Clonidine for Tic Disorders in Children and Young People

Traffic light classification - Amber 2
Information sheet for Primary Care Prescribers

Indications

Tic Disorders including:

- Chronic Motor Tic Disorder
- Chronic Vocal Tic Disorder
- Transient Tic Disorder
- Tourette Syndrome in children, young people and adults as part of a comprehensive treatment program

These are off-label (unlicensed) indications for both adults and children.

This information sheet covers the use of clonidine for Tic Disorders in children and young people under 18 years of age.

Therapeutic summary

Clonidine is a noradrenergic (a-2 agonist) treatment recommended by the European Clinical Guidelines for Tourette Syndrome and other Tic Disorder[1]. It is indicated as a treatment for tics particularly in children where the side effect profile is more benign compared to antipsychotic medication.

Clonidine is one of many medicines that have been tried in the management of Tourette's syndrome and tic disorders which are hypothesised to be related to disturbance of monoamine metabolism (including dopamine, noradrenaline, and serotonin) in the brain.

Clonidine acts by stimulating the pre-synaptic alpha 2 adrenoceptors, thereby decreasing noradrenaline release from both central and peripheral sympathetic nerve terminals. It is used mainly in those patients with a combination of ADHD and mild tics given its efficacy in treating ADHD symptoms in addition to tics. It also has helpful benefits from an analgesic, sedative and anxiolytic perspective[1,2].

Response to clonidine is usually seen within 4-6 weeks which families need to be made aware of and supported through this time.

Medicines Initiation

Clonidine is rated as Amber 2 in the Nottinghamshire Area Prescribing Committee joint formulary which means that it is suitable to be prescribed in primary care after specialist recommendation or initiation. Recommendations should only be given by a specialist with expertise in tic disorders (i.e. a Child and Adolescent Psychiatrist, general or community Paediatrician, Advanced Clinical Practitioner or appropriately qualified non-medical prescriber).

Products available

Clonidine 25microgram tablets. Cost x 112 tablets = £11.65[3]
Clonidine 100microgram tablets. Cost x 100 tablets = £8.04[3]
Clonidine 50micrograms/5mL oral solution sugar free. Cost x 100mL = £216.10[3]. Use should be avoided where possible due to cost.

Clonidine 50micrograms/5mL oral solution (non-sugar free) = not in the drug tariff. This is a "special" and therefore, is an unlicensed product and cost can vary.

The prices stated above are accurate as per the Drug Tariff at the time of guideline review.

For swallowing difficulties, clonidine tablets can be dispersed in water or crushed and mixed with a small amount of soft food such as yogurt, honey, or jam[4]. This is off-label (unlicensed) use.

Kidzmed is an e-learning resource for healthcare professionals teaching children how to swallow pills.

Medicines for children have a patient and carer information leaflet called "Helping your child to swallow tablets".

Dosages and route of administration

- Clonidine is given orally with or without food.
- It is usually given in two to three divided doses daily to reduce the risk of side effects.
- The initial dose and subsequent dosing will be recommended by the specialist and stated in written communication.
- The usual starting dose is 25micrograms once daily at night with subsequent titrations of 25microgram increments. Titrations should be weekly to fortnightly depending on response and tolerance to side effects. Children may be titrated more cautiously.
- The therapeutic window of clonidine, as described in the Maudsley Prescribing Guidelines, is 3-5micrograms per kg of body weight[5]. Doses above 200-300micrograms per day can be sedating and should be regularly monitored.
- Most of the dose is usually administered at night to avoid sedation during the day. This also has the added benefit of treating co-morbid sleep difficulties.

Duration of Treatment and Treatment Discontinuation

Following an adequate treatment response, drug treatment should be continued for as long as it remains clinically effective, with a regular 6-monthly review when stable. This includes 6-monthly physical health monitoring (blood pressure, pulse, weight, and height).

In adolescents whose symptoms persist into adulthood, and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. Often in later teenage years young people and adults find that their symptoms naturally reduce to a more tolerable level, especially after moving into a more conducive education or work environment.

If symptoms reduce, or for any other reason the young person wishes to reduce and withdraw treatment, typically this is done by reducing the overall dose by 25micrograms. This can be done every 2-4 days. Some individuals prefer to reduce the dose slower than this to be able to judge any exacerbation in severity and frequency of symptoms. It is advisable not to decrease the dose any quicker than this due to the risk of rebound hypertension on abrupt withdrawal. Other potential discontinuation symptoms include agitation, restlessness, palpitations, nervousness, tremor, headache and nausea[6].

Monitoring Requirements and Responsibilities

Pre-treatment assessment to be performed by specialist and will include:
Assessment of Tics using the Yale Global Tic Severity Scale, descriptive reports from the service user/parents/school (if deemed necessary) to obtain longevity of symptoms, medical history, family history and review of physical health (including height, weight, baseline blood pressure and pulse).

Monitoring
Physical health monitoring should be performed at baseline and 6-monthly. Monitoring of the patient's response and assessment of continued need should also be performed 6-monthly. Monitoring can be performed by the specialist, if remaining open to their caseload. Monitoring can also be performed by primary care under instruction of the specialist.

See table below for physical health monitoring requirements.

