Checklist for Healthcare Professionals for Rybrila 160 microgram/ml (glycopyrronium bromide) – Risk minimisation of anticholinergic side effects

Rybrila is approved for symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.

Anticholinergic side effects associated with the use of Rybrila may be dose dependant and difficult to assess in a disabled child.

There are different strengths of oral glycopyrronium solution currently available in Ireland. The dosing schedule of each strength may differ. This should be taken into consideration when prescribing glycopyrronium bromide oral solution.

Rybrila should be prescribed by physicians specialised in the treatment of paediatric patients with neurological disorders, who should also conduct monitoring and dose changes.

Due to lack of long-term safety data, Rybrila is recommended for short-term intermittent use.

The treating physician should bring to the attention of the patient's parent/ caregiver the possible common anticholinergic side effects, as shown in the checklist below that may occur with the use of Rybrila and provide advice on how to recognise and prevent or minimise them.

During the course of treatment, anticholinergic reactions should be assessed in the patient by the physician, indicating the date and result of the assessment using the labels provided, which should be attached to the patient's notes. The format of the checklist is provided below for your information.

Checklist for assessment of anticholinergic effects – Rybrila 160 microgram/ml oral solution (glycopyrronium bromide)	
Name of patient:	
Date of the assessment:	
Anticholinergic reaction	**Result of assessment**
Urinary retention	
Constipation	
Pneumonia	
Allergic reaction	
Dental caries	
Cardiovascular effects	
CNS effects	
Overheating	

It is important to make sure an accurate dose is given each time, in order to prevent harmful effects of Rybrila seen with dosing errors or overdose. In order to give Rybrila safely, the dosing table on the *Reminder Card for Caregivers* should be completed by the physician with the proposed dose at each dose change. *The Reminder Card for Caregivers* should be handed to patient's parents/caregivers.

Important information to be brought to the attention of the parent/caregiver:

- To give Rybrila exactly as the doctor has directed.
- To check with the treating doctor if parent/caregiver is not sure about the right dose.
- To give Rybrila at least one hour before, or two hours after meals.
- To avoid giving Rybrila with a high fat meal as it reduces the amount of medicine absorbed.
- To make the parent/ caregiver aware that there are different strengths of glycopyrronium bromide oral solutions available, and to be mindful which one is prescribed and dispensed.
- Obligation to measure the dose of Rybrila using the special measuring device (oral syringe) provided in the carton, and to carefully check the level on the syringe.
- To stop giving Rybrila and seek urgent medical advice if any of the following side effects occur:

    - Constipation
    - Urinary retention
    - Pneumonia
    - Allergic reaction

- To inform that side effects can sometimes be difficult to recognise in patients with neurological problems who cannot easily express how they feel. To decrease the dose to the previous one and contact the treating doctor if the parent/caregiver thinks that a troublesome side effect is occurring after increasing a dose. To talk to their doctor if they are unsure about whether the child is experiencing any side effect.
- To avoid exposing the patient to hot or very warm weather to prevent overheating and the possibility of heat stroke. To check with the child's doctor during hot weather to see if the dose of Rybrila should be reduced.
- To ensure adequate daily dental hygiene and regular dental health checks to reduce the risk of dental caries.
- If the child seems unwell, check the child's pulse rate and report very slow or very fast heart rate.
- To look for changes in the general well-being or behaviour since the child cannot always express how they feel and tell the treating healthcare professional.

Additional points to emphasise:

- To report any side effects to their doctor, including those not listed as a side effect in the Product Information Leaflet.
- To seek urgent medical advice immediately if the child is given too much Rybrila,even if the child seems well.
- To tell the child's doctor if the child is taking, has recently taken or might take any other medicines. To consult with the prescribing doctor at no longer than three monthly intervals to ensure that Rybrila is still an appropriate treatment for the child.
- To read the Patient Information Leaflet.

More detailed information about Rybrila can be found in the Summary of Product Characteristics [http://www.hpra.ie/img/uploaded/swedocuments/Licence_PA22701-001-001_27072021103120.pdf].

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to

Clinigen

Email: medicalinformation@clinigengroup.com ; Fax: +44(0)1932 824284

Alternatively, report to

HPRA Pharmacovigilance

Website: www.hpra.ie

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