Barking, Havering and Redbridge University Hospitals NHS Trust

Barking and Dagenham, Havering & Redbridge Clinical Commissioning Groups, General Practitioners and Barking, Havering & Redbridge University Hospitals NHS Trust Shared Care Guidelines

DRUG NAME: GROWTH HORMONE (SOMATROPIN)

Shared Care Guidelines for use of Human Growth Hormone (somatropin) for the treatment of growth failure in Children in accordance with NICE TA 188 (2010)

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AS AND FILED IN PATIENTS HEALTHCARE RECORDS

Patient Name : **Date of Birth:** **NHS No:**

Name of Referring Consultant: **Contact number:**

INTRODUCTION – Indication and Licensing

Growth hormone is available as biosynthetic growth hormone with a sequence identical to human pituitary growth hormone. It is prepared by recombinant DNA technology and since the withdrawal of cadaveric (pituitary) growth hormone in 1985 after the association with a slow virus infection (Jacob Creutzfeld Disease) was appreciated, is the only growth hormone available in the United Kingdom. Growth hormone is made from either E.Coli bacteria or a mammalian cell line which acts as hosts to recombinant plasmids containing the human GH gene. The following Manufacturers produce these GH products; Pfizer, Lilly, Novo Nordisk, Ipsen, Sandoz, Merk Serono and Ferring[1].

Administration of GH is by subcutaneous injection or needle free transjection on a nightly single injection basis. In order to mimic the normal physiology of GH secretion, we usually recommend that GH injections are given in the evening. Depending on the brand chosen, the injections may be prepared from multi-dose ampoules, by using cartridges in a pen injection device or the use of prefilled pens.

Growth hormone has a role in protein, lipid and carbohydrate metabolism, as well as in increasing growth in children. Growth hormone of human origin (HGH; somatotrophin) has been replaced by a growth hormone of human sequence, somatropin.

Indication:

NICE[2] recommends **Somatropin**; Recombinant Human Growth Hormone (rhGH) as a treatment option for children with growth failure associated with any of the following conditions:

- **Growth hormone deficiency (GHD)** – where the body does not produce enough, or any, growth hormone[3] resulting in the following short stature conditions: idiopathic isolated GH deficiency, congenital hypopituitarism or acquired hypopituitarism.

- **Turner syndrome (TS)** - a genetic disorder that affects roughly 1 in every 2,000 baby girls and only affects females. A girl with TS only has one X sex chromosome rather than the usual two (XX). Almost all girls with TS are shorter than average and have underdeveloped ovaries resulting in lack of monthly periods and infertility[3]. TS is confirmed by chromosome analysis.

- **Prader-Willi syndrome (PWS)** – a rare genetic condition caused by a genetic defect on chromosome number 15. Symptoms may cause include: a constant desire to east food, which seems driven by a permanent feeling of hunger and can easily lead to dangerous weight gain, restricted growth leading to short stature, restricted muscle tone, learning difficulties, lack of sexual development, behavioural problems such as temper tantrums or stubbornness [3].

- **Chronic renal insufficiency (CRI)** – renal function decreased to less than 50%[1].

- **Born small for gestational age (SGA**) - with subsequent growth failure at 4 years of age or later[2]. Various thresholds for height and weight at birth are used to define 'SGA'. The three most commonly used being:
  - a height at birth that is 2 standard deviations or more below the population average, or
  - a weight at birth that is 2 standard deviations or more below the population average, or
  - a weight at birth below the 10th percentile

- **Short stature homeobox-containing gene (SHOX) deficiency** – The SHOX gene provides instructions for making protein that regulates activity of other genes essential for the development of skeletal muscle[3].

Treatment with somatropin should always be initiated and monitored by a paediatrician with specialist expertise in managing growth hormone disorders; maintenance treatment can be prescribed in the community under a shared care protocol.

