

Only for the use of Medical Professionals

Oxycort[®] Acucap

Dry Powder Inhaler

Formoterol Fumarate Dihydrate and Budesonide

Description

Oxycort[®] Acucap is a combination of Formoterol Fumarate Dihydrate and Budesonide. Formoterol Fumarate Dihydrate 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.

Indications

Oxycort[®] Acucap is indicated for the treatment of asthma and COPD.

Asthma: **Oxycort[®] Acucap** is indicated in the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting β_2 adrenoceptor agonist) is appropriate.

COPD: **Oxycort[®] Acucap** is indicated for the symptomatic treatment of severe COPD ($FEV_1 < 50\%$ predicted normal) and a history of repeated exacerbations despite regular therapy with long-acting bronchodilators.

Dosage and Administration

Asthma

Dosage should be individualized and adjusted according to the severity of disease. When control has been achieved, the dose should be titrated to the lowest effective dose.

There are two treatment approaches:

A. Maintenance therapy: **Oxycort[®] Acucap** can be taken as regular maintenance treatment with a separate rapid acting bronchodilator as rescue. Patients should be advised to have their separate rapid acting bronchodilator available for rescue use at all times.

Adults (18 years and older):

Oxycort[®] 6/100 Acucap: 1-2 **Oxycort[®] Acucap** twice daily; reduced to 1 **Oxycort[®]** once daily if control is maintained. Some patients may require up to maximum of 4 **Oxycort[®] Acucap** twice daily.

Oxycort[®] 6/200 Acucap: 1-2 **Oxycort[®] Acucap** twice daily; reduced to 1 **Oxycort[®]** once daily if control is maintained. Some patients may require up to maximum of 4 **Oxycort[®] Acucap** twice daily.

Oxycort[®] 12/400 Acucap: 1 **Oxycort[®] Acucap** twice daily. Some patients may require up to maximum of 2 **Oxycort[®] Acucap** twice daily.

Adolescents (12 – 17 years)

Oxycort[®] 6/100 Acucap: 1-2 **Oxycort[®] Acucap** twice daily; reduced to 1 **Oxycort[®] Acucap** once daily if control is maintained.

Oxycort[®] 6/200 Acucap: 1-2 **Oxycort[®] Acucap** twice daily; reduced to 1 **Oxycort[®] Acucap** once daily if control is maintained.

Oxycort[®] 12/400 Acucap: 1 **Oxycort[®] Acucap** twice daily.

Children (6-11 years)

Oxycort[®] 6/100 Acucap: 1-2 **Oxycort[®] Acucap** twice daily; reduced to 1 **Oxycort[®] Acucap** once daily if control is maintained.

B. Maintenance and reliever therapy: **Oxycort**[®] Acucap can be taken as regular maintenance treatment and as needed in response to symptoms. Patients take a daily maintenance dose of **Oxycort**[®] Acucap and in addition take **Oxycort**[®] Acucap as needed in response to symptoms. Patients should be advised to always have **Oxycort**[®] Acucap available for use.

Adults (18 years and older): The recommended maintenance dose is 2 **Oxycort**[®] Acucap per day, given either as one inhalation in the morning and evening or as 2 **Oxycort**[®] Acucap in either the morning or evening. For some patients a maintenance dose of 2 **Oxycort**[®] Acucap twice daily may be appropriate. Patients should take 1 additional **Oxycort**[®] Acucap as needed in response to symptoms. If symptoms persist after a few minutes, an additional **Oxycort**[®] Acucap should be taken. Not more than 6 **Oxycort**[®] Acucap should be taken on any single occasion.

A total daily dose of more than 8 **Oxycort**[®] Acucap is not normally needed; however, a total daily dose of up to 12 **Oxycort**[®] Acucap could be used for a limited period. Patients using more than 8 **Oxycort**[®] Acucap daily should be strongly recommended to seek medical advice.

COPD

Oxycort[®] 6/200 Acucap: 2 **Oxycort**[®] Acucap twice daily.

Oxycort[®] 12/400 Acucap: 1 **Oxycort**[®] Acucap twice daily.

Side Effects

As the combination inhaler contains Formoterol Fumarate Dihydrate 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 Dihydrate: 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 have been reported.

Contraindications

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

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 Symbicort should be discontinued immediately.

Pregnancy and lactation

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.

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.

Overdosage

The signs and symptoms of Formoterol overdose are tremor, headache, palpitations, tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Acute overdose 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

Oxycort® Acucap must not be swallowed and can be used with **any inhaler device**. Remove Acucap capsule from the blister pack just prior to use, as Acucap exposed to moisture may not tear easily.

Avoid storage in direct sunlight or heat. Store below 30°C. Keep away from children.

Package quantities

Oxycort® 6/100 Acucap: Each box contains 32 capsules in alu-alu blister strips. Each Acucap capsule contains Formoterol Fumarate Dihydrate BP 6 µg and Budesonide BP 100 µg.

Oxycort® 6/200 Acucap: Each box contains 32 capsules in alu-alu blister strips. Each Acucap capsule contains Formoterol Fumarate Dihydrate BP 6 µg and Budesonide BP 200 µg.

Oxycort® 12/400 Acucap: Each box contains 32 capsules in alu-alu blister strips. Each Acucap capsule contains Formoterol Fumarate Dihydrate BP 12 µg and Budesonide BP 400 µg.sss

® Registered Trade Mark



ACI Limited