

SHARED CARE GUIDELINE FOR GLYCOPYRROLATE

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of glycopyrrolate when used for sialorrhoea in children

2. The Guidance

2.1. See below for the Shared Care Guideline.

GLYCOPYRROLATE

This shared care guideline sets out details for the sharing of care of children suffering from sialorrhoea prescribed glycopyrrolate (also known as glycopyrronium). This guideline provides additional limited information necessary to aid in the treatment of these patients. As with all shared care guidelines it highlights relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and *does not* replace them.

INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE

Sialorrhoea, or drooling, affects approximately a third of patients with cerebral palsy, but is also associated with a number of chronic childhood disorders. Excessive drooling has both medical and social implications. In severe cases drooling can cause skin irritation, infection and dehydration, and therefore medical intervention becomes necessary. Drooling can be caused by poor swallowing mechanisms as well as excessive saliva production. Current drug treatment for the condition aims to dry up secretions, hence reducing drooling. Saliva production and secretion is thought to be controlled by the parasympathetic nervous system via muscarinic receptors, and therefore antimuscarinic drugs, such as glycopyrrolate, have become the treatment of choice. It should be noted that these drugs do not stop drooling completely, but can reduce the symptoms that patients experience. Glycopyrrolate is one of the best tolerated antimuscarinic agents. It does not cross the blood brain barrier easily. This means that the central effects, such as drowsiness and confusion, are less pronounced than with other antimuscarinic agents, such as hyoscine. It also has a much longer half life than other antimuscarinic drugs, and therefore needs to be taken less frequently.

Glycopyrrolate given by the oral route for control of upper airway secretions and hypersalivation is currently unlicensed in the UK.

PREPARATIONS AND DOSAGE

Glycopyrrolate is available as 1mg and 2mg tablets, as well as a 1mg/ml solution. The tablets (Morningside Pharmaceuticals) are licensed for treatment of gastric ulcers. The tablets may be dispersed in water and given orally or flushed down PEG / NG tubes when the liquid is not available. The oral solution is obtained from specialist suppliers.

1mg/ml liquid from Nova laboratories Ltd, Martin House, Gloucester Crescent, Wigston, Leicester, LE18 4YL. Tel. 0116 2230099

Glycopyrrolate doses vary widely as patient response is so variable. The usual dose range is 40-100 micrograms/kg given 3-4 times a day. The patient will have received at least one month's treatment, been shown to respond to the treatment and the dosage stabilised before it is requested that prescribing responsibility is transferred to the GP. In some patients

tolerance to glycopyrrolate may develop requiring the dose to be increased. If tolerance does develop the patient should be referred back to the specialist team.

CONTRAINDICATIONS AND PRECAUTIONS

Glycopyrrolate will not be prescribed for:

- Patients with urinary tract obstruction
 - Patients with ileus or pyloric stenosis
 - Patients with glaucoma
 - Patients with severe ulcerative colitis
 - Children under 1 month of age
 - Patients who are pregnant or breast feeding
 - Patients with myasthenia gravis
- Caution should be exercised when prescribing glycopyrrolate in patients with either renal or hepatic impairment.
 - Caution should be exercised when prescribing glycopyrrolate in asthmatic patients.
 - Caution should be exercised when glycopyrrolate is prescribed concomitantly with drugs with antimuscarinic effects, such as sedating antihistamines and some antidepressants, as the risk of side effects will be increased.
 - Glycopyrrolate may antagonise pro-motility drugs such as domperidone and metoclopramide, so should be used with caution in patients taking these drugs.

MONITORING

There are no specific monitoring requirements.

SIDE EFFECTS

The side effects of glycopyrrolate are predictable, reversible and arise from the drug's mode of action.

Typical antimuscarinic effects include:

- tachycardia, hypotension, cardiac arrhythmias
- constipation, oesophageal reflux, dry mouth
- blurred vision, pupillary dilation, raised intraocular pressure
- drowsiness, headache, dizziness
- hallucinations, confusion, insomnia, tremor
- fever caused in part by reduced sweat production

These side effects are **not** dose related and there is significant variation in tolerability to the drug between patients. The rate of side effects is high (32-69% of patients), but these adverse reactions are rarely severe. However, up to 35% of patients and their families will choose to stop therapy due to these adverse effects.

There have been occasional reports of allergic reactions to glycopyrrolate, including anaphylaxis.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of patients who are prescribed glycopyrrolate can be shared between the specialist and the general practitioners. GPs are invited to participate. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DoH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

Referral criteria

- ❑ Glycopyrrolate will be initiated by the consultant in patients with severe drooling who have tried other antimuscarinic treatments but have found these therapies inadequate or intolerable due to side effects.
- ❑ The patient will have received at least one month's treatment, been shown to respond to the treatment and the dosage stabilised, before prescribing is transferred to the GP.

