PATIENT ALERT CARD – FOR CAREGIVER

Glycopyrronium Bromide 1 mg Tablets
Glycopyrronium Bromide 2 mg Tablets

The side effects associated with glycopyrronium bromide may be dose dependent and difficult to assess in a disabled patient. The patient's doctor will talk to you about common side effects that may occur and how to manage them.

This patient alert card is an aid which helps to provide the patient's caregiver with essential information on the administration of glycopyrronium bromide tablets and the management and minimisation of side effects. It is important that this card is given to the treating doctor to record guidance on dosing.

The information below is provided as a guide for the patient's caregiver. For more detailed information on this product please refer to the patient information leaflet.

For any additional enquiries about this product or if you need additional copies of the patient alert card you may email: regulatory@drugsrus.co.uk.

Marketing Authorisation Holder: DAWA Limited, 5 Sandridge Close, Harrow HA1 1XD, United Kingdom.

Manufacturer: Drugsrus Limited, 5 Sandridge Close, Harrow HA1 1XD, United Kingdom.

ESSENTIAL INFORMATION ON THE ADMINISTRATION OF GLYCOPYRRONIUM BROMIDE TABLETS

- The dosage of glycopyrronium bromide tablets should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions.
- Always follow the doctor's instructions when giving glycopyrronium bromide tablets. You should check with the patient's doctor if you are not sure. The dose should not be increased without consultation with the patient's doctor.
- It is important to make sure an accurate dose is given each time, to prevent harmful effects of glycopyrronium bromide seen with dosing errors or overdose.
- Glycopyrronium bromide tablets should be taken at least one hour before or two hours after meals. If the patient's specific needs determine that co-administration with food is required, it is important to give glycopyrronium bromide at consistent times in relation to food intake.
- Avoid administration of glycopyrronium bromide tablets with high-fat meals.
- The treating doctor will complete the dosing regimen included with this patient alert card when treatment is started and at each dose change. Its purpose is to the patient's caregiver with respect to the correct dose to be given.

MANAGEMENT AND MINIMISATION OF SIDE EFFECTS

Like all medicines, glycopyrronium bromide tablets can cause side effects, although not everybody gets them.

If any of the following serious side effects occur, stop using the medicine and seek urgent medical advice. After evaluating the event, the prescriber will decide if treatment should remain stopped or if this should continue at a lower dose

- 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 can sometimes be difficult to detect side effects in patients with neurological problems who cannot easily tell you how they feel. If you feel a troublesome side effect is occurring after increasing a dose, you should decrease the dose to the previous one used and contact the patient's doctor.

To avoid overheating and the possibility of heatstroke, you should avoid exposing the patient to hot or very warm temperatures (hot weather, high room temperature). Check with the treating doctor during hot weather to see if the dose of this medicine 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.

As a precaution you should regularly check the patient's pulse and contact the patient's doctor if the heartbeat is very slow or very rapid.

You should look for any changes in the patient's well-being or behaviour and tell the patient's doctor.

Please refer to the dose administration table for the correct dose to be given to the patient.

DOSE REGIMEN (to be completed by treating doctor)

Patient Name:		Date of Birth:	
Doctor's name:			
Doctors contact details:			
Treatment Number	Dose (mg)	Treatment Start Date (dd/mm/yy)	Treatment End Date (dd/mm/yy)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
Additional comments:			

OTHER INFORMATION

- Talk with the patient's doctor **immediately** or go to the emergency department of the nearest hospital right away if the patient is given more glycopyrronium bromide tablets than they should, even if the patient seems well.
- Check with the patient's doctor at least every 3 months to make sure glycopyrronium bromide is still right for the patient.
- Tell the patient's doctor if they are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- 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.
- If the patient gets any side effects, talk to the patient's doctor, pharmacist, or nurse.

This patient alert card was revised in June 2022