PATIENT PATHWAY

Clinical Speciality / Indication (see above for definitions)	Prescribing Initiated by	Prescribing Continued by (detail when suitable for transfer to occur)	Monitored by (detail when suitable for transfer to occur IF APPROPRIATE)	Duration of treatment
GHD TS PWS	Paediatrician with specialist expertise in managing growth hormone disorders in children.	GP (General Practitioner) under this shared care protocol. Suitable to transfer from Hospital Specialist to GP once GH device and dose has been stabilised.	Paediatrician in Hospital with specialist expertise in managing growth hormone disorders in children. The patient to get at least one month's supply from the hospital before GP continues to prescribe. Only suitable to transfer from hospital specialist to GP once GH device and dose has been stabilised.	Treatment with GH should be discontinued if any of the following apply*: -Growth velocity increases less than 50% from baseline in the first year of treatment -Final height is approached and growth velocity is less than 2cm total growth in 1 year -There is insurmountable problems with adherence -Final height is attained - In PWS evaluation of response to therapy should also consider body composition.
CRI	Paediatrician with specialist expertise in managing growth hormone disorders in children. Great Ormond Street Hospital (GOSH) initiation <u>only</u>, *not by BHRUT*			
SGA with subsequent growth failure at 4 years of age or later	Paediatrician with specialist expertise in managing growth hormone disorders in children.			
SHOX deficiency	GOSH initiation *<u>only</u> (Not started at BHRUT but treatment MAY be continued at BHRUT)*			

*Treatment <u>should not</u> be discontinued by default. The decision to stop treatment should be made in consultation with the patient and/or legal guardian either by:
- a paediatrician with specialist expertise in managing GH disorders in children[2].

- an adult endocrinologist, if care of the patient has been transferred from paediatric to adult services. The product licence for each manufacturer is as follows: *BHRUT Formulary products are shaded – If consultant wishes to initiate or continue treatment with a non-formulary product they must follow local guidelines and complete a non-formulary request form and submit via pharmacy.*

Manufacturer (product)	Specific Indication for GH				
	GHD	TS	CRI	PWS	SGA
Ferring (Zomactron ®)	X	X			
Ipsen (Nutropin Aq®)	X	X	X		
Serono (Saizen®)	X	X	X		X
Lilly (Humatrope®)	X	X	X		X
Novo (Norditropin®)	X	X	X		X
Pfizer (Genotropin®)	X	X	X	X	X
Sandoz (Omnitrope®)	X	X	X	X	X

The choice of product is made on an individual basis after informed discussion between the responsible clinician and the patient and/or their legal guardian about the advantages and disadvantages of the products available, taking into consideration the therapeutic need and the likelihood of adherence to treatment. If after that discussion, more that one product is suitable, the least costly product should be chosen[2] (see 'Costs' section of this document).

Costs vary minimally between products and products have been shown to be equipotent in terms of growth effect. There is also evidence that patient choice of device, training and support (in hospital and at home) and home delivery all improve compliance with therapy. The overall decision regarding choice of GH product depends on many factors including licensed indication, type of delivery device, age of child etc. and needs to be made by the specialist unit. It is also important that any changes in the brand should be made by the specialist centre as training in a new injection technique may be required.

Injection Equipment

The pharmaceutical companies provide all necessary equipment free of charge. Storage containers and sharps disposal bins are also provided. In addition, they also provide 24 hour support via the telephone. This will all be arranged by the hospital when treatment is initiated.

As mentioned above, GH is administered by subcutaneous or intramuscular injection. The GH devices available broadly fall into two groups:

- Needled devices: pen, needle and syringe
- Needle-free devices

Manufacturer (product)	Pen Device	Pre-filled needle/syringe	Needle –free device
Ferring (Zomactron ®)			X
Ipsen (Nutropin Aq®)	X		
Serono (Saizen®)	X	X	X
Lilly (Humatrope®)	X		
Novo (Norditropin®)	X	X	
Pfizer (Genotropin®)	X	X	X
Sandoz (Omnitrope®)	X		

DOSE AND ADMINISTRATION

Refer to table below for growth hormone dose recommendations in children; classified by indication (diagnosis)

- Administration by subcutaneous or intramuscular injection (see table below)
- Dose adjustments are based on the clinical response and the patient's experience of adverse events
- The site of administration should be varied to prevent lipoatrophy.

Diagnosis	Route of administration	Doses	
		micrograms/kg daily	mg/m^2 daily
Growth hormone deficiency (GHD)	SC or IM*	23 - 39	0.7 – 1
Gonadal dysgenesis (Turners Syndrome)	SC	45 - 50	1.4
Prader-Willi syndrome (PWS) Children with growth velocity greater than 1cm/year in combination with energy restricted diet:	SC	35**	1**
Chronic renal insufficiency (CRI)	SC	45 – 50***	1.4***
Growth disturbance in children born small for corrected gestational age whose growth has not caught up by 4 years of age or later	SC	35	1
SHOX deficiency -Diagnosis of SHOX confirmed by GOSH/Treatment Initiated by GOSH – Current doses from GOSH Shared Care Guideline	SC	45 - 50	NICE approved: 1.4

