

This fact sheet has been produced for those patients starting on, or already taking, growth hormone (GH) to inform them of the symptoms of deficiency, diagnosis criteria and the NICE guidelines for GH replacement in adults. There are various treatment options shown in this fact sheet to help inform and empower your choice.

Adult growth hormone replacement

In 2003, the National Institute for Clinical Excellence (NICE) approved GH treatment in adults, which gave an end to the post-code lottery funding for GH. There has been development and improvement of GH injection devices. Support services and an abundance of information on GH treatment are now available for our patients. This fact sheet is a complementary resource and you should read the Pituitary Foundation booklets for more information. Similarly, some of the services and treatment options described here may not be available across the country and we would advise you to consult your endocrine team to explore services offered in your area.

GH treatment in adults and NICE guidelines

GH is produced by the pituitary gland which is controlled by the hypothalamus. It controls growth in children and is involved in the maintenance of normal body weight, muscle and bone strength and well-being in adults. GH deficiency in adults can result in loss of energy, fatigue and depression, which can lead to a decreased quality of life. If you have not been diagnosed with GH deficiency and feel extremely tired for no apparent reason, you should talk to your doctor or nurse. You can read the Pituitary Foundation booklets for more details on causes and diagnosis of GH deficiency. The aim of GH treatment is to improve your quality of life and well being, although there are additional health-related benefits from this treatment. The GH used is known as recombinant human growth hormone (rhGH) which is a synthetic preparation.

One of the most remarkable achievements was the approval of GH treatment in adults by NICE in 2003. This gives equal access to treatment funding for all patients with severe

GH deficiency across the country; you no longer have to live in the “right area” to be entitled to GH treatment. NICE recommends that GH should be used to treat adults older than 25 years when they suffer from GH deficiency and a severely affected quality of life. The criteria are:

- **You should have a peak GH level of less than 9 mU/litre in an insulin tolerance test, or another reliable dynamic test.**
- **Your quality of life is severely affected (impaired) by GH deficiency. This is measured using a questionnaire called *Quality of Life Assessment of Growth Hormone Deficiency in Adults* or *AGHDA-QoL* and you should answer YES to 11 or more of the 25 questions.**
- **You should already be receiving replacement for any other deficiencies of pituitary hormones if you have one or more other deficiencies, and these should be optimal before GH is started.**

After starting GH, your quality of life is assessed nine months later and you are expected to have a 7-point improvement on the AGHDA-QoL questionnaire compared to the pre-GH score. Should this be the case, you will be advised to continue on lifelong GH treatment, unless your individual circumstances change and/or GH is contraindicated. If your quality of life has not improved at all within 9 months (taking into account that you had no other major negative events in your life during this time), you will be asked to stop your GH treatment. Adult patients younger than 25 years, who are diagnosed with GH deficiency, should be given GH treatment until peak bone mass is achieved (this is at around 25 years old and is measured with a Bone Mineral Density scan).

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Continuation of GH past peak bone mass is based on the assessment of the quality of life as per above points. For more information, you can ask your clinician or visit the NICE website on www.nice.org.uk.

Treatment start and long term monitoring

Before starting your GH treatment, you will normally have a consultation with an endocrine specialist nurse (or an endocrinologist), who will explain what this treatment involves, its purpose, long-term monitoring and then they will organise your treatment start. Many hospitals offer patients the choice of which GH device they would like while others simply prescribe the GH of their choice. The main point to remember is that it is the device that is different and the medicine is the same i.e. Recombinant GH. The average starting GH dose for an adult is 0.2 – 0.3 mg daily. GH is given by injection into the fatty tissue just under the skin (subcutaneous). Ideally, the injection is performed in the evening to mimic natural GH production which happens during sleep. A lot of patients are very worried at the idea of self-injecting, but with reassurance and training from your nurse, this fear can be overcome. There are helpful aids which come with most devices to make the process easier for the individual.

You will be seen in the endocrine clinic at regular intervals, especially during the first 9 months, to assess your response to treatment and to make adjustments to your GH dose according to your needs. The blood test performed measures Insulin-like Growth Factor 1 (IGF-1) which will guide your GH dose increase. IGF-1 is a protein mainly produced by the liver under GH stimulation; severe GH deficiency is often associated with low IGF1. You should ensure that IGF-1 is part of your routine endocrine check up, as it is the only way to know if you are taking the right dose of GH.

As IGF-1 can drop if you have missed a number of GH doses prior to your blood test, it is very important that you do not miss any injections (or if you do, you should point this out to your clinician so IGF-1 results can be interpreted accordingly). Overdosing with GH and exceeding normal range for IGF-1 can lead to unpleasant side effects and complications.

Support services for GH treatment

As a patient on GH treatment, you should have access to an endocrinologist and an endocrine specialist nurse who will advise you and monitor your treatment. The Pituitary Foundation can also provide you with information and support. In addition, most pharmaceutical companies producing GH sponsor home services (their name can vary depending on the GH brand) which provide a wide range of support services for patients on GH treatment. When starting your treatment, an endocrine nurse can visit you at your home to train you on the injection device and teach you how to do your injections.

