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 or you may have 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

1. What Glycopyrronium Bromide oral solution is and what it is used for

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 5ml dose of oral solution contains 1 mg of glycopyrronium bromide.

Glycopyrronium Bromide is used, in combination with other medicines, to treat paralytic ileus 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 had a heart attack or are suffering from heart disease, irregular heart beats or high blood pressure, because this medicine may have a change to your normal heart rate
- you have heart condition characterised by a faster heart beat than normal (this can be caused by conditions such as an overactive thyroid gland, 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 environmental temperature is high, as this medicine will reduce the amount you sweat, and help to lower 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 the usual dose. 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 combinations are taken together.

Please tell the doctor or you are taking or have recently taken:

- Antidepressants such as amitriptyline, clomipramine, lofexidine or imipramine (known as tricyclic antidepressants) or monoamine oxidase inhibitors (MAOIs) such as phenelzine, moclobemide or linezolid, selegline or tranylcypromine
- Phenothiazines such as chlorpromazine, fluphenazine, prochlorperazine, metoclopramide, trifluoperazine, used to treat mental illness, such as anxiety, or nausea, vomiting or vertigo
- Anticholinamides such as scopolamine, used to treat allergies
- Parasympathomimetics such as carbarch, neostigmine or pyostigmamine 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)
- Cisapride or haloperidol, used to treat schizophrenia
- Nefopam, used to treat acute and chronic pain
- Domperidone or metoclopramide, used to treat nausea and vomiting
- Amantidine or levodopa, used to treat Parkinson's disease
- Memantine, used to treat Alzheimer's disease
- Slow-dissolving dispersible tablets, diisopyramid 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 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 before taking this medicine.

- As a precautionary measure, the use of Glycopyrronium Bromide oral solution during pregnancy should be avoided.
- Breastfeeding 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. 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 (parahydroxybenzoate) and sodium propylparahydroxybenzoate (E217) and sodium methyl parahydroxybenzoate (E219). These may cause allergic reactions (possibly delayed) and exceptionally, bronchospasms (a narrowing of the airways).

*FT006*
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:

- 5ml (1mg), three times a day (in the morning, early afternoon and at bedtime). You may require 10ml (2mg) at bedtime to control symptoms overnight. When your symptoms are controlled, a dose of 5ml (1mg) two times a day may be sufficient.
- Do not take more than 20ml (4mg) 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.
- Avoid taking the medicine with 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.
- Do not use any left-over medicine if you are a child or this medicine is not recommended for children.

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/heaviness
- 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)
- Diarrhoea
- 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).

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 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 5ml of oral solution contains 1mg 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)
  - Trianetin (E118)

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 150ml amber glass bottle with a child resistant cap. Each pack contains one 150ml bottle and one dosage cup.

Marketing Authorisation Holder

Colonis Pharma Limited
Quantum House
Hobson Industrial Estate
Burnopfield
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NE16 6EA
United Kingdom

Manufacturer

Dales Pharmaceuticals Limited
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