

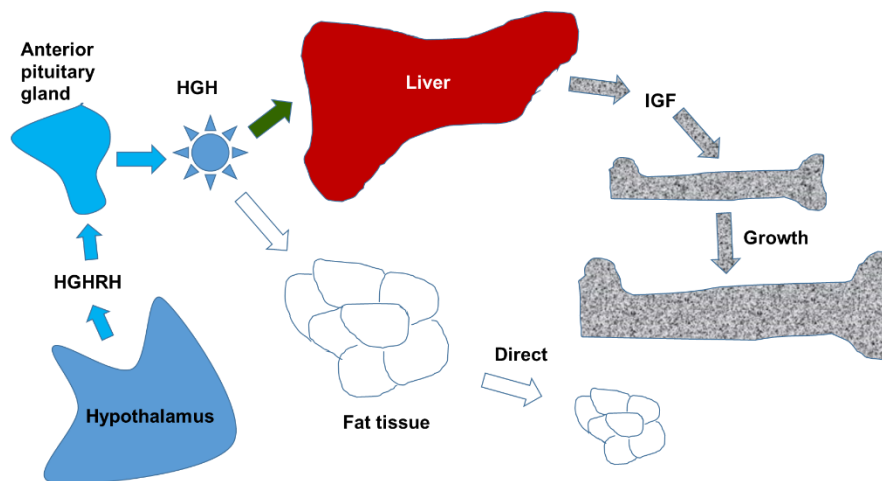
## HGH – Fact Sheet

### Molecule

Human growth hormone (HGH, Nutropin®, Humatrope®, Genotropin®, Norditropin®, Saizen®), also known as somatotropin, is a 191-amino acid, single-chain, non-glycosylated polypeptide. Its molecular weight is 22.1 kDa.

### Mode of Action

In response to stimuli by the hypothalamus, mainly via HGH releasing hormone (HGHRH), HGH is synthesized and secreted by somatotropic cells within lateral wings of the anterior pituitary gland. It is anabolic and stimulates growth, cell reproduction and cell regeneration. The effects are exerted on all tissues, divided into indirect (growth) and direct. Most of these effects of HGH are mediated by insulin-like growth factors (IGFs).



### Indication

HGH is indicated as replacement therapy in persons with growth hormone deficiency. There is off-label prescription and use of HGH for a variety of other applications.

### Patent Situation

Patents already expired and a variety of originators or biosimilars are marketed or in development.

### Market and Competitive Field

Human pituitary-derived HGH was available since the late 1950s and in 1981 Genetech developed the first recombinant product. There are a variety of originators and medicinal products similar to reference product Genotropin® from Pfizer on the market. Omnitrope® was approved by the EMA in 2006 as the world's first biosimilar medicine. Other biosimilars are in development as well. Overall, HGH market is highly consolidated and crowded with a variety of global players. Total sales in 2017 were nearly 2 billion Euro.

	HGH
	*Genotropin® Humatrope® Saizen®
	e.g. Omnitrope® Valtropin™
<b>Clone selection / comparability</b>	
Affinity to recombinant target – kinetics (Biacore)	GH-R
Cell-based bioassay	
<b>(Pre)clinical application</b>	
Pharmacokinetics (ECL or ELISA)	
Immunogenicity (Biacore / ELISA / bioassay)	
<b>Batch release EU</b>	

\*Examples for tradename of registered products

