Only for the use of Medical Professionals

Oxycort® HFA

Inhalation Aerosol
Formoterol Fumarate and Budesonide

Description
Oxycort® HFA inhalation aerosol is a combination of Formoterol Fumarate and Budesonide. Formoterol Fumarate is a very potent, selective, long acting β_2 agonist with a rapid onset of action; it attaches to β_2 receptors on the smooth muscle cells that surround the airways, causing the muscle cells to relax and opening the airways. Budesonide is a glucocorticosteroid with potent anti-inflammatory activity. **Oxycort ® HFA** is an environment friendly inhaler and does not contain chlorofluorocarbons (CFCs) as propellant. It uses hydrofluoroalkane (HFA) as propellant which is environment friendly.

Indications
Oxycort® HFA is indicated for the treatment of asthma in patients 12 years of age & older and for the maintenance treatment of chronic obstructive pulmonary disease (COPD).

Oxycort® HFA Inhaler is not indicated for the relief of acute bronchospasm.

Dosage and Administration
1. Asthma:
For patients 12 years of age and older, the dosage is 2 inhalations twice daily (morning and evening, approximately 12 hours apart). The recommended starting dosages for **Oxycort®** HFA are based upon patients' asthma severity. The maximum recommended dosage is **Oxycort® HFA** 4.5/160 mcg twice daily.
Improvement in asthma control following inhalation of **Oxycort®** HFA can occur within 15 minutes, although maximum benefit may not be achieved for 2 weeks or longer after beginning treatment. Individual patients will experience a variable time to onset and degree of symptom relief.
For patients who do not respond adequately to the starting dose after 1-2 weeks of therapy with **Oxycort® HFA** 4.5/80, replacement with **Oxycort® HFA** 4.5/160 may provide additional asthma control.
If a previously effective dosage regimen of **Oxycort® HFA** fails to provide adequate control of asthma, the therapeutic regimen should be re-evaluated and additional therapeutic options, (e.g., replacing the lower strength of **Oxycort® HFA** with the higher strength, adding additional inhaled corticosteroid, or initiating oral corticosteroids) should be considered.
2. COPD (Chronic Obstructive Pulmonary Disease):
For patients with COPD the recommended dose is **Oxycort® HFA** 4.5/160 Inhaler: 2 inhalations; twice daily. If shortness of breath occurs in period between doses, an inhaled short-acting β_2-agonist should be taken for immediate relief.

Side Effects
As the combination inhaler contains Formoterol Fumarate and Budesonide, the type and severity of adverse reactions associated with each of the compounds may be expected. There is no incidence of additional adverse events following concurrent administration of the two compounds.
Adverse events, which have been associated with Formoterol Fumarate Dihydrate and Budesonide, are given below:
Formoterol Fumarate : Tremor, palpitations and headache are common adverse events. Cardiac arrhythmias, muscle cramps and hypersensitivity reactions, including rash, oedema and angio-oedema are uncommon and rare.

Budesonide: Hoarseness, candida infection in the oropharynx and throat irritation may occur in some patients. Cutaneous hypersensitivity reactions, respiratory tract infections, immunosuppression, growth effect in children, glaucoma & cataract have been reported.

Precautions
Caution should be taken in patients with diabetes mellitus, thyrotoxicosis, untreated hypokalaemia, severe hypertension and severe cardiovascular disorders, such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Paradoxical bronchospasm may occur, with an immediate increase in wheezing and shortness of breath after dosing. If the patient experiences paradoxical bronchospasm the medication should be discontinued immediately.

Pregnancy and lactation
Pregnancy category C. There is no clinical data for the use of formoterol and budesonide on exposed pregnancies are available. Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the suckling child are anticipated. It is not known whether formoterol passes into human breast milk.
Administration of drugs during pregnancy and lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus or child.

Contraindications
This combination inhaler is contraindicated in patients with a history of hypersensitivity to any of the ingredients.

Drug Interactions
Co administration with potent CYP3A4 inhibitors (e.g., Ketoconazole, Ritonavir) should be avoided, as there is potential for increased systemic exposure to Budesonide. Both non-selective and selective
β blockers should be avoided in patients with asthma, unless there are compelling reasons for their use. Caution should be practiced while administering to patients with MAO (Monoamine oxidase inhibitor) inhibitors or Tri-cyclic anti-depressants or during 2 weeks of discontinuation.

Overdosage
The signs and symptoms of Formoterol overdose are tremor, headache, palpitations, tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Acute overdosage of Budesonide, even in excessive doses, is not expected to be a clinical problem. Chronic overdose of inhaled Budesonide may lead to adrenal suppression.

Pharmaceutical Precaution
Do not puncture, break or incinerate pressurized canister even when apparently empty.
Avoid storage in direct sunlight or heat.
Store below 30°C.
Keep away from eyes.
Keep away from children.

Package quantities
Oxycort® HFA 4.5/80 Inhaler: Each canister contains 120 metered doses, each actuation delivers Formoterol Fumarate Dihydrate BP 4.5 µg and Budesonide BP 80 µg.

Oxycort® HFA 4.5/160 Inhaler: Each canister contains 120 metered doses, each actuation delivers Formoterol Fumarate Dihydrate BP 4.5 µg and Budesonide BP 160 µg.

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