

Reminder card for caregivers: Glycopyrronium Bromide 1mg/5ml Oral Solution

How to manage common side effects:

There are different strengths of liquid Glycopyrronium Bromide available in the UK. Check carefully the product label to ensure that you have been given Glycopyrronium Bromide 1mg/5ml for your child.

Glycopyrronium Bromide 1mg/5ml has been prescribed for your child or adolescent to treat excessive production of saliva (sialorrhoea).

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

The side effects associated with Glycopyrronium Bromide 1mg/5ml (an anticholinergic drug) may be dose dependent (i.e. get worse as the dose is increased) 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 Glycopyrronium Bromide 1mg/5ml seen with dosing errors or overdose.

Important information on the administration of Glycopyrronium Bromide 1mg/5ml:

- Always give Glycopyrronium Bromide 1mg/5ml exactly as your 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 Glycopyrronium Bromide 1mg/5ml at least one hour before or two hours after meals. If the child's specific needs determine that administration at the same time as food is required, it is important to give Glycopyrronium Bromide 1mg/5ml at consistent times in relation to food intake. Do not give with high fat foods.
- You must measure and check the dose of Glycopyrronium Bromide 1mg/5ml using the special measuring device (oral syringe) provided. Always double check if the correct volume of Glycopyrronium Bromide 1mg/5ml is pulled 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's 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.			

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 some patients with neurological 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 Glycopyrronium Bromide 1mg/5ml 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 heartbeat 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 Glycopyrronium Bromide 1mg/5ml, 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 three months to make sure Glycopyrronium Bromide 1mg/5ml is still right for the child.

For more detailed information about taking Glycopyrronium Bromide 1mg/5ml read the Patient Information Leaflet. This can also be obtained from your child's doctor or can be downloaded from www.medicines.org.uk/emc/product/13136/pil

If your child gets any side effects, talk to your doctor, pharmacist or nurse.
This includes any possible side effects not listed in the package leaflet.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively, you can call **0800 731 6789** for free, Monday to Friday between 9am and 5pm. By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report any side effects to Rosemont Pharmaceuticals Ltd on **0113 244 1400** or pharmacovigilance@rosemontpharma.com

Marketing Authorisation Holder

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