CHECKLIST FOR HEALTHCARE PROFESSIONALS

Glycopyrronium Bromide 1mg/5ml Oral Solution

Somex Pharma

Warning: Glycopyrronium Bromide is NOT interchangeable with other glycopyrronium products without dose adjustment. When switching between products, the specific dose recommendations for each product must be followed to avoid overdose and anticholinergic side effects.

The Checklist For Healthcare Professionals is an aid to help you evaluate and discuss the risks associated with glycopyrronium bromide oral solution with the patient's carer. It provides important information on the management and minimisation of side effects.
The information below is provided as a guide for the healthcare professional. For more detailed information on this product please refer to the summary of product characteristics.

For any additional enquiries about this product or if you need additional copies of the checklist for HCP you may email ds@somexpharma.com
There are different strengths of oral glycopyrronium solution currently available in the UK. The dosing schedule of each strength may differ. This should be taken into consideration when prescribing glycopyrronium bromide oral solution.

Marketing Authorisation Holder and Manufacturer:
Strandhaven Limited T/A Somex Pharma
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MANAGEMENT AND MINIMISATION OF SIDE EFFECTS

- Glycopyrronium bromide oral solution is indicated for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) due to chronic neurological disorders of childhood-onset in patients 3 years and older.
- Due to the lack of long term safety data, glycopyrronium bromide oral solution is recommended for short-term intermittent use.
- Physicians who are specialised in the treatment of patients with neurological disorders should prescribe glycopyrronium bromide oral solution. The physician should also regularly monitor the patient and change the dose accordingly.
- Glycopyrronium bromide is an anticholinergic drug and the most common side effects are those typically associated with this type of treatment. These effects are often dose-dependent and difficult to evaluate in a disabled child.
- The treating physician should make the patient's caregiver aware of the possible anticholinergic effects which can occur and should guide the carer on how to prevent or reduce them.
- During the treatment, anticholinergic side effects should be assessed in the patient by the treating physician. The following checklist for the assessment of anticholinergic side effects should be used.

Checklist for assessment of side effects associated with glycopyrronium bromide use.	
Doctor's name:	
Date of assessment:	
Anticholinergic effects	Result of Assessment
Constipation	
Urinary Retention	
Pneumonia	
Allergic Reaction	
Overheating	
Dental disease	
CNS effects	
Cardiovascular effects	

- The dosage of glycopyrronium bromide oral solution should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. To aid accurate dosing, a dosage regimen is given as part of a reminder card for the caregiver. The reminder card should be completed by the physician with the initial dose and any subsequent dose change.

ESSENTIAL INFORMATION ON GLYCOPYRRONIUM BROMIDE ORAL SOLUTION TO BE PROVIDED TO THE PATIENT'S CAREGIVER

The patient's caregiver should be made aware of the following essential points:

- To administer glycopyrronium bromide oral solution as the doctor has prescribed.
- To contact the patient's doctor if the patient's carer is not sure about the exact dose to be administered to the patient.
- To administer glycopyrronium bromide oral solution at least one hour before or two hours after meals or at consistent times with respect to food intake.
- To avoid administration of glycopyrronium bromide oral solution with high-fat meals.
- To not increase the dose of glycopyrronium bromide oral solution without the permission of the patient's doctor.
- To stop using this medicine and seek urgent medical advice if any of the following serious side effects occur.
  - Constipation (difficulty in passing stool)
  - Urinary retention (difficulty in passing urine)
  - Pneumonia (severe chest infection)
  - Allergic reaction (rash, itching, red raised itchy rash (hives), difficulty in breathing or swallowing, dizziness)
- It is sometimes difficult to detect side effects in patients with neurological problems who cannot adequately express how they feel. In these situations, if the patient's caregiver observes any side effects after increasing the dose, then they should decrease the dose to the previous one and immediately contact the treating doctor.
- To avoid overheating and the possibility of heat stroke, the patient's carer should avoid exposing the patient to hot or very warm weather. To check with the doctor during hot weather to see if the dose should be reduced.
- The risk of dental disease can increase with reduced salivation. It is important that daily dental hygiene checks and regular dental health checks are performed.
- The patient's caregiver should regularly check the patient's pulse and contact the patient's doctor if the heartbeat is very slow or rapid.
- The patient's caregiver should observe any changes in the patient's behaviour or well-being and convey the same to the patient's treating doctor.

ADDITIONAL INFORMATION TO EMPHASISE

The patient's caregiver should be made aware of the following additional points:

- To consult a doctor **immediately** or go to the emergency department of the nearest hospital right away if the patient is given more glycopyrronium bromide oral solution than they should, even if the patient seems well.
- Tell the patient's doctor if they are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- To report any side effects to the healthcare professional.
- To read the Patient Information leaflet.
- To consult with the prescribing doctor at no longer than 3 monthly intervals to ensure that glycopyrronium bromide is still an appropriate treatment for the patient.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9 am and 5 pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

For additional information, the patient's caregiver can also refer to the patient information leaflet provided with this product.

This checklist for healthcare professionals was revised in July 2025