



Supotaria™ ConviCap

Glycopyrronium 50 µg

Presentation

Supotaria™ ConviCap: Each capsule contains Glycopyrronium Bromide BP equivalent to 50 µg of Glycopyrronium.

Description

Glycopyrronium is a long-acting, specific antimuscarinic agent, in clinical medicine often called an anticholinergic. It has a similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, inhibition of M3-receptors at the smooth muscle results in relaxation. The high potency and slow receptor dissociation found its clinical correlate in significant and long-acting bronchodilation in patients with COPD.

Indication and Uses

Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Dosage & Administration

The recommended dosage of Glycopyrronium is inhalation of the contents of one capsule once daily with the ConviHaler device at the same time of day.

Side-effects

Inhaled medicines may cause inhalation-induced bronchospasm, dehydration, dry mouth, constipation, dizziness, insomnia, skin and subcutaneous tissue disorders, immune system disorders.

Precautions

Glycopyrronium, as a once daily maintenance bronchodilator, should not be used for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur after administration of Glycopyrronium inhalation powder. As with other anticholinergic drugs, Glycopyrronium should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction.

Use in Pregnancy & Lactation

Pregnancy:

There is a limited amount of data from the use of Glycopyrronium in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at clinically relevant doses.

Lactation:

Glycopyrronium should not be used in pregnant or nursing women unless the expected benefit outweighs any possible risk to the unborn child or the infant.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Drug interactions

Although no formal drug interaction studies have been performed, Glycopyrronium inhalation powder has been used concomitantly with other drugs, commonly used in the treatment of COPD, including sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids without clinical evidence of drug interactions.

Overdose

High doses of Glycopyrronium may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a single inhaled dose of up to 150 micrograms Glycopyrronium in healthy volunteers.

Storage

- 1) Should be stored at temperature not exceeding 25°C but do not freeze.
- 2) Should be stored in cool and dry place, protected from light.

Commercial Pack

Supotaria™ ConviCap: Each box contains 5 Alu-Alu blister strips of 6 capsules.