

## Reminder Card for Caregivers

Rybrila 160 microgram/ml Oral Solution (glycopyrronium bromide)

# HOW TO MANAGE COMMON SIDE EFFECTS

There are different strengths of liquid glycopyrronium bromide available in Ireland. Check carefully the product label to ensure that you have been given Rybrila for your child.

Rybrila has been prescribed for your child or adolescent to treat excessive production of saliva (sialorrhoea).

It is not recommended for children less than 3 years of age.

The side effects associated with Rybrila (an anticholinergic drug) may be dose dependent and difficult to assess in a disabled child. Your child's doctor will talk to you about common side effects that may occur and how to manage them.

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.

## Important Information on the administration of Rybrila:

- Always give Rybrila exactly as the doctor has told you. You should not increase the dose without the doctor's permission. Check with your doctor if you are not sure.
- Give Rybrila at least one hour before or two hours after meals. If the child's specific needs determine that co-administration with food is required, it is important to give Rybrila at consistent times in relation to food intake. Do not give with high fat foods.
- You must measure and check the dose of Rybrila using the special measuring device (oral syringe) provided. Always double check if the correct volume of Rybrila is measured into the syringe. Instructions on how to use the syringe are provided in the Patient Information Leaflet.
- The administration table at the end of this card should be completed by the prescribing physician initially and at each dose change. Its purpose is to remind the caregiver of the correct dose to be given to the child.

## Dose administration table:

PATIENT NAME:

DOB:

DOCTOR'S NAME:

DOCTOR'S CONTACT DETAILS:

DOSE PRESCRIBED (TO BE COMPLETED BY THE DOCTOR)

| No   | Dose (ml) | Start date (dd-mmm-yy) | End date (dd-mmm-yy) |
|------|-----------|------------------------|----------------------|
| 1.   |           |                        |                      |
| 2.   |           |                        |                      |
| 3.   |           |                        |                      |
| 4.   |           |                        |                      |
| 5.   |           |                        |                      |
| 6.   |           |                        |                      |
| etc. |           |                        |                      |

## How to manage important side effects:

- If any of the following side effects occur, stop giving the medicine to the child and seek urgent medical advice;
  - Difficulty in passing stools (constipation)
  - Difficulty in passing urine or unable to completely empty the bladder (urinary retention)
  - Severe chest infection (pneumonia)
  - Allergic reaction (rash, itching, red raised itchy rash (hives), difficulty breathing or swallowing, dizziness)
- Side effects can sometimes be difficult to detect in some patients with neurologic problems who cannot adequately express how they feel. If you think that a troublesome side effect is occurring after increasing the dose, decrease the dose to the previous one and contact the child's doctor.
- Avoid exposing the child to hot or very warm weather to avoid overheating and the possibility of heat stroke. Check with the child's doctor during hot weather or if the child has a fever, to see if the dose of Rybrila should be reduced.
- Since reduced salivation can increase the risk of dental disease, daily dental hygiene and regular dental health checks should be performed.
- Check the child's pulse at regular intervals. Check with the child's doctor if the heart beat is very slow or very rapid.
- You should look for any changes in the child's well-being or behaviour and tell the child's doctor

## Additional information

- Seek urgent medical advice immediately if the child is given too much Rybrila, even if the child seems well.
- Tell the child's doctor if your child is taking, has recently taken or might take any other medicines.
- Check with the child's doctor at least every 3 months to make sure Rybrila is still right for the child.

Further information about taking Rybrila can be found in the Patient Information Leaflet which can be obtained from your child's doctor or can be downloaded from [<http://www.hpra.ie/img/uploaded/swedocuments/763cd4bd-c78d-49c1-b279-9c8f6ff0a1e2.pdf>].

Please refer to the dose administration table below for the correct dose to be given to your child.

For more detailed information about Rybrila read the Patient Information Leaflet which can be obtained from your child's doctor or can be downloaded from [<http://www.hpra.ie/img/uploaded/swedocuments/763cd4bd-c78d-49c1-b279-9c8f6ff0a1e2.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](mailto:medicalinformation@clinigengroup.com)  
Fax: +44(0)1932 824284

Alternatively, report to:  
HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

Marketing Authorisation Holder:  
Clinigen Healthcare B.V., Schiphol Boulevard 359, WTC Schiphol Airport, D Tower 11th floor, 1118BJ Schiphol, Netherlands

[medicalinformation@clinigengroup.com](mailto:medicalinformation@clinigengroup.com)