

Surrey & North West Sussex Area Prescribing Committee (APC)

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG &

Surrey Heath) Crawley CCG and Horsham & Mid-Sussex CCG

Pharmacological Management of Hypersalivation in Children

Scope: MND, acquired brain injury, neurodisability, cerebral palsy, long term ventilation with drooling and other neurological conditions, and drug-induced hypersalivation.

ASSESSMENT OF SEVERITY/RESPONSE TO TREATMENT:

Severity of drooling can be assessed subjectively via discussion with patients and their carers/parents and by observation. Amount of drooling can be quantified by measuring the number of bibs required per day and this can also be graded using the Thomas-Stonell and Greenberg scale:

- 1 = Dry (no drooling)
- 2 = Mild (moist lips)
- 3 = Moderate (wet lips and chin)
- 4 = Severe (damp clothing)

CONSIDERATIONS FOR PRESCRIBING/TITRATION

No evidence to support the use of one particular treatment over another. Drug choice is to be determined by individual patient factors.

When prescribing/titrating antimuscarinic drugs to treat hypersalivation always take account of:

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- Coexisting conditions (for example, history of urinary retention, constipation, dental issues, reflux etc.)
- Use of other existing medication affecting the total antimuscarinic burden
- Risk of adverse effects.
- Route of administration- consider suitability of medications via enteral tubes or use alternatives e.g. topical
- Titrate dose upward until the desired level of dryness, side effects or max. dose reached.

Take into account the preferences of the patients and their carers/ parents, and the age range and indication covered by the marketing authorisations. (see individual <u>summaries of product characteristics, BNF</u> or <u>BNFc</u> for full prescribing information).

Bue DRUG TREATMENT FOR CHILDREN

All medicines for this indication in children requires specialist recommendation to GP

•Hyoscine hydrobromide 300microgram tablets ('off-label') or 300microgram/5mL oral suspension (Special). Dose as per BNFc according to the appropriate age range

•Hyoscine hydrobromide (Scopoderm[®]) 1.5mg patch ('off-label')

Dose as per BNFc according to age

Apply to hairless area of skin behind ear. Ensure patch removed prior to applying next patch. The patch can be cut and the remainder kept in the original packaging until required for the next dose

•Glycopyrronium bromide liquid 1mg/5ml (Colonis) (*licensed in* >3 years of age for hypersalivation in chronic neurological disorders)

Dose as per BNFc or SPC according to the appropriate age range

•Glycopyrronium bromide liquid 400 micrograms/ ml (Sialanar[®] 320 micrograms/ml glycopyrronium) (licensed in >3 years of age for hypersalivation in chronic neurological disorders)

Dose as per BNFc according to the appropriate age range

NB: doses in BNFc expressed as glycopyrronium bromide

•Glycopyrronium bromide 1mg or 2mg tablets ('unlicensed Special')

Dose as per BNFc according to the appropriate age range

If not tolerated or is ineffective at maximum tolerated dose then Re-refer any patient who fails to respond, to specialist. Second line option to be initiated only after specialist review

SECOND LINE DRUG TREATMENT FOR CHILDREN Children > 3 years:

•Trihexyphenidyl (Benzhexol)

('off-label') tablets 2mg, oral solution 5mg/5mL initially 1mg twice daily, increase in 2 weeks to 2mg twice daily as necessary and as tolerated; titrate dose every 2 weeks to a max. 2mg three times daily

If not tolerated or is ineffective at maximum tolerated dose then refer any patient who fails to respond, to specialist

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OTHER CONSIDERATIONS

ANTIMUSCARINICS

HYOSCINE HYDROBROMIDE

Hyoscine (Scopoderm[®]) patch may be advantageous over other treatments; ease of administration, maintenance of steady state concentrations and a lower incidence of systemic side effects relative to other antimuscarinics. It is useful for patients with intractable swallowing difficulties who may have problems with choking from normal saliva production

GLYCOPYRRONIUM BROMIDE

- Slower in onset but causes less tachycardia than hyoscine or atropine
- Has long duration of action and has lower incidence of CNS effects (e.g. sedation, restlessness) due to its inability to cross the blood-brain barrier

TRIHEXYLPHENIDYL

Side effects include tachycardia, constipation, hallucination and memory impairment

DRUG-INDUCED HYPERSALIVATION

- The main medication groups that are associated with drooling are antipsychotics, particularly clozapine, and direct and indirect cholinergic agonists that are used to treat dementia of the Alzheimer type and myasthenia gravis.
- The exact mechanism of clozapine-induced hypersalivation is unknown however it is paradoxical to its antimuscarinic action. The treatment of drug-induced hypersalivation is the same as other forms of hypersalivation, with antimuscarinics. Therefore, cumulative antimuscarinic burden (e.g. increased constipation, blurred vision, confusion, tachycardia and arrhythmia) is a particular risk in this patient group.

Cost Comparison Costs based on Drug Tariff, January 2020; excluding VAT (Prices correct at time of publication, but please refer to current Drug Tariff for up to date prices)		
Drug	Typical Doses	Cost per 28 days (approx.)
Glycopyrronium bromide oral solution 1mg/5mL (Colonis) Glycopyrronium bromide oral solution 400micrograms/mL (Sialanar®) Glycopyrronium bromide tablets (NB-Not to be routinely used due to cost) Hyoscine patch 1.5mg (Scopaderm [®]) Hyoscine hydrobromide 300micrograms tablets	1mg 3 times daily 1,600 micrograms (4ml) 3 times daily 1mg 3 times daily 1 patch every 72 hours 300 micrograms 3 times daily	£273.00 £460.80 £645.99 £64.35 £12.88
Hyoscine hydrobromide 300 microgram/5mL oral suspension (Special) Trihexyphenidyl 5mg/5ml oral solution Trihexyphenidyl tablets	300 micrograms 3 times daily 5mg 3 times daily 5mg 3 times daily	£88.55 £83.10 £17.91

References:

- 1. British National Formulary for Children www.medicinescomplete.com/mc/bnfc Accessed Jan 2019
- 2. British National Formulary www.medicinescomplete.com/mc/bnflegacy/current/ Accessed Jan 2019
- 3. Summary of Product Characteristics. Glycopyrronium bromide oral solution 1mg/5ml Accessed April 19
- 4. Summary of Product Characteristics. Glycopyrronium bromide oral solution 400mcg/mL Accessed Jan 19
- 5. Hypersalivation what are the treatment alternatives to glycopyrronium and hyoscine? SPS website Accessed Aug 2018
- 6. Hypersalivation what drug treatment options are available? SPS website Accessed Aug 2018
- 7. Hypersalivation can hyoscine hydrobromide be used to treat it? SPS website Accessed Aug 2018
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- 9. NICE NG62 Cerebral palsy in under 25s: assessment and management Jan 2017
- 10. NICE NG42 Motor neurone disease: assessment and management Feb 2016
- 11. The Maudsley. Prescribing Guidelines in Psychiatry 13th Edition (Wiley Blackwell)
- 12. NHS Business Service Agency. Drug Tariff, Accessed April 2019
- 13. NICE Evidence Summary (ES5) Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide