Reminder Card for Caregivers

Glycopyrronium Unicorn Pharma 320 micrograms/ml 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 Unicorn Pharma 320 micrograms/ml oral solution for your child. This medicine is NOT interchangeable with other glycopyrronium products without dose adjustment by the child's doctor.

Glycopyrronium Unicorn Pharma 320 micrograms/ml oral solution 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 Glycopyrronium Unicorn Pharma 320 micrograms/ml (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 Glycopyrronium Unicorn Pharma 320 micrograms/ml seen with dosing errors or overdose.

Important Information on the administration of Glycopyrronium Unicorn Pharma 320 micrograms/ml oral solution :

- Always give Glycopyrronium Unicorn Pharma 320 micrograms/ml 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 Glycopyrronium Unicorn Pharma 320 micrograms/ml 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 Glycopyrronium Unicorn Pharma 320 micrograms/ml at consistent times in relation to food intake. Do not give with high fat foods.
- You must measure and check the dose of Glycopyrronium Unicorn Pharma 320 micrograms/ml using the special measuring device (oral syringe) provided. Always double check if the correct volume of Glycopyrronium Unicorn Pharma 320 micrograms/ml 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 NAME:..... DOB:.....

DOCTOR'S NAME:.....

DOCTOR'S CONTACT DETAILS:.....

DOSE PRESCRIBED (TO BE COMPLETED BY THE DOCTOR)

No	Dose (ml)	Start date (dd/mm/yy)	End date (dd/mm/yy)
1.			
2.			
3.			
4.			
5.			

Additional comments:

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;
  - o Difficulty in passing stools (constipation)
  - o Difficulty in passing urine or unable to completely empty the bladder (urinary retention)
  - o Severe chest infection (pneumonia)
  - o 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 Glycopyrronium Unicorn Pharma 320 micrograms/ml 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.
- 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.

Additional information

- Seek urgent medical advice immediately if the child is given too much Glycopyrronium Unicorn Pharma 320 micrograms/ml, 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 Glycopyrronium Unicorn Pharma 320 micrograms/ml is still right for the child.

Further information about taking Glycopyrronium Unicorn Pharma 320 micrograms/ml can be found in the Patient Information Leaflet and can be obtained from your child's doctor.

Please refer to the dose administration table for the correct dose to be given to your child.
For more detailed information about Glycopyrronium Unicorn Pharma 320 micrograms/ml read the Patient Information Leaflet which can be obtained from your child's doctor or can be downloaded from https://www.medicines.org.uk/emc/product/102537/pil

This reminder card is also available for download from the emc website https://www.medicines.org.uk/emc/product/102537/rmms

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 the 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 9am and 5pm. 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.

You can also report any side effects to pv@unicornpharma.co.uk.

Marketing Authorisation Holder:
Unicorn Pharmaceutical Limited,
Devonshire House, 582 Honeypot Lane, Stanmore, HA71JS, United Kingdom
pv@unicornpharma.co.uk

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