





GENERIC NAME: budesonide

DRUG CLASS AND MECHANISM

Budesonide is a man-made glucocorticoid steroid related to the naturally-occurring hormone, cortisol or hydrocortisone which is produced in the adrenal glands. It is used for treating asthma by inhalation. Glucocorticoid steroids such as cortisol or budesonide have potent anti-inflammatory actions that reduces inflammation and hyper-reactivity (spasm) of the airways caused by asthma. When used as an inhaler, the budesonide goes directly to the inner lining of the inflamed airways to exert its effects. Only 39% of an inhaled dose of budesonide is absorbed into the body, and the absorbed budesonide contributes little to the effects on the airways.

PRESCRIPTION: Yes

PREPARATIONS:

- * Pulmicort Turbuhaler 200 mcg: each 200 mcg actuation delivers 160 mcg of budesonide.
- * Pulmicort Respules, 0.25 mg/2ml, 0.5 mg/2ml suspension, and 1 mg/2ml

PRESCRIBED FOR

The budesonide inhaler is used for the control of asthma in persons requiring continuous, prolonged treatment. Such patients may include those with frequent asthmatic episodes requiring bronchodilators, for example, albuterol (Ventolin) or those with asthmatic episodes at night.

DOSING

Budesonide is used to prevent asthmatic attacks and should not be used to treat an acute attack of asthma. The Turbuhaler is used for individuals six years of age or older. Effects can be seen within 24 hours, but maximum effects may not be seen for 1-2 weeks or longer. Doses vary widely. Adults usually receive 1 to 4 actuations (puffs) twice daily. Children usually receive 1 to 2 puffs twice daily. For those with mild asthma, treatment once daily may be sufficient.

Pulmicort Respules are used for individuals 12 months to eight years of age. Effects are seen in 2 to 8 days, but maximum effects may not be seen for up to 4 to 6 weeks. Pulmicort Respules are used with a jet nebulizer. They usually are taken as one or two doses for a total of 0.5-1 mg daily.

DRUG INTERACTIONS

Ketoconazole (Nizoral, Extina, Xolegel, Kuric) increases the concentrations in blood of budesonide, and this may lead to an increase in the side effects of budesonide. No drug interactions have been described with inhaled budesonide.

USES

This is an anti-inflammatory medication (corticosteroid) used in the prevention of asthma. It is not used to relieve an asthma attack. If an asthma attack occurs, use other medication as prescribed.

HOW TO USE

This medication is inhaled into the lungs using a special inhaling device. Follow the directions for using this medicine provided by your doctor. This medicine comes with a patient information leaflet. Read it carefully. If you are not sure how to use this device, reread the patient information leaflet or ask your pharmacist. After the dose is loaded, breathe out. Place the mouthpiece between your lips and breathe in rapidly and deeply through your mouth. The drug will be inhaled as you breathe in. Hold your breath for 10 seconds to assure it reaches deep into your lungs. Slowly breathe out. Do not exhale into device. Replace the cover. If the inhaler device is dropped, shaken, or you accidentally breathe into the device after the dose has been loaded, you will lose your dose. Load and inhale another dose. Do not use the inhaler if it has been damaged or if the mouthpiece has become detached. If two inhalations are prescribed, wait at least one minute between inhalations. If using other inhalers, use this one (the corticosteroid) last and wait several minutes after using the other(s) before using this one. To prevent dry mouth and hoarseness, rinse your mouth after each use. Do not swallow the rinse solution. It is important to practice good oral hygiene to prevent mouth infections while using this medication. This medication works best if used

consistently at even intervals. It is usually used once in the morning and evening. Do not increase your dose, use this more frequently or stop using this medication without first consulting your doctor.

SIDE EFFECTS

The most commonly noted side effects associated with inhaled budesonide are mild cough or wheezing; these effects may be minimized by using a bronchodilator inhaler, for example, albuterol (Ventolin), prior to the budesonide. Oral candidiasis or thrush (a fungal infection of the throat) may occur in 1 in 25 persons who use budesonide without a spacer device on the inhaler. The risk is even higher with large doses but is less in children than in adults. Hoarseness or sore throat also may occur in 1 in 10 persons. Using a spacer device on the inhaler and washing one's mouth out with water following each use reduces the risk of both thrush and hoarseness. Less commonly, alterations in voice may occur.

High doses of inhaled glucocorticoid steroids may decrease the formation and increase the breakdown of bone leading to weakened bones and ultimately osteoporosis and fractures. High doses may suppress the body's ability to make its own natural glucocorticoid in the adrenal gland. It is possible that these effects are shared by budesonide. People with suppression of their adrenal glands (which can be tested for by the doctor) need increased amounts of glucocorticoid steroids orally or intravenously during periods of high physical stress, for example, during infections, to prevent serious illness and shock.

Hypersensitivity reactions such as anaphylaxis, rash, contact dermatitis, itching, angioedema, and bronchospasm have been reported with use of inhaled budesonide. Use should be discontinued if such reactions occur.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as remembered; do not use it if it is near the time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

STORAGE

Always replace the cover. Store inhaler at room temperature between 59 and 86 degrees F (15 and 30 degrees C) in a dry place away from moisture.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world



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