Prescribing information for Oral Glycopyrronium – for hypersalivation in children and young people with a neurological condition

This prescribing information document outlines the prescribing responsibilities between the specialist and GP. GPs are invited to participate. If the GP feels that such prescribing is outside their area of expertise or have clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, clinical responsibility for the patient's health remains with the specialist.

If a specialist asks the GP to prescribe but the GP is not happy to continue prescribing, they must inform the specialist within 2 weeks of receiving the request.

Consultant details	GP details	Patient details
Name:	Name:	Name:
Address:	Address:	NHS Number:
Email:	Email:	Date of birth:
Contact number:	Contact number:	Contact:

Licensed Indication

The use of glycopyrronium in the treatment of hypersalivation in children and young people with neurological disorder is unlicensed.

However NICE Evidence summary: unlicensed or off-label medicine[1] provides efficacy of treatment vs placebo.

Preparations

Oral glycopyrronium is available as 1mg and 2mg tablets and various strengths of oral solution/suspension. Tablets are licensed for the treatment of gastric ulcers. The oral solution is not available as a licensed product and must be obtained from specialist suppliers. If a liquid formulation is required, the preferred product is glycopyrronium bromide 2mg/5ml oral suspension which is unlicensed, but there's a standard drug tariff price for the product.

Dosage and administration

Child 1 month to 18 years: 40-100micrograms/kg (max 2mg) 3-4 times daily, adjusted according to response. Doses should be given 1 hour before or 2 hours after meals[2].

Specialist responsibilities

- Discuss the benefits and side effects of treatment with the patient.
- Initiate and stabilise treatment with glycopyrronium
- Notify the patient of off-label/ unlicensed use, and gain appropriate informed consent (see overleaf).
- Ask the GP whether he or she is willing to participate in sharing prescribing responsibilities.
- Continue to prescribe until GP has agreed to take over prescribing.
- Advise the patient it may take up to two weeks for a community pharmacy to obtain a supply and ensure the patient has adequate supply given this when transferring care.
- Communicate to the GP re-established regimen; follow up arrangements and when to refer back.
- Communicate promptly with the GP when treatment is changed.
- Review patient annually, and give advice on stopping treatment.
- Have a mechanism in place to receive referral of a patient from the GP in the event of rare or severe side-effects or significant increase in hypersalivation.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Primary Care responsibilities

- Reply to the request for shared care as soon as practicable by faxing back signed form. If declining the request, please indicate the reason for declining.
- Prescribe the glycopyrronium at the dose recommended, from the agreed date.
- Adjust the dose as advised by the specialist.
- Monitor treatment as stated overleaf and report significant findings to the specialist.
- Report to & seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
- Refer back to specialist if the patient's condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Treatment should continue at transition into adult services.
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Communication

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Hospital Pharmacy Dept:				
Other:				

Monitoring

There are no specific monitoring requirements for specialist or GP. In accordance with good practice guidelines annual review would be expected.

Contra-indications, Special warnings/precautions & adverse effects[3]

Contra-indications:

Hypersensitivity to the active substance(s) or to any of the excipients in the preparation used. In common with other antimuscarinics: angle-closure glaucoma; myasthenia gravis; paralytic ileus; pyloric stenosis; prostatic enlargement.

Special warnings/precautions:

Should also be used with caution in gastro-oesophageal reflux disease, ulcerative colitis, acute myocardial infarction, hypertension, conditions characterised by tachycardia (including hyperthyroidism, cardiac insufficiency, cardiac surgery) because of the increase in heart rate produced by its administration, coronary artery disease and cardiac arrhythmias. Diarrhoea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.
As Glycopyrronium Bromide inhibits sweating, patients with increased temperature (especially children) should be observed closely. In the presence of a high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with use of Glycopyrronium Bromide tablets. Because of prolongation of renal elimination, repeated or large doses of Glycopyrronium Bromide should be avoided in patients with uraemia. Large doses of quaternary anticholinergic compounds have been shown to block end plate nicotinic receptors. This should be considered before using Glycopyrronium Bromide in patients with myasthenia gravis. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Adverse Effects

Glycopyrronium Bromide may produce the following effects which are extensions of its fundamental pharmacological actions: dry mouth, difficulty in micturition, inhibition of sweating. Side-effects of antimuscarinics include constipation, transient bradycardia (followed by tachycardia, palpitation and arrhythmias), reduced bronchial secretions, urinary urgency and retention, dilatation of the pupils with loss of accommodation, photophobia, flushing, and dryness of the skin. Side-effects that occur occasionally include confusion (particularly in the elderly), nausea, vomiting, and giddiness; very rarely, angle-closure glaucoma may occur**.**

Drug Interactions[3]

Many drugs have antimuscarinic effects; concomitant use of two or more of such drugs can increase side-effects such as dry mouth, urine retention and constipation. Concomitant use can also lead to confusion in the elderly. Anticholinergic agents may delay absorption of other medication given concomitantly.
Concurrent administration of anticholinergics and corticosteroids may result in increased intraocular pressure. Concurrent use of anticholinergic agents with slow-dissolving tablets of digoxin may cause increased serum digoxin levels. Increased antimuscarinic side-effects: amantadine; tricyclic antidepressants; antihistamines; clozapine; disopyramide; MAOIs; nefopam; pethidine; phenothiazines (increased antimuscarinic side effects of phenothiazines but reduced plasma concentrations) Possibly increased antimuscarinic side-effects: tricyclic (related) antidepressants. Domperidone/Metoclopramide: antagonism of effect on gastro-intestinal activity. Ketoconazole: reduced absorption of ketoconazole Levodopa: absorption of levodopa possibly reduced. Memantine: effects possibly enhanced by memantine Nitrates: possibly reduced effect of sublingual nitrates (failure to dissolve under the tongue owing to dry mouth) Parasympathomimetics: antagonism of effect. Ritodrine: tachycardia

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data in the Summary of Product Characteristics or the British National Formulary for Children

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[1] NICE Evidence summary: unlicensed or off-label medicine 15 Hypersalivation: oral glycopyrronium bromide July 2013

[2] BNF for Children September 2015-2016

[3] SmPC Glycopyrronium tablets 1mg available at http://www.mhra.gov.uk/spc-glycopyrronium