Package Leaflet: Information for the Patient
Glycopyrronium Bromide 1 mg/5 ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Glycopyrronium Bromide oral solution
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1. What Glycopyrronium Bromide oral solution is and what it is used for

This medicine is called Glycopyrronium Bromide and belongs to a group of medicines called anticholinergic or antimuscarinic drugs. It contains the active substance glycopyrronium bromide. Each 5 ml dose of oral solution contains 1 mg of glycopyrronium bromide.

- Glycopyrronium Bromide is used, in combination with other medicines, to treat peptic (stomach) ulcers in adults

2. What you need to know before you take Glycopyrronium Bromide oral solution

Do not take Glycopyrronium Bromide oral solution if:

- you are allergic (hypersensitive) to glycopyrronium bromide or any of the other ingredients of this medicine (listed in section 6)
- you have glaucoma (increased pressure in the eye)
- you have a condition called myasthenia gravis which leads to muscle weakness and fatigue
- you have obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus)
- you have an enlarged prostate gland (prostatic hypertrophy)

Warnings and precautions
Talk to your doctor or pharmacist before taking Glycopyrronium Bromide if:

- you are over 60 years of age
- you have gastric reflux (a condition in which the liquid stomach contents backs up into the gullet)
- you have ulcerative colitis (a chronic inflammation of the large intestine (colon) which can cause abdominal pain, diarrhoea and bleeding from the back passage)
- you have just had a heart attack or are suffering from heart disease, irregular heart beats or high blood pressure, because this medicine can cause a change to your normal heart rate
- you have a condition characterised by a faster heart beat than normal (this can be caused by conditions such as an overactive thyroid gland, heart failure or heart surgery)
• you are due to have surgery (including at the dentist) during which you will be ‘put to sleep’ using inhalation anaesthesia. This is because this medicine may cause a change in your normal heart rhythm
• you have diarrhoea, especially if you have had an ileostomy or colostomy
• you have a high temperature (fever) or the environmental temperature is high, as this medicine will reduce the amount you sweat, making it harder for your body to cool down
• you have kidney disease, because this medicine’s dose may need to be decreased
• you have been told by your doctor that you have an intolerance to some sugars, because this medicine contains sorbitol

Children
This medicine is not recommended for children. Talk to your doctor or pharmacist before taking this medicine if you are a child or this medicine has been prescribed for a child.

Other medicines and Glycopyrronium Bromide oral solution
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines you have bought without a prescription.

• If your doctor tells you to take both this medicine and one or more similar medicines such as oxybutynin, then you may need to take less than the usual dose of this medicine. This is because elderly people may become confused and there is an increased risk of other side effects such as dry mouth, retention of urine and constipation when Glycopyrronium Bromide and similar medicines are taken together.

Please tell the doctor if you are taking or have recently taken:
• Antidepressants such as amitriptyline, clomipramine, lofepramine or imipramine (known as tricyclic antidepressants) or monoamine oxidase inhibitors (MAOIs) such as phenelzine, moclobemide, rasagiline, selegiline or tranylcypromine
• Phenothiazines such as chlorpromazine, fluphenazine, prochlorperazine or trifluoperazine, used to treat mental problems or nausea, vomiting or vertigo
• Antihistamines such as promethazine, used to treat allergies
• Parasympathomimetics such as carbachol, neostigmine or physostigmine which affect the transmission of nerve impulses to muscles
• Corticosteroids such as prednisolone, used to treat various conditions including asthma and inflammation
• Inhaled anaesthetics, given to you before you have surgery (including at the dentist)
• Clozapine or haloperidol, used to treat schizophrenia
• Nefopam, used to treat acute and chronic pain
• Domperidone or metoclopramide, used to treat nausea and vomiting
• Amantadine or levodopa, used to treat Parkinson’s disease
• Memantine, used to treat Alzheimer’s disease
• Slow-dissolving digoxin tablets, disopyramide or atenolol, used to treat heart problems
• Metformin, used to treat type 2 diabetes
• Glyceryl trinitrate tablets, used to treat angina. These may not dissolve under the tongue as well as usual because this medicine can cause a dry mouth
• Topiramate or zonisamide, used to treat epilepsy and to prevent migraines

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

• As a precautionary measure, the use of Glycopyrronium Bromide oral solution during pregnancy should be avoided.
• Breast feeding should be discontinued during treatment with this medicine.
Driving and using machines
Glycopyrronium Bromide may make you feel drowsy or cause your eyesight to become blurred and this could interfere with your ability to drive or operate machinery safely. Do not drive or operate machinery until these effects have fully cleared. If you are in any doubt, ask your doctor for advice.

