RYBRILA

Glycopyrronium bromide 0.2 mg/ml, oral solution

The healthcare professional (HCP) checklist is an aid to help you evaluate and discuss the risks associated with Rybrila with the patient's caregiver. It provides important information on the management and minimization 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 HCP checklist you may email Customer_Support@cts.co.il.

MANAGEMENT AND MINIMISATION OF

SIDE EFFECTS

- Rybrila is indicated for the Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.
- Due to the lack of long term safety data, Rybrila is recommended for short-term intermittent use.
- Physicians who are specialized in the treatment of patients with neurological disorders should prescribe Rybrila.

  The physician should also regularly monitor the patient and change the dose accordingly.
- Rybrila 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 caregiver 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 Rybrila 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 Rybrila 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 patient alert card for the caregiver. The patient alert card should be completed by the physician with the initial dose and any subsequent dose change.

ESSENTIAL INFORMATION ON RYBRILA TO BE PROVIDED TO THE PATIENT'S CAREGIVER

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

- To administer Rybrila as the doctor has prescribed.
- To contact the patient's doctor if the patient's caregiver is not sure about the exact dose to be administered to the patient.
- To administer Rybrila at least one hour before or two hours after meals or at consistent times with respect to food intake.
- To avoid administration of Rybrila with high-fat meals.
- To not increase the dose of Rybrila 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 immediately seek advice from the prescriber.
- To avoid overheating and the possibility of heat stroke, the patient's caregiver 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 behavior 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 Rybrila 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 Rybrila is still an appropriate treatment for the patient.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

Adverse reactions can also be reported to CTS by E-mail to drug.safety@cts.co.il.

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

Marketing Authorization Holder: CTS Ltd.

This HCP checklist was approved according to the guidelines of the Ministry of Health in 11/2025.

ILRMP Version 1.0.