*SC= Subcutaneous Injection, IM = Intramuscular Injection
** Maximum dose 2.7mg daily {note 1mg = 3 international units (iu)}
*** Note: Higher doses may be needed, adjusted if necessary after 6 months

MONITORING BY BHRUT

Parameter	IGF-I (insulin-like growth factor)	TFTs (thyroid function tests)
Target level	Age related range ng/ml	TSH normal range 0.4 – 4.5 miu/L
Frequency of monitoring	Variable to individual patient (6 monthly – annual)	Annual
Action	Dose titration as appropriate according to response	Appropriate action as necessary

KEY ADVERSE EFFECTS & ACTIONS

GH therapy is safe and adverse effects are uncommon with recommended dosages but include the table below:

Adverse effects	**Symptoms/signs**	**Actions** (for *GP to take if identified in primary care)*
Reactions at injection site	Local discomfort, Lipoatrophy	Injection site inspection and site rotation advice/counselling
Raised Intracranial Pressure (ICP)	Severe recurrent headache, visual problems, nausea and vomiting	Funduscopy recommended. If raised ICP confirmed: consider benign intracranial hypertension (NOTE: rare cases reported) and refer back to hospital specialist.
Relative deficiencies of other pituitary hormones	Hypothyroidism symptoms (reported in 5-10% of patients undergoing treatment with GH) In diabetes mellitus: insulin resistance, hyperglycaemia	If associated TSH deficiency, correction with levothyroxine is essential if a response to GH is to be achieved. Adjustment of anti diabetic therapy may be necessary as somatropin may reduce insulin sensitivity
Fluid retention Arthralgia, myalgia, carpal tunnel syndrome, paraesthesia, antibody formation	Peripheral oedema Musculoskeletal pain, pains and numbness on fingers/wrist CNS disorders	Contact hospital specialist with expertise in growth hormone disorders. NOTE: Oedema may be exacerbated in Turner's Syndrome but is rare in other patients.

Guideline written by: Dinesh Gupta, assistant Chief Pharmacist, Clinical Services and Eamonn McArdle, Clinical Pharmacist
Consulted with Dr Morgan Keane, Consultant Paediatrician Date: February 2017
Date written: February 2018 Review date: February 2021
Approved by: BHRUT Medicines Optimisation Group Date February 2018
Approved by: BHR CCGs Area Prescribing Sub -Committees Date April 2018

Antibody development has been observed in some rHGH treated patients, but rarely affects the clinical response to treatment.

Acute leukaemia has been reported in both untreated GHD children as well as GH treated children. Studies show that there is no increased incidence over standard population data so these reports are chance associations. The incidence in treated children is not higher even in children who have had leukaemia previously or a bone marrow transplant.

Overdose in the acute situation is likely to lead to transient hypoglycaemia. The consequences of long-term treatment or overdose are unknown but carry the risk of pituitary gigantism or acromegaly. However these occur only with higher sustained levels of GH than standard levels of GH than standard therapeutic doses.

Interactions:
Corticosteroids in supra-physiological doses may interfere with growth promoting actions of GH. 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 the specialist consultant.

Diabetic patients may require their glycaemic control measures reviewed (including oral hypoglycaemics and insulin therapy).

This only lists the key important ADRs - For comprehensive information on cautions, contra-indications and interactions please refer to the current British National Formulary for Children and Summary of Product Characteristics.

Contra-indications:
- evidence of tumour activity (complete anti tumour therapy and ensure intracranial lesions inactive before starting
- post renal transplantation
- patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure should not be treated with somatropin.
- growth promotion in children with growth epiphyses.

PREGNANCY AND BREAST FEEDING

No clinical data on exposed pregnancies is available and it is not known whether somatropin is excreted in human milk.
If pregnancy occurs: Refer to antenatal clinic immediately (joint antenatal and endocrine clinic). Somatropin is not recommended during pregnancy and in women of childbearing potential not using contraception.

For comprehensive information please refer to the current British National Formulary for Children and Summary of Product Characteristics.

SHARED CARE

Shared care guideline: is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and/or legal guardian and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and/or legal guardian and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use.

General considerations for shared care

1. A patient with confirmed GH deficiency whom has been stabilised on an established dose.
2. Biosynthetic GH has a good safety record; monitoring of response is not required more frequently than every 3 – 6 months. Dose adjustments may be required annually by BHRUT.
3. Bearing in mind the high cost nature (Non-PBR) of GH, continuation has to be justified by objective evidence of accelerated growth rate and improvement of predicted final height. The growth specialist has the facilities for this assessment and can assist the GP in formulating a treatment plan.

