FSH – Fact Sheet

Molecule

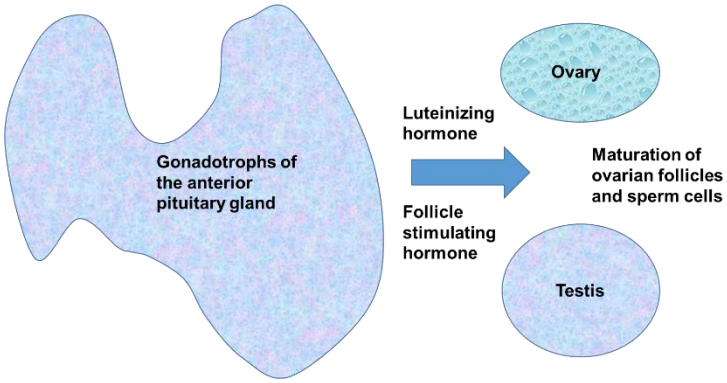
Follicle stimulating hormone (FSH) consists of two non-covalently linked glycoproteins designated as alpha- and beta-subunits, which consist of 92 and 111 amino acids, respectively. The molecular weight is 22.7 kDa. Follitropin is the corresponding recombinantly produced molecule and is marketed as follitropin alpha (Gonal F®) and follitropin beta (Puregon®). The amino acid sequences of follitropin alpha and beta are identical to that of FSH, and there are only differences in glycosylation patterns.

Mode of Action

FSH is synthesized and secreted by the gonadotrophs of the anterior pituitary gland. In general, it regulates the development, growth, pubertal maturation, and reproductive processes of the body including maturation of ovarian follicles and sperm cells. FSH and luteinizing hormone (LