120x160mm

Glynvair™

(Glycopyrronium)

Highnoon

COMPOSITION
Each capsule contains:
Glycopyrronium (as Bromide) 50mcg

Each delivered dose contains:
Glycopyrronium (as Bromide) 44mcg

DESCRIPTION
Glycopyrronium is a competitive antagonist at muscarinic acetylcholine receptors and belongs to the class of drugs known as anticholinergics.

MECHANISM OF ACTION
Glycopyrronium is a long-acting muscarinic antagonist which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation. It has competitive and reversible nature of antagonism. The bronchodilation following inhalation of glycopyrronium is predominantly a site-specific effect.

PHARMACOKINETICS
Glycopyrronium is poorly absorbed from the gastrointestinal tract; about 10% to 25% is absorbed after an oral dose. Glycopyrronium bromide penetrates the blood brain barrier only poorly. Glycopyrronium is excreted in the bile and urine.

INDICATIONS
It is indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

DOSAGE AND ADMINISTRATION
This product is for inhalation use only.
The recommended dose is the inhalation of the content of one capsule once daily. It is recommended to be administered, at the same time of the day each day. If a dose is missed, the next dose should be taken as soon as possible. Patients should be instructed not to take more than one dose in a day.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the ingredients.

ADVERSE EFFECTS
The reported adverse events are; paradoxical bronchospasm, immediate hypersensitivity reactions including anaphylaxis, angioedema & rash, worsening of narrow angle glaucoma, worsening of urinary retention, upper respiratory tract infection, nasopharyngitis, sinusitis, oropharyngeal pain, rash, pruritus, gastroenteritis, atrial fibrillation, insomnia, hypersensitivity, dysuria, vomiting, diabetes mellitus, pain in extremity. Dysuria, productive cough, hyperglycaemia, nausea, diarrhoea, upper abdominal pain, pneumonia, fatigue, back pain, rhinitis, arthralgia, bronchitis, dyspnoea, wheezing, increase risk of infection, pain, dental caries, asthenia, cystitis, numbness, throat irritation, abdominal discomfort, urinary disorder, paraesthesia, anhidrosis, bradycardia, bronchial secretion decrease, mydriasis and photophobia.

DRUG INTERACTION
- Concurrent administration of short-acting and long-acting sympathomimetic (beta-agonists) bronchodilators (including indacaterol), methylxanthines, oral and inhaled steroids showed no increase in adverse drug reactions.
- There is a potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid its coadministration with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic effects.
- Cimetidine, an inhibitor of organic cation transport which is thought to contribute to the renal excretion of glycopyrronium, increased total exposure (AUC) to glycopyrronium by 22% and decreased renal clearance by 23%. Based on the magnitude of these changes, no clinically relevant drug interaction is expected when glycopyrronium is co-administered with cimetidine or other inhibitors of organic cation transport.

WARNINGS AND PRECAUTIONS
Deterioration of Disease and Acute Episodes
Glycopyrronium should not be initiated in patients with acutely deteriorating or potentially life-threatening episodes of COPD. Glycopyrronium has not been studied in patients with acutely deteriorating COPD. The initiation of glycopyrronium in this setting is not appropriate.
It should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. It has not been studied in the relief of acute symptoms, and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta 2 agonist.
COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If glycopyrronium no longer controls the symptoms of bronchoconstriction; the patient's inhaled, short-acting beta 2 agonist becomes less effective; or the patient needs more inhalation of short-acting beta 2 agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of glycopyrronium, beyond the recommended dose is not appropriate in this situation.

Paradoxical bronchospasm
As with other inhaled medicines, glycopyrronium can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing, it should be treated immediately with an inhaled, short-acting bronchodilator; glycopyrronium should be discontinued immediately, and alternative therapy instituted.

Hypersensitivity
Immediate hypersensitivity including anaphylaxis reactions have been reported. If signs suggesting allergic reactions occur, in particular, angioedema (including difficulties in breathing or swallowing, swelling of the tongue, lips, and face), urticaria or skin rash, it should be discontinued immediately, and alternative therapy instituted. It should be used with caution in patients with severe hypersensitivity to milk proteins.

Narrow angle glaucoma
Glycopyrronium should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema). Instruct patients to contact their doctor immediately should any of these signs or symptoms develop.

Worsening of urinary retention
Glycopyrronium should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

USE IN SPECIAL POPULATION
Pregnancy
There are no adequate and well controlled studies with glycopyrronium in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. However, glycopyrronium should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus.

Lactation
It is unknown whether glycopyrronium is excreted in human milk. However, glycopyrronium (including its metabolites) was excreted in the milk of lactating rats. The use of glycopyrronium by breast-feeding women should only be considered if the expected benefit to the woman is greater than any possible risk to the infant.

Fertility
Reproduction studies and other data in animals do not indicate a concern regarding fertility in either males or females.

Elderly population
No adjustment of the dosage of glycopyrronium in geriatric patient is warranted. It can be used at the recommended dose in elderly patients (75 years of age and older).

Renal impairment
It can be used at the recommended dose in patients with mild to moderate renal impairment. In patients with severe renal impairment or end-stage renal disease requiring dialysis it should be used only if the expected benefit outweighs the potential risk since the systemic exposure to glycopyrronium may be increased in this population.

Hepatic impairment
No studies have been conducted in patients with hepatic impairment. Glycopyrronium is predominantly cleared by renal excretion and therefore no major increase in exposure is expected in patients with hepatic impairment. No dose adjustment is required in patients with hepatic impairment.

Paediatric population
The safety and efficacy of glycopyrronium in paediatric patients have not been established. Glycopyrronium is not indicated for use in children.

OVERDOSAGE
High doses of glycopyrronium may lead to anticholinergic signs and symptoms such as nausea, vomiting, dizziness, light headedness, blurred vision, obstipation or difficulty in voiding and increased intraocular pressure (causing pain, vision disturbance, or reddening of the eyes).

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30ºC. Keep in a dry place. Protect from light.

ROTACAP IS INTENDED FOR USE THROUGH ROTAFLO OR REVOLIZER ONLY AND IS NOT TO BE SWALLOWED.

PRESENTATION
Glynvair Rotacaps: Alu. Alu. Blister Pack of 3 x 10's.

120x160mm

گلن وائیر™

(گلائیکوپائرونیم)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

روٹا کیپسول کھانے کیلئے نہیں ہے۔
صرف روٹافلو یا ریوولائزر کے ذریعے استعمال کریں۔

Manufactured by
HIGHNOON LABORATORIES LTD
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www.highnoon-labs.com

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