4. A minority of candidates for GH therapy have had, or continue to have complex health disorders requiring specialist management e.g. Brain tumour in established remission. These children are under follow-up by a Consultant Paediatric Endocrinologist who specialises in late-effects of cancer treatment at GOSH/UCLH and would be outside the scope of this shared care guideline.

Responsibilities of Hospital Consultant

Assessment of the patient who has been referred by the GP or the Community Paediatric Service.

1. Completion of the required investigations to establish a firm diagnosis. The Consultant will provide the GP with a full report justifying the need for GH therapy. Diagnostic criteria may include: Justifying GH need as per NICE[2]
2. Ensure that the patient/family understand the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and provide clarification where appropriate.
3. Ensure that the patient/legal guardian is an informed recipient of growth hormone therapy.
4. Ensure that the patient/carer understands their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate and the Shared Care Patient Information Form. [See appendix 2]. Arranging for the family and patient to be instructed in the storage, preparation and administration of GH injections.
5. Send a letter to the GP requesting shared care for this patient [See appendix 1].
6. Initiate treatment and prescribe until the GP formally agrees to share care with the expectation that the GP will continue prescribing after one month supply by BHRUT.
7. Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
8. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
9. Evaluation of any reported adverse effects by GP or patient.
10. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
11. Inform GP of patients who do not attend clinic appointments.
12. Ensure suspected adverse drug reactions are appropriately reported via the yellow card scheme to MHRA.

Responsibilities of General Practitioner

1. Monitor patients overall health and well-being.
2. Report any adverse events or significant new medical presentations to the consultant, where appropriate.
3. Report any adverse events to the MHRA, where appropriate.
4. Prescribe GH maintenance treatment as described in this shared care guideline.

Responsibilities of CCG

1. To provide feedback to BHRUT via the Trust Medicines Optimisation Group.
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support trusts in resolving issues that may arise as a result of shared care.

Responsibilities of Patient/ Legal Guardian

1. Administer the medication as prescribed and as agreed.
2. Report any adverse effects to their GP and/or specialist.
3. Ensure they have a clear understanding of their treatment.
4. Report any changes in disease symptoms to GP and/or specialist.
5. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy.
6. Undertake any monitoring as requested by the GP and/or specialist.

Products available on the Formulary

Prescribing and dispensing information – For prices see latest BNFC

Drug Product	Formulation and strength
Genotropin® (Pfizer)	**Injection**, 5.3-mg (16-unit) cartridge , 12-mg (36-unit) cartridge **GoQuick® injection**, 5.3-mg (16-unit) prefilled pen; 12-mg (36-unit) prefilled pen **MiniQuick® injection**, 0.2-mg (0.6-unit) syringe ; 0.4-mg (1.2-unit) syringe ; 0.6-mg (1.8-unit) syringe ; 0.8-mg (2.4-unit) syringe ; 1-mg (3-unit) syringe ; 1.2-mg (3.6-unit) syringe ; 1.4-mg (4.2-unit) syringe ; 1.6-mg (4.8-unit) syringe ; 1.8-mg (5.4-unit) syringe ; 2-mg (6-unit) syringe
Humatrope® (Lilly)	**Injection**, 6-mg (18-unit) cartridge ; 12-mg (36-unit) cartridge ; 24-mg (72-unit) cartridge
Norditropin® (Novo Nordisk)	**SimpleXx® injection**, somatropin (epr) 3.3 mg (10 units)/mL,.5-mL (5-mg, 15-unit) cartridge ; 6.7 mg (20 units)/mL,1.5-mL (10-mg, 30-unit) cartridge ; 10 mg (30 units)/mL, 1.5-mL (15-mg, 45-unit) cartridge. **NordiFlex® injection**, somatropin (epr) 10 mg (30 units)/mL, 1.5mL (15-mg, 45-unit) prefilled pen
NutropinAq® (Ipsen)	**Injection**, somatropin (rbe), 10 mg (30 units) 2-mL cartridge
Omnitrope® (Sandoz)	**Injection**, somatropin (rbe) 3.3 mg (10 units)/mL, 1.5 mL (5-mg, 15-unit) cartridge ; 6.7 mg (20 units)/mL, 1.5 mL (10-mg, 30-unit) cartridge NOTE: BIOSIMILAR MEDICINE
Saizen® (Merck Serono)	**Injection**, somatropin (rmc), 5.83 mg (17.5 units)/mL, 1.03-mL (6-mg, 18-unit) cartridge ; 8 mg (24 units)/mL, 1.5-mL (12-mg, 36-unit) cartridge , 2.5-mL (20-mg, 60-unit) cartridge **Click.easy®**, 8-mg (24-unit)
Zomacton® (Ferring)	**Injection**, 4-mg (12-unit) vial (with diluent) 10-mg (30-unit) vial (with diluent)

