Using a printed guideline? Always check you are using the most up to date version. See https://ipnsm.hscni.net

Somatropin, Somatrogon and Somapacitan (Growth Hormone analogues)

Endocrinology Shared Care Guideline

Specialist Details	Patient Identifier
Name: _____	
Location: _____	
Tel: _____	**Date:** _____

Introduction

Growth hormone deficiency is managed with biosynthetic Growth Hormone.
Somatropin, Somatrogon and Somapacitan are human growth hormone analogues.
Somatrogon and Somapacitan are long acting formulations.
Growth hormone is a biological medicine and must be prescribed and dispensed by brand name.
Licensed indications Not all products are licensed for all indications. Refer to BNF, BNFC or individual SPCs.

Dosage and administration:

Growth hormone:

- Deficiency of growth hormone in children (including use post radiotherapy) in children: 0.023–0.039 mg/kg daily by subcutaneous injection.
- Turner syndrome: 0.045 – 0.050 mg/kg daily by subcutaneous injection.
- Prader-Willi syndrome: 0.035 mg/kg by subcutaneous injection.
- Chronic renal insufficiency in children: 0.045 - 0.05 mg/kg daily by subcutaneous injection.
- Children who are born small for gestational age with subsequent growth failure at ≥ 4 years of age: 0.03 mg/kg daily by subcutaneous injection.
- SHOX deficiency in children : 0.045 – 0.050 mg/kg daily by subcutaneous injection ,
- Adult growth hormone deficiency: initially 0.15 – 0.4 mg daily by subcutaneous injection gradually increased if required.

Available as: Genotropin®, Norditropin®, Omnitrope®, Saizen®, Zomacton®
Pen devices for use with the injection cartridges are not prescribable on the NHS but are provided by the clinic.

Somatrogon:

- Growth hormone deficiency in children and adolescents: 0.66 mg/kg once weekly by subcutaneous injection.

Available as: Ngenla® solution for injection in pre-filled pen; 24 mg/1.2 mL, and 60 mg/1.2 mL pre-filled pen

Somapacitan:

- Growth hormone deficiency in children, adolescents and adults: Refer to BNF, BNFC.

Available as: Sogroya® solution for injection in pre-filled pen; 10 mg/1.5 mL and 15mg/1.5mL

Hospital specialist responsibilities

- Diagnose the condition and assess if the patient is suitable for treatment as per NICE Guidance.
- Provide the patient with relevant information on use, side-effects and need for monitoring of medication.
- Arrange for patients or carer to be trained to administer injections.
- Arrange shared care with the patient's GP.
- Monitor response to treatment using insulin like growth factor (IGF-1) plasma levels, height and weight measurements, pituitary hormones and pubertal status (if appropriate).
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Thyroid function tests as clinically indicated.
- Review results of safety monitoring and request additional tests as required.
- Provide any other advice or information on therapy or associated therapy to the GP if required.
- Advise GP on discontinuation of therapy (this is not necessarily contemporaneous with cessation of growth in stature).

GP responsibilities

- Prescribe by brand. Prescribe an appropriate supply of cartridges/pens per prescription; pack sizes are small and depending on the dose required multiple packs need to be issued. Continued prescribing is appropriate for patients attending regular review.
- Prescribe needles, needle clipping device (e.g. BD safe-clip) and 1L sharp bin, according to the preparation required.
- Advise the specialist if non-compliance is suspected.
- Inform the specialist of new prescriptions that may interfere with treatment e.g. Steroids.
- Report adverse drug reactions to initiating specialist and usual bodies (e.g. CHM, MHRA).
- Ensure no significant drug interactions with other medicines.

Adverse effects, precautions and contraindications

Contraindications include:

- Do not use if evidence of active malignancy: use with caution if history of malignant disease.
- Pregnancy.
- Disorders of the epiphysis: may be used with caution. Slipped upper femoral epiphysis may occur in overweight teenagers on GH treatment.
- Patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions.
- Severe obesity or severe respiratory impairment in Prader-Willi syndrome.

Caution advised with:

- Use after renal transplantation may be considered if risks outweigh benefits.
- Diabetes: GH is an insulin antagonist and can therefore unmask latent diabetes. Adjustment of antidiabetic therapy may be necessary in patients with established diabetes.
- Papilloedema.
- Relative deficiencies of other pituitary hormones notably hypothyroidism.
- Resolved intracranial hypertension -monitor closely.
- Initiation of treatment close to puberty not recommended in child born small for gestational age.
- Silver-Russell syndrome.
- Undiagnosed central (secondary) hypoadrenalism as growth hormone may unmask symptoms.

Side effects:

- Headaches have been reported early in treatment which usually resolve. Intracranial hypertension is rare, but any patient with severe persistent headache should be referred for early review. Fundoscopy for papilloedema recommended if severe or recurrent headache.
- Peripheral oedema is common but tends to decrease as therapy progresses. Incidence is reduced if lower doses are used initially.
- Carpal tunnel syndrome, arthralgia and myalgia in adults: usually dose dependant and transient.
- Visual problems.
- Insulin resistance, hyperglycaemia, hypoglycaemia.
- Leukaemia in children with growth hormone deficiency also reported.

Pregnancy: Discontinue and refer back to specialist if pregnancy discovered or planning to become pregnant- no information available.

Breast feeding: No information available - absorption from breastmilk is unlikely.

Common drug interactions

Use growth hormone with caution in association with:

- **Oestrogens:** increased doses of growth hormone may be required
- **Corticosteroids (above replacement doses):** the growth promoting effect of growth may be inhibited
- **Glucocorticoid replacement therapy:** Increase in maintenance or stress dose may be required.

Communication

For any queries relating to this patient's treatment with growth hormone, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC or the BNF

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