Specialist:

- ❑ Make any necessary diagnoses and communicate these to the GP and other professionals involved in the patient's care.
- ❑ Discuss the treatment options with the patient, their parent(s) and carer(s), to include explanation of the unlicensed nature of glycopyrrolate, obtaining appropriate consent to treatment and to share care with the GP. A patient information leaflet is attached in the Appendix of this document.
- ❑ Request the GP to take over prescribing in a clear letter. This letter should include full clinical details and document that the unlicensed nature of glycopyrrolate has been discussed with the patient/parent/carer and consent obtained
- ❑ Ensure the patient has at least 4 weeks supply remaining **from the date the GP accepts the request** to continue prescribing. This will allow 2 weeks for the surgery to set up the prescription and provide it to the patient and then 2 weeks for the pharmacy to obtain supplies.
- ❑ Ensure the patient/parent/carer is fully aware of the need to obtain a prescription from their GP within 2 weeks and take it immediately to their chosen community pharmacy / dispensing surgery so that arrangements can be made to obtain stocks.
- ❑ Continuing need for prescription to be reviewed at least annually.
- ❑ Communicate any changes, recommendations, changes, outcomes or other important information to the GP.
- ❑ Provide advice to the GP if they have clinical queries relating to the underlying condition or use of glycopyrrolate.
- ❑ Take back care of the patient should the GP feel unable to continue to manage the prescribing of glycopyrrolate.

General Practitioner:

- ❑ If the GP agrees to shared care he/she will notify the consultant in writing without undue delay.
- ❑ Ensure that the patient, their parent(s) and carer(s) has understood and consented to the unlicensed use of glycopyrrolate. A patient information leaflet is attached as the Appendix to this document.
- ❑ Accept the request to continue prescribing of glycopyrrolate within the boundaries of this shared care protocol, for which prescribing responsibilities will commence 4 weeks from the date of reply.
- ❑ Prescribe appropriate quantities for the patient on a regular basis.
- ❑ Carry out further dose titration according to the specified schedule, or discontinue the medication, when necessary or requested.
- ❑ Communicate any problems to the Specialist looking after the patient.
- ❑ Only ask the Specialist to take back the prescribing should unmanageable problems or tolerance to the drug develop and allow an adequate notice period (4 weeks is a suggested minimum).

Patient: and parent / carer responsibilities

- ❑ Be aware that having their prescription dispensed at one chosen community pharmacy / dispensing surgery should ensure continuity of supply, unless there are good reasons to change.
- ❑ Take all prescriptions received to the pharmacy / dispensing surgery as soon as possible so that they have adequate time to obtain supplies of this medicine. It may take up to two weeks for glycopyrrolate products to arrive from the supplier.
- ❑ Report any concerns or adverse effects to the GP, Specialist or Pharmacist.
- ❑ Patient information leaflet can be found as an Appendix to this document.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM

Appendix

Glycopyrrolate – Information for patients, parents and carers

Your child has been prescribed glycopyrrolate, which helps to reduce secretions. It is being used to reduce drooling.

What is glycopyrrolate?

Glycopyrrolate is known as an 'anticholinergic' or 'antimuscarinic'.

How should glycopyrrolate be taken?

Glycopyrrolate is usually given by mouth 3-4 times each day, although the dose needed varies as each child responds differently to the medication. Your child may also need larger doses as treatment continues because in some cases the body may become tolerant to the effects of the glycopyrrolate, and therefore more glycopyrrolate is needed to get the same effects.

Glycopyrrolate is available as both a liquid and tablets. The tablets can be crushed and mixed in water if the liquid is not available. The crushed tablets can also be mixed with water and flushed down a PEG or NG tube.

Does glycopyrrolate have any side effects?

Along with its needed effects glycopyrrolate can cause side effects, such as dry mouth, thirst, blurred vision, confusion, difficulty urinating (passing water) and mood changes. These side effects may ease as your child continues to take glycopyrrolate. However, if these symptoms continue and become troublesome discuss them with your doctor.

Rarely, glycopyrrolate can cause allergic reactions resulting in difficulties in breathing and skin rashes. If you think your child is having an allergic reaction stop the drug and seek medical advice straight away.

Does glycopyrrolate interact with other medicines?

Glycopyrrolate has not been found to affect any other medication. However, other medications that have antimuscarinic effects, such as some antihistamines, should be avoided if possible as these may increase the risk of side effects. If you have any concerns please discuss these with your GP or pharmacist.