RESOURCES AVAILABLE

Barking, Havering and Redbridge University NHS Trust	
Consultant Paediatricians Dr. K Banerjee Email: kaushik.banerjee@bhrhospitals.nhs.uk Dr. M Keane Email: morgan.keane@bhrhospitals.nhs.uk Dr. M Kumarasamy Email: maitrayee.kumarasamy@bhrhospitals.nhs.uk	Paediatrics Secretary Telephone : 01708 435000 Ext 3938 Paediatrics Secretary Fax: 01708503538
Paediatric Pharmacist Dinesh Gupta Email: dinesh.gupta@bhrhospitals.nhs.uk	Direct Line: Dinesh Gupta: 01708 435142

Pharmacy Medicines Information Department (24 hour answer phone)	Telephone: 01708 435 418
NHS Prescribing Team	Telephone: 0300 330 1349

References

1. British National Formulary for Children (BNF) (2017 - 2018); Section 6.4
2. National Institute for Health and Care Excellence (NICE) (2010) Human growth hormone (somatropin) for the treatment of growth failure in children. Technology appraisal guidance. Published: 26 May 2010 www.nice.org.uk/guidance/ta18
3. NHS Choices website (for definitions of growth hormone deficiency conditions).
4. Summary of Product Characteristics (SPC) for Somatropin products all checked and accessed via https://www.medicines.org.uk/emc/ on 19th January 2018
5. Add GOSH SCG as mentioned above

Refer to the NHS Barking and Dagenham, Havering and Redbridge CCG website to obtain the latest version of this guideline

Appendix 1

Barking, Havering and Redbridge University NHS Trust (BHRUT)

SOMATROPIN IN CHILDREN SHARED CARE AGREEMENT LETTER

Name of GP: ……..… Address: …….
…….....
. ……..
..……

Dear GP

Re: Patient's Name: ……..……

Date of Birth: ……..……

Hospital Number: ……..……

Indication for use of Somatropin (Recombinant Human Growth Hormone):

.....……

Route: Intramuscular / Subcutaneous *DELETE AS APPROPRIATE*

Dose: …… micrograms per day

Enclosed is a copy of the shared care guidelines for Growth Hormone (Somatropin) to be retained in the patient's healthcare record.

Should you agree to shared care, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

Please sign below and ***return this letter*** to the Hospital Specialist if you agree to the shared care arrangements for this patient.

Many thanks

Hospital Specialist:	GP
Signature…….....	Signature……...
Name ……..……....	Name …….....
Date……	Date……..…..……....

If you are not taking on shared care for this patient please state the reason why and return this letter to the Hospital Specialist.

……

Appendix 2

Barking, Havering and Redbridge University NHS Trust (BHRUT)

Shared Care Patient Information Form

This form will be completed by Dr Keane or Dr Banerjee and given to the patient/legal guardian.

Your child has been prescribed growth hormone for: (TICK AS APPROPRIATE)

- ☐ Growth hormone insufficiency (GHD)
- ☐ Turner syndrome
- ☐ Prader-Willi Syndrome (PWS)
- ☐ Short for gestational age (SGA)
- ☐ Chronic Renal Insufficiency (CRI)
- ☐ SHOX deficiency

Your GP has been given all the necessary information regarding your child's condition and treatment.

The success of this treatment also depends on you. Your GP/ Practice Nurse needs to see you every ……..

The date for your next hospital appointment is ……

How this treatment works:

Human growth hormone (somatropin) is a hormone produced by the pituitary, which is a small gland inside the head. Growth hormone is essential for growth in children. It also has important effects on how the body deals with protein, fats and carbohydrates not only during childhood but also throughout adult life.

Some children do not produce enough growth hormone or do not respond as expected to growth hormone, and so they do not grow as they should. They are much shorter than would be expected for their age.

Growth hormone is given to increase growth in children who have growth hormone deficiency, Turner syndrome or Prader-Willi syndrome (PWS). For children with PWS, growth hormone treatment is also given to improve body composition – children with PWS often have too much body fat and growth hormone can help to correct this.