Home service will provide you, free of charge, with your treatment starter pack (injecting device, needles, sharps boxes etc), information on GH treatment (on-line, DVD and in print format) and continuous supplies of your needles, sharps boxes etc (also known as “stores”); most of them will also collect clinical waste from your home at the time of stores delivery. Home service can also dispense your GH which will be delivered to your house on a regular basis. A lot of our patients find this a great service as they do not have to attend their GP practice and local chemist for repeat prescriptions on a monthly basis. Finally, most home services have a helpline which you can ring if you have any concerns regarding your treatment, for example, if you need a new supply of needles or your pen device is not working.

Injection devices:

Needle pen devices

As the name states, these devices resemble a pen (with diameter of about half inch) in which the GH vial is inserted. Injections are relatively painless and the needle is very thin and short (about a third of an inch). The single-use needle is attached to the front of the pen and it should be disposed into the sharps box immediately after each injection. Pen devices are re-usable and can last for three to four years. The following pen devices are currently available in the UK:



1. GenotropinPen®

Genotropin 5.3mg and 12mg vials by Pfizer (pen must match vial size). This is a battery operated pen; dose increments of 0.1 for the 5.3mg vial and 0.2 for the 12mg vial. Powder and liquid vial mixed within the pen and is fairly easy; the GH drug requires refrigeration at all times



2. Genotropin Go Quick

This is a pre-filled disposable device which requires some assembly and also needs to be stored in the refrigerator.



3. NutropinAQ Pen®

For use with NutropinAQ 10mg vial by Ipsen Pharmaceuticals (battery operated; dose increments of 0.1; liquid form; should be refrigerated at all times)

4. NordiPen®

5, 10 and 15 by NovoNordisk for use with Norditropin SimpleXx 5mg, 10mg and 15mg. Liquid vials (no reconstitution required). It has a manual dose dial, dose increments of 0.05 for the 5mg vial and 0.1 for the 10 and 15mg vials, Vials should be stored in the fridge until they are put into the device. Once the pen is in use vials can be stored at room temperature for up to 28 days.



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5. Nordiflex

Is a prefilled, multi-dose, disposable GH pen which requires no refrigeration. This is available in 15mg dose only.

The Norditropin PenMate

Is an accompanying device for the NordiPen and provides an auto-inserting and hidden needle option



6. HumatroPen3®

For use with Humatrope 6mg, 12mg and 24mg vials by Elli Lilly and Company (battery operated, it requires reconstitution before inserting in the pen; requires refrigeration once reconstituted). The 24mg vial can be useful for children who require large GH doses, especially girls with Turner's syndrome, as vials can last longer.



7. Omnitrope Pen5®

For use with Omnitrope, 5mg vials by Sandoz (manual dose dial; dose increments of 0.05 liquid form; should be refrigerated at all times.

Needle free devices

Some patients, mostly children and adolescents, have needle phobia and are unable to overcome the fear of needles and cope with injections. There are two needle-free devices for GH:

1) Cool.click®

(name of the device) for Saizen Click.Easy 8mg (name of GH) by Merck Serono

2) Zomajet2Vision®

For Zomacton 4 and 10mg by Ferring Pharmaceuticals.

These devices inject GH by creating a fine stream of high-pressure jet liquid which penetrates the skin and deposits medication in the subcutaneous (fat) tissue without the use of a needle. For patients with a genuine fear of needles, these are excellent devices and can improve patient adherence to treatment. The "needle-free" concept can sometimes be misinterpreted for "pain-free" and some patients may choose this option because they think that they can have painless injections. However, this is not the case and injections can be as painful (or even more) as a needle device. It is useful to have an open discussion with your endocrine nurse and explore whether it is indeed needle phobia you are experiencing or you believe that the needle-free device will give you pain-free injections.



All pens have similar features and it is not very important which one you use in order to replace your GH. To dial your dose, you turn the knob at the top of the pen; the dose appears on the window on the side of the pen. All pens have a needle-guard for a hidden needle option; this can also provide better support for the pen on the injection site and guides the needle through the skin. Patients with dexterity or visual difficulties often find the battery operated pens easier to use. Each pen has a plunger, which when pushing, by pressing down the dial knob, it delivers the medication under the skin through the needle. When all liquid in the vial is used, the pen will not allow you to dial your daily dose and this tells you that you need to insert a new vial. Most patients find this part the most difficult step to remember and perform correctly. You should contact your nurse for assistance if you have any doubts; similarly all companies provide DVDs and illustrated leaflets with step-by-step user instruction manual which you can follow.

Depending on your daily dose and the concentration of the vial, one vial can last from 5 and up to 28 days. All vials should be discarded 28 days after the first injection. A simple way to calculate how many days each vial will last is by dividing the concentration of your vial with your daily dose (e.g. a 10mg vial on a 0.5 mg daily dose will last 20 days). If you need to travel with your GH, you will be supplied with a cool bag which can keep the drug temperature safe for approximately 12 hours.

