Leeds NHS

Somatropin: Amber Drug Guidance for the treatment of Growth Hormone Insufficiency and related conditions in Paediatrics

Amber Drug Level 1 (traffic light definitions)

Amber Level 1: Medicines recommended by a specialist, which could offer a valuable alternative/addition to the patients' treatment. These medicines are considered suitable for GP prescribing following specialist recommendation. Monitoring maybe required. A brief prescribing guidance document will be available for these drugs, but there is no requirement for full amber drug guidance. All patients on Amber Level 1 drugs should still be regularly reviewed in primary care regarding their Amber Drug treatment

We have recommended that your patient is started on somatropin for the treatment of growth hormone insufficiency, Turner Syndrome and Prader Willi syndrome in childhood. Please consider and prescribe as appropriate. This licensed medication is suitable for prescribing in primary care after specialist assessment and recommendation. It is appropriate to prescribe for the condition stated in the traffic light list.

Prescribing Information

Drug:	**Somatropin**
Indication:	**Growth Hormone Deficiency in paediatrics** **Turner syndrome and chronic renal failure** **Prader Willi Syndrome** Licensed drug for licensed indication
Classification:	Amber Level 1
Monitoring:	Routine disease monitoring should continue and patient specific monitoring will be indicated in the clinic letter. The patient's growth and development will be monitored by the specialist team and dose amended accordingly.
Follow up:	The patient will remain under the Paediatric Endocrinology team whilst on treatment and reviewed every 3-6 months

The following is a summary of prescribing information only. Consult the BNF and SPC for full and current prescribing information. Link to Leeds formulary.

The following information has been added only if it differs from the BNF and SPC or supports that information.

Dose: By subcutaneous injection once daily. Doses are calculated on an individual basis by the hospital, but are usually based on the following information:

- Growth hormone deficiency: 23-39micrograms/kg/day or

- Turner syndrome and chronic renal failure: 45-50micrograms/kg/day
- Prader Willi syndrome : 35micrograms/kg/day

Formulation: By subcutaneous injection. Products available: Genotropin®, Humatrope®, Norditropin SimpleXX®, NutropinAq®, Omnitrope®, Saizen® and Zomacton®.

The most cost effective brand should be considered, but the device used to administer the drug is different with each brand, so must be prescribed by brand. This consideration and trial of the dummy devices occurs in the specialist clinic to ensure the patient can manage the administration. This training is given by the specialist nursing team.

Adverse drug reactions: **Local discomfort at the site of injection** and tissue atrophy maybe caused by frequent subcutaneous injections in the same site. This may be avoided by varying the site.
Headache may be noted transiently in some patients on higher doses. Rarely benign intracranial hypertension has been reported, this causes papilloedema that can be detected by fundoscopy.
Oedema may be exacerbated in Turner syndrome patients but is rare in other patients.
Diabetes mellitus -hGH exerts effects on both carbohydrate and lipid metabolism. It is both anabolic and diabetogenic and, in theory, hyperglycaemia and ketosis may occur but is rarely seen in practice. In children with existing diabetes mellitus, glycaemia control and insulin therapy may need readjustment; the induction of insulin resistance is also a rare occurrence.
Antibody development has been observed in some patients with hGH. It rarely affects the clinical response to treatment.
Slipped femoral epiphysis has been reported to occur with a slight increase in frequency
Acute leukaemia has been reported both in untreated GH-deficient children as well as hGH treated children. Studies show that there is no increased incidence over standard population data so these reports are chance associations.
Overdose in the acute situation is likely to lead to transient hypoglycaemia followed by hyperglycaemia. The long term treatment consequences of overdose are unknown but carry the risk of pituitary gigantism or acromegaly.
If any adverse drug reactions occur speak to the specialist team who will advise on management of the patient

Cautions/Contra-indications: Somatropin products should not be used when there is any evidence of tumour activity and anti-tumour therapy must be completed prior to starting therapy.

Treatment needs to be reviewed in patients who become acutely critically unwell.

Hypersensitivity to the active substances or any of the excipients.

Interactions: **Corticosteroids** in supraphysiological doses may interfere with the growth promoting actions of growth hormone. Children with co-existing ACTH deficiency should have their glucocorticoid replacement dose carefully adjusted to avoid an inhibitory effect on growth. Titration of doses should be managed by a specialist consultant.

Oral hypoglycaemics and insulin: somatropin may affect glucose metabolism. Glycaemic control measures may need to be reviewed and a plan communicated with the GP.

Pregnancy/breast-feeding: There is minimal information regarding use in pregnancy and breast feeding. Specialist advice would need to be sought. Patients should be recommended to discuss with the consultant if considering pregnancy or that the specialist is informed ASAP if the patient becomes pregnant.

Communication

Contact Names and Details

Leeds Teaching Hospitals NHS Trust
Medicines Information phone number and e-mail: 0113 2064344
medicines.information@nhs.net

Medicines Information Patient Helpline phone number: 0113 2064376

Consultant Paediatric Endocrinologists: 0113 3923700
Children's Endocrine Nurse Specialists: 0113 3922366

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Declarations of Interest

Declarations of Interest by authors

All (or any) declarations of interest were declared and considered, through the appropriate process.

Contributors are to declare any changes to their declaration of interest submission within 28 days.

Responsibilities of Specialist

Secondary care clinician responsibilities:

- Diagnosis of condition and ensuring other treatment options have been fully explored
- Teaching patients how to administer subcutaneously
- Liaison with the General Practitioner (GP) to initiate prescribing of the amber medicine using a written request, and will advise the GP on the selection of brand (after reviewing the dummy devices in hospital)
- Advising GP on dose to be prescribed
- Outlining to the GP when therapy may be reduced and stopped assuming no relapse in patient's condition. Review periods to be agreed
- Responding to issues raised by GP

Responsibilities of GP

GP responsibilities:

- Checking for allergies, interactions and contra-indications on initiation and when changing treatment
- Prescribing the amber medicine after receiving request from secondary care clinician This needs to be prescribed by brand.
- Monitoring the patient's overall health and wellbeing, observing patient for evidence of ADRs and liaising with secondary care clinician if necessary.
- Routine disease monitoring should continue
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient's physical health status that may affect prescribing or appropriateness of the amber medicine
- Reducing/stopping treatment in line with secondary care clinician's original request

Responsibilities of Patient/Carer

Patient/carer responsibilities:

- To be responsible for administering somatropin subcutaneously as prescribed
- To understand the potential for adverse events and report these to the GP
- To check with the community pharmacist that there are no interactions with somatropin, when buying any over the counter medicines or herbal/homoeopathic products
- To check with dentists or other specialists who may prescribe medicines that there are no interactions with somatropin
- To contact the GP, Specialist or Medicines Information patient helpline if further information or advice is needed about somatropin