Growth Hormone is also given to some children who were tiny at birth (small for their gestational age (SGA) and who have not caught-up in growth by 4 years of age.

If you experience any of the following side effects please see your GP:

- severe or recurrent headache/sickness
- problems with your eyesight
- muscle or joint pain or tingling

If you have any concerns about your treatment contact your GP or the hospital.

Hospital contact details are:

Consultants: Dr M Keane
Paediatrics Secretary: 01708 435000 Ext 3938

Paediatrics Fax: 01708 503538

Dr K Banerjee
Paediatrics Secretary: 01708 435000 Ext 3938
Paediatrics Fax: 01708503538

Dr M Kumarasamy
Paediatrics Secretary: 01708 435000 Ext 3938
Paediatrics Fax: 01708 503538

Paediatric Pharmacist: Dinesh Gupta: 01708 435 142

Details of relevant Support Groups:

www.heightmatters.org.uk

Child Growth Foundation
2 Mayfield Ave
Chiswick
London
W4 1PW
Tel: 020 8994 7625
www.childgrowthfoundation.org

Turner Syndrome Support Society (UK)
12 Irving Quadrant
Hardgate
Clydebank
G81 6AZ
Tel 01389 380385
Fax 01389 380384
www.tss.org.uk

The Pituitary Foundation
(PitPat) of the Society for Endocrinology,
17/18 The Courtyard,
Woodlands, Almondsbury,
Bristol
BS12 4NQ
Tel: 0117 927 3355

Appendix 3

Information for Patients prescribed Somatropin (Growth Hormone)

You have been prescribed **somatropin** by a specialist for the treatment of growth hormone deficiency.

What is Growth Hormone?

Growth hormone is normally produced by the pituitary gland, which lies at the base of the brain. Naturally occurring human growth hormone is also called somatotrophin. It helps to control the body's use of proteins, carbohydrates and lipids. Growth hormone is also involved in the growing process in children, as it has an effect on the growth of bones.

Growth hormone deficiency is the term used when the amount of growth hormone produced is much lower than usual. Growth hormone deficiency can happen as a result of damage to the pituitary gland or to the part of the brain called the hypothalamus, which is closely linked to the pituitary. Such damage can be caused by a tumour in the area or by the treatment the person had for the tumour (surgery or radiotherapy). Growth hormone deficiency can also happen if there has been a problem with the blood supply to the pituitary or hypothalamus.

What should I know about my medication?

- Read all of the information in the leaflet supplied with your medication before using it
- Do not use if you are allergic to somatropin, to phenol or any other ingredient listed in the product ingredients
- If any of the side effects (see list below) become troublesome or you notice any side effects not listed in the information leaflet, please tell your doctor or pharmacist
- Tell your doctor or pharmacist if you have any other medical conditions and if you are taking other medicines or have recently taken any. This includes medicines obtained without a prescription
- Inject your daily dose into the skin every evening before bedtime
- Tell your doctor if you inject too much somatropin
- If you forget a dose, take the next dose as usual at the normal time. Do not take a double dose to make up for a forgotten dose. Keep a record of any missed doses and inform your consultant or GP at your next appointment
- Do not stop using somatropin without discussing with your doctor first

What are the main side effects in adults?

Very common: (affects more than 1 user in 10)

- Swollen hands and feet due to fluid retention

Common: (affects 1 to 10 users in 100)

- Headache
- Feeling of skin crawling
- Numbness or pain mainly in fingers
- Joint pain and stiffness, muscle pain

Uncommon: (affects 1 to 10 users in 1,000)

- Type 2 diabetes
- Carpel tunnel syndrome – tingling and pain in fingers and hands
- Itching (can be intense) and pain in area of injection
- Muscle stiffness

Recommended Patient Help Groups:

The Pituitary Foundation
PO Box 1944, Bristol BS99 2UB
Tel/Fax 08707743355 email: helpline@pituitary.org.uk

The Prader-Willi Syndrome Association UK (PWSA UK) provides information and support for people whose lives are affected by PWS. You can call the PWSA helpline on 01332 365676.

Guideline written by: Dinesh Gupta, assistant Chief Pharmacist, Clinical Services and Eamonn McArdle, Clinical Pharmacist
Consulted with Dr Morgan Keane, Consultant Paediatrician Date: February 2017
Date written: February 2018 Review date: February 2021
Approved by: BHRUT Medicines Optimisation Group Date February 2018
Approved by: BHR CCGs Area Prescribing Sub -Committees Date April 2018