Glycopyrronium Bromide oral solution contains E420 (sorbitol), E217 and E219
- This medicine contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- This medicine contains sodium propyl parahydroxybenzoate (E217) and sodium methyl parahydroxybenzoate (E219). These may cause allergic reactions (possibly delayed) and exceptionally, bronchospasms (a narrowing of the airways).

3. How to take Glycopyrronium Bromide oral solution
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is:
- 5 ml (1 mg), three times a day (in the morning, early afternoon and at bedtime). You may require 10 ml (2 mg) at bedtime to control symptoms overnight. When your symptoms are controlled, a dose of 5 ml (1 mg) two times a day may be sufficient
- Do not take more than 20 ml (4 mg) per day

Directions for use
- This medicine should be taken at least one hour before or two hours after a meal.
- This medicine is for oral use only.
- Carefully pour the solution into the dosage cup provided. Use the markings on the side of the cup to measure the correct amount to take.
- Pour the measured amount from the dosage cup into your mouth and swallow it.
- After use, wash the dosage cup with clean water (do not put it in a dishwasher).

Children
This medicine is not recommended for children. Talk to your doctor or pharmacist before taking this medicine if you are a child or this medicine has been prescribed for a child.

If you take more Glycopyrronium Bromide oral solution than you should
If you take more of this medicine than you have been prescribed you are more likely to experience side effects. Consult your doctor or get medical advice immediately. If possible, give any leftover solution, the bottle and this leaflet to the medical staff so they know what you have taken.

If you forget to take Glycopyrronium Bromide oral solution
- If you forget to take a dose, take it as soon as possible. Then take the next dose at the correct time, in accordance with the instructions given to you by your doctor. However, if your next dose is due, do not take the dose you have missed; just take the next dose as normal.
- **Do not take a double dose to make up for the forgotten one.**
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following side effects **tell your doctor**:
- Dry mouth
- Reduced movement of the stomach and intestines leading to constipation
• Difficulty passing urine
• Increased body temperature
• Reduced sweating
• Difficulty swallowing
• Difficulty talking
• Thirst
• Slow heart beats followed by rapid, pounding/fluttering and irregular heartbeats
• Reduced secretions in the airways
• Urgency to pass urine
• Enlarged pupils accompanied by visual disturbances
• Increased sensitivity towards light (photophobia)
• Flushing
• Dry skin
• Confusion, especially in the elderly
• Feeling sick (nausea)
• Being sick (vomiting)
• Drowsiness
• Dizziness
• Eye disorder (glaucoma)

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. **This includes any possible side effects not listed in this leaflet.**

You can also report side effects directly to the relevant medicines authority (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom:** The Yellow Card Scheme
Medicines and Healthcare Products Regulatory Agency
151 Buckingham Palace Road
Victoria, London, SW1W 9SZ
United Kingdom
www.yellowcard.mhra.gov.uk

**Malta:** ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3
Rue D’Argens
Gżira G ŻR-1368
Malta
www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. **How to store Glycopyrronium Bromide oral solution**

• Keep this medicine out of the sight and reach of children.
• Do not use this medicine after the expiry date, which is stated on the label after EXP. The expiry date refers to the last day of that month.
• This medicine should be stored below 25°C in its original bottle.
• Do not freeze.
• Keep the bottle in the original carton in order to protect from light.
• **Once the bottle has been opened, this medicine should be used within 28 days.**
• Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
6. Contents of the pack and other information

What Glycopyrronium Bromide oral solution contains
- The active substance is glycopyrronium bromide. Each 5 ml of oral solution contains 1 mg of glycopyrronium bromide.

- The other ingredients are:
  - Glycerol
  - Sorbitol (E420) (see section 2)
  - Sodium methyl parahydroxybenzoate (E219) (see section 2)
  - Sodium propyl parahydroxybenzoate (E217) (see section 2)
  - Citric acid monohydrate
  - Trisodium citrate dihydrate
  - Strawberry flavour:
    - Flavouring substance
    - Maltodextrin (maize)
    - Acacia (E414)
    - Triacetin (E1518)

What Glycopyrronium Bromide oral solution looks like and contents of the pack
Glycopyrronium Bromide oral solution is a clear, colourless, strawberry flavoured liquid supplied in a 150 ml amber glass bottle with a child resistant cap. Each pack contains one 150 ml bottle and one dosage cup.

Marketing Authorisation Holder
Colonis Pharma Limited
Quantum House
Hobson Industrial Estate
Burnopfield
County Durham
NE16 6EA
United Kingdom

Manufacturers
Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Labialfarma
Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A.
Felgueira
Sobral Mortágua
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Portugal

Quantum Pharmaceutical Limited
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