculosis.

Pregnancy: As with other inhaled corticosteroids, budesonide inhaler has not been reported to be associated with an increased incidence of congenital abnormalities when used within the recommended dose. Therefore, it may be used during pregnancy when the potential benefits to the mother outweigh the possible risks to the fetus.

Moreover, if **Sonidar** inhaler is effective before pregnancy, it is advisable to continue regular maintenance dosing during pregnancy.

Lactation: It is not known whether inhaled corticosteroids are distributed into breast milk. However, problems in human have not been documented.

Side Effects

Generally, inhaled corticosteroids have considerably fewer systemic effects than oral corticosteroids. Some adverse effects have been reported following the prolonged inhalation of high doses of corticosteroids including a small increased risk of glaucoma, cataract, and effect on bone metabolism.

Hoarseness of the voice and candidiasis of the mouth or throat have only been reported with large doses. Candidiasis usually responds to antifungal lozenges without the need for discontinuing the therapy. Rinsing the mouth with water or cleaning child's teeth after inhalation of the dose may also be helpful.

Rarely, hypersensitivity reactions including rash and angioedema have been reported.

Overdosage

Acute overdosage with budesonide inhaler, even in excessive doses, is not expected to be a clinical problem. When used chronically in excessive doses, systemic glucocorticosteroid effects, such as hypercorticism and adrenal suppression, may appear.

Drug Interactions

Significant drug interactions are unlikely to occur with usual doses of inhaled budesonide.

Presentation

Sonidar inhaler. Canister of 100 or 200 metered doses.

- Store at a temperature of 15 - 25°C. Do not refrigerate. Avoid storage in direct sunlight or heat. Store canister with nozzle end down.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,
Union of Arab States.

Any information ? Call Our Toll Free No. (971) 800-4994



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