Genotropin MiniQuick



This can be stored in room temperature for up to three months and has the great advantage of making travelling much easier. It is a fixed dose, preservative

free, single-use injection device with two compartments, powder and diluent, which you need to mix prior to each injection. They are packaged in a seven-day supply and needles are included; there is an optional needle guard which hides the needle from view and makes injections easier. Dose strength varies from 0.2 mg to 2.0 mg, with increments of 0.2 mg, which may present slight restrictions when you are on an odd-number daily GH dose. We advise patients to use the nearest dose for the duration of travel, for example if your dose is 0.7 mg daily, you can use 0.6 or 0.8 mg depending on your IGF-1 result; your endocrine nurse or doctor can advise you accordingly. You should carry medication with you at all times and it is useful to carry a travel letter from your GP or endocrine nurse for airport security. Although this device does not require refrigeration, you will have to take extra care and ensure that the drug is kept cool at a temperature below 25 degrees Celsius and away from sun exposure, especially in hot climates



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Electronic injection device

EasyPod® for Saizen Click.Easy 8.0 mg vials by Merck Serono (below) is an electronic fully automated injection device. There is a removable back cover if you would like to personalise your EasyPod. It is popular with young adults and patients who like technology. The sensors at the base of the device activate only on contact with human skin and allow delivery of the injection, so you can be assured that you have injected your GH. It has a hidden needle and comfort settings can be individualised, for example how fast and deep you want the needle to go into your skin. Similarly, it has a pre-set dose; for your daily injections, all you need to do is turn on the device, insert a new needle and inject by pressing the button on top of the device. If you cannot remember whether you had your injection or not, the device records the date of your last injection and will alert you if you try to have a second injection on the same day. The very attractive feature of this device is its calendar recording; if you have missed an injection, the date on the calendar will be red, whilst your injection dates will be in green (so you will know exactly how many injections you have missed, if any).

Although, the device menu can seem complex, you will receive full training on its use and the nurse will pre-set all settings to match your individual preferences and needs. Compared to the pen devices, it is quite large in size, although patients with dexterity problems find it easier to hold during an injection. The GH vials come in ready prepared liquid format and just require to be inserted into the EasyPod. Some people may still use Saizen Click Easy which needs reconstitution (mixing) before use in the



EasyPod and many patients find this quite a complex and time consuming process. Please ask your endocrine nurse if you wish to change from Click Easy to Saizen Solution for Injection (new ready prepared cartridge) available in 6mg, 12mg and 20mg. The drug should be refrigerated at all times.

GH treatment has come a long way and with access to the right clinical support and information, patients receive appropriate treatment and do not suffer the long term consequences of GH deficiency which can often be detrimental to their well being and psychosocial life. Despite the great developments in GH treatment, by no means one can say that perfection has been achieved and there is a lot more we have to learn. A lot of patients find daily injections inconvenient and painful; others find having to reconstitute GH or change the vial in a re-usable device regularly quite a chore.

Quality of Life Assessment of Growth Hormone Deficiency in Adults Questionnaire:

The *AGHDA-QoL Questionnaire* asks you to answer ‘yes’ or ‘no’ to 25 statements. Each ‘yes’ scores 1 point; the higher the score, the worse the quality of life

		yes	no
1	I have to struggle to finish jobs		
2	I feel a strong need to sleep during the day		
3	I often feel lonely even when I am with other people		
4	I have to read things several times before they sink in		
5	It is difficult for me to make friends		
6	It takes a lot of effort for me to do simple tasks		
7	I have difficulty controlling my emotions		
8	I often lose track of what I want to say		
9	I lack confidence		
10	I have to push myself to do things		
11	I often feel very tense		
12	I feel as if I let people down		
13	I find it hard to mix with people		
14	I feel worn out even when I've not done anything		
15	There are times when I feel very low		
16	I avoid responsibilities if possible		
17	I avoid mixing with people I don't know well		
18	I feel as if I'm a burden to people		
19	I often forget what people have said to me		
20	I find it difficult to plan ahead		
21	I am easily irritated by other people		
22	I often feel too tired to do the things I ought to do		
23	I have to force myself to do all the things that need doing		
24	I often have to force myself to stay awake		
25	My memory lets me down		
	Total score:		

A copy of the *AGHDA-QoL questionnaire* can be downloaded from this site:
www.pituitary.org.uk/images/stories/AGHDA_questionnaire.pdf

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- Receive our members' newsletter, Pituitary Life, three times a year full of the latest information, updates and patient stories, to help you better understand, or manage your pituitary condition.
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Individual membership costs £20.00 for a full year, which is only £1.66 a month! (Family, concessionary and life membership rates are also available). To become a member, please complete the form below and return to us with your payment (cheques made payable to The Pituitary Foundation) to:

The Pituitary Foundation

86-88 Colston Street

Bristol

BS1 5BB

If you would like to pay for your membership by standing order, please contact 0117 370 1333, or to join online visit www.pituitary.org.uk

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Individual	<input type="checkbox"/> £20.00 (annual)	Family	<input type="checkbox"/> £35.00 (annual)
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Signature:		Date:	

This information sheet provides general information only. All patients are different and if you have any questions, please contact your endocrinologist or GP

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