Does glycopyrrolate require a doctor's prescription?

Yes. In the UK, glycopyrrolate products are only available on a doctor's prescription and are available as a product that is licensed for a different indication (for the treatment of gastric ulcers). This means that the prescribing doctor, when using the tablets for an unlicensed indication (drooling) takes full and complete responsibility for the use of this product in their patient. It also means that any patient information leaflet accompanying the tablets will not describe their use for drooling.

Can I obtain glycopyrrolate from my GP?

In principle your GP is able to prescribe glycopyrrolate in the same way as your hospital. However, some GPs may not wish to prescribe glycopyrrolate as it is not currently licensed for drooling in UK. If this is the case, you will need to obtain supplies through your local hospital.

How will the pharmacist obtain glycopyrrolate?

Your local pharmacy will be able to obtain supplies as below:

1mg and 2mg tablets (Morningside Pharmaceuticals) – should be available from wholesalers

1mg/ml liquid from Nova laboratories Ltd, Martin House, Gloucester Crescent, Wigston, Leicester, LE18 4YL. Tel. 0116 2230099

Please remember to organise further supplies two weeks before you run out, as glycopyrrolate products may take several days to arrive from the supplier.

Where can I obtain further information?

You can obtain further information from your consultant.

Request for other formats

Please ask if you would like to receive this leaflet in large print, braille, on CD or in any other languages. If you would like the leaflet in an alternative format please contact the NHS Kernow Communications Team at communications@kernowccg.nhs.uk or call 01726 627800



3. Monitoring compliance and effectiveness

Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	No specific tool
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Medicines Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Relevant Clinical Staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Diversity & Human Rights Policy'](#) or the [Equality and Diversity website](#).

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Glycopyrrolate Shared Care Guideline		
Date Issued/Approved:	September 2017		
Date Valid From:	September 2017		
Date Valid To:	11 November 2020		
Directorate / Department responsible (author/owner):	Paediatric Dept M Wilcock, Head of Prescribing Support Unit, Pharmacy Department, RCHT		
Contact details:	01872 253548		
Brief summary of contents	Some clinical issues and details of prescribing responsibilities for GP and specialists		
Suggested Keywords:	Shared care		
Target Audience	RCHT	CCG	CFT
	✓	✓	
Executive Director responsible for Policy:	Medical Director		
Date revised:	September 2017		
This document replaces (exact title of previous version):	Glycopyrrolate shared care guideline v1.1		
Approval route (names of committees)/consultation:	Cornwall Area Prescribing Committee		
Divisional Manager confirming approval processes	Not required		
Name and Post Title of additional signatories			
Signature of Executive Director giving approval	{Original Copy Signed}		
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only
Document Library Folder/Sub Folder	Clinical / Pharmacy		
Links to key external standards	None		
Related Documents:	None		
Training Need Identified?	No		

Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
20 Nov'13	V1.0	New version in this format	M Wilcock
Sept'14	V1.1	Minor amendment to tablet availability	M Wilcock
Sept'17	V1.2	New date of approval	M Wilcock

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as <i>policy</i>) to be assessed: Shared care guideline for glycopyrrolate	
Directorate and service area: Pharmacy	Is this a new or existing Procedure? Existing
Name of individual completing assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow	Telephone: 01726 627953
1. Policy Aim*	To provide information on prescribing of glycopyrrolate to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives*	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. Policy – intended Outcomes*	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
5. How will you measure the outcome?	If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.
5. Who is intended to benefit from the Policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.
6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b. If yes, have these groups been consulted? c. Please list any groups who have been consulted about this procedure.	No Cornwall & IoS Area Prescribing Committee

7. The Impact			
Please complete the following table.			
Are there concerns that the policy could have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	
Sex (male, female, trans-gender / gender reassignment)		✓	

Race / Ethnic communities /groups		✓	
Disability - learning disability, physical disability, sensory impairment and mental health problems		✓	
Religion / other beliefs		✓	
Marriage and civil partnership		✓	
Pregnancy and maternity		✓	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> • You have ticked “Yes” in any column above and • No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or • Major service redesign or development 			
8. Please indicate if a full equality analysis is recommended.		Yes	No ✓
9. If you are not recommending a Full Impact assessment please explain why.			
Signature of policy developer / lead manager / director		Date of completion and submission	
Names and signatures of members carrying out the Screening Assessment	1. Dan Thomas 2. Mike Wilcock		

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead,
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,
Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed _____ Dan Thomas and Mike Wilcock _____

Date _____ September 2014 _____