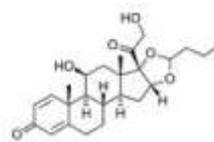


Rx BUDESONIDE FORMOTEROL

(This combination medication is an oral inhaler used, as long-term treatment)



USES

This combination medication is an oral inhaler used, as long-term treatment, to prevent or decrease the symptoms of asthma (e.g., wheezing, trouble breathing). It works by decreasing the swelling (inflammation) and the narrowing of the air passages in the lungs. This medication does not work immediately and should not be used for acute asthma attacks. Use other quick-relief medicines/inhalers only as needed for sudden shortness of breath or asthma attacks (e.g., short-acting beta-agonists such as albuterol), not on a regular daily schedule. Consult your doctor.

HOW TO USE

Learn all preparation and usage instructions in the product package. If any of the information is unclear, consult your doctor or pharmacist. Inhale this medication by mouth usually once or twice daily; or use as directed by your doctor. Your dosage is based on your medical condition and response to therapy. Use this medication exactly as prescribed; do not use it more frequently or use more inhalations than prescribed. Doing so may decrease the effectiveness of the drug and increase the risk of side effects. Do not stop using this medication without consulting your doctor. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased. Gargle and rinse your mouth after using this medication to help prevent dryness, relieve throat irritation, and to prevent mouth infections (e.g., thrush). Do not swallow the rinse solution. If you need to use 4 or more puffs daily of your short-acting inhaler, or use more than 1 short-acting inhaler every 8 weeks for acute asthma attacks, tell your doctor or pharmacist immediately. This could be a sign of worsening asthma, which is very serious. Do not breathe into (exhale into) the inhaler, take the inhaler apart, or wash the mouthpiece of the inhaler. Keep the inhaler dry at all times and always use the inhaler in a level (horizontal) position.

SIDE EFFECTS

Headache, nausea, nervousness, trouble sleeping, or throat irritation may occur. If any of these effects persist or worsen, notify your doctor promptly. Tell your doctor immediately if any of these serious side effects occur: uncontrolled muscle movements (tremor) or muscle cramps, irregular or unusually fast heartbeat. Tell your doctor immediately if any of these unlikely but serious side effects occur: white/patchy spots in the mouth or throat, worsening or increased frequency of asthma symptoms (e.g., coughing, wheezing, trouble breathing). Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: chest pain, mental/mood changes. An allergic reaction to this product is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, severe trouble breathing (e.g., increased wheezing). If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Tell your doctor your medical history, especially of: kidney or liver problems, heart disease (e.g., arrhythmias), high blood pressure, seizure disorders, thyroid problems (hyperthyroidism), diabetes, low potassium (hypokalemia), any allergies. If you have switched from an oral corticosteroid (e.g., prednisone tablets) to this inhaler within the past 12 months, or if you have been using this product in higher-than-usual doses and suddenly stop using it, your body may not produce enough natural steroids. You may need to start taking additional corticosteroids, especially if your body is stressed due to a major infection, surgery or injury. Deaths have sometimes occurred during such stresses, due to low steroid levels. Tell your doctor immediately if any of the following side effects occur: unusual weakness, sudden weight loss, dizziness. Consult your doctor or pharmacist for more details, and inform them that you use (or have used) any type of corticosteroid. Carry a warning card or medical ID bracelet that identifies your need for oral corticosteroids during times of stress as noted. Consult your doctor or pharmacist now for specific advice regarding stress situations; you may need to carry a supply of corticosteroid tablets as a precaution. Caution is advised when using this drug in children. Though it is unlikely to occur with inhaled steroids (budesonide), this medication may temporarily slow down a child's rate of growth, but it will probably not affect final adult height. Monitor your child's height periodically. This medication should be used only when clearly needed during pregnancy or labor/delivery. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

Tell your doctor of all prescription and nonprescription medication you may use, especially: azole antifungals (e.g., itraconazole, ketoconazole), cimetidine, HIV protease inhibitors (e.g., indinavir, ritonavir), macrolide antibiotics (e.g., clarithromycin, erythromycin), beta-blockers (e.g., atenolol, propranolol). Do not start or stop any medicine without doctor or pharmacist approval.

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. Symptoms of overdose may include: severe tremor, dizziness, rapid breathing.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59 and 86 degrees F (15 and 30 degrees C) 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.

Taj DRUG WORLD

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