Ongoing monitoring	**Frequency**
Heart Rate and Blood Pressure	Baseline and 6-monthly Before and after each dose change. Compare with previous measurements. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.
Weight and Height	Baseline and 6-monthly
ECG	Not recommended unless there is a clinical indication.
Blood monitoring	Not recommended unless there is a clinical indication.
Medication related side-effects*	At each visit

*Consider using standard symptom and side effect rating scales during treatment as an adjunct to clinical assessment.

Explicit criteria for review and/or discontinuation of clonidine

Sustained resting bradycardia	Consider dose reduction and discuss with the specialist team if requiring support. Seek cardiology input if necessary.
Orthostatic hypotension	Consider dose reduction if there are immediate concerns. Discuss with the specialist team if requiring support.
Dry mouth	Discuss with the specialist team if requiring support.
Sedation	Discuss with the specialist team if requiring support.
Repeated sudden withdrawal of clonidine	Sudden withdrawal places the patient at risk of rebound hypertension. Due to this risk, Clonidine should be reduced carefully by 25micrograms every 2-4 days. The patient and carer should be informed of this reduction to reduce the risk. Discuss with the specialist team if requiring support.
Patient/family requesting dose change	Discuss with the specialist team if requiring support. Physical observations could be obtained in primary care.
Failure to attend for physical health monitoring checks	It may be appropriate to provide repeat prescriptions if a patient misses one physical health monitoring appointment and a follow-up appointment can be arranged. If multiple appointments are missed, repeat prescriptions should not be issued. However, there is a risk of rebound hypertension on abrupt clonidine

	withdrawal. Due to this risk, clonidine should be reduced carefully by 25micrograms every 2-4 days. The patient and carer should be informed of this reduction to reduce the risk. Discuss with the specialist team if requiring support.

For a full list of side effects refer to the BNF/BNFC or Summary of Product Characteristics (SPC).

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

Contraindications[6,7]

- Severe bradyarrhythmia resulting from either sick-sinus syndrome or AV block of 2nd or 3rd degree.
- Known hypersensitivity to the active substance or to any of the excipients listed in SPC.
- Rare hereditary conditions that may be incompatible with an excipient listed in the SPC, such as galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Precautions[6,7]

- Cerebrovascular disease, coronary insufficiency, and heart failure
- Mild to moderate bradyarrhythmia
- Occlusive peripheral vascular disorders such as Raynaud's disease
- Polyneuropathy
- Constipation
- History of depression
- Renal insufficiency
- Abrupt withdrawal should be avoided; it is associated with rebound hypertension, agitation, restlessness, tremor, palpitations, nervousness, headache, and nausea.
- May cause decreased lacrimation.

Pregnancy and Breast-Feeding[6,7, 8, 9]

There is a limited amount of data on the use of clonidine in pregnant women. Clonidine passes the placental barrier and may lower fetal heart rate. Clonidine should not be used in pregnancy, unless the expected benefit is thought to outweigh any possible risk to the foetus.

There is a limited amount of data on taking clonidine while breastfeeding, but information shows that a small amount of clonidine passes into the breast milk. This is unlikely to cause side effects in the baby, but it is not known for certain yet. The risks and benefits of breastfeeding while taking clonidine should be discussed with the mother. If a mother breastfeeds while taking clonidine, she should be advised to inform a healthcare professional if the baby is not feeding as well as usual, is unusually sleepy or looks paler than usual.

The risk of pregnancy should be considered when initiating clonidine and if appropriate, information on the risks of clonidine in pregnancy and breastfeeding should be provided. This should be revisited when young people transition into adulthood.

Clinically Relevant Medicine Interactions and their Management[6,7]

- Antihypertensive agents – concurrent use may lead to an increased hypotensive effect
- Diuretics - concurrent use may lead to an increased hypotensive effect
- Vasodilators - concurrent use may lead to an increased hypotensive effect
- Beta blockers – concurrent use can cause bradycardia, dysrhythmia, and hypotension
- Cardiac glycosides - concurrent use can cause bradycardia or dysrhythmia
- Mirtazapine – may antagonise the antihypertensive effect of clonidine (but note that antihypertensive effect is not the desired clinical effect of clonidine in Tic Disorders)

- Tricyclic antidepressants – may reduce or abolish the antihypertensive effects of clonidine (but note that antihypertensive effect is not the desired clinical effect of clonidine in Tic Disorders)
- Monoamine oxidase inhibitors (MAOIs) - concurrent use may lead to an increased hypotensive effect
- Antihistamines – additive CNS depressant effects
- Antipsychotics – concurrent use may lead to an increased hypotensive effect
- Anxiolytics and hypnotics – additive CNS depressant effects
- Guanfacine - concurrent use may lead to an increased hypotensive effect

For a full list of contraindications, precautions and drug interactions refer to the BNF/BNFC and SPC.

Information Given to Patient / Carer

- The specialist will provide relevant, age-appropriate written information to people with tic disorder and their families and carers about diagnosis, assessment, support groups, self-help, psychological treatment, drug treatment and possible side-effects.
- Written information sheets can be found at:

Medicines for Children – Clonidine for Tourette's syndrome, ADHD and sleep-onset disorder

Specialist contact details

Patients prescribed clonidine for the treatment of tic disorders are likely to be under community or hospital paediatric services or child and adolescent mental health services (CAMHS). For specific support, contact the relevant clinic from the information provided in individual patient correspondences. For general enquiries to help support prescribing decisions, contact the CAMHS Developmental Neuropsychiatry Tic Disorder Service on 0115 8230269.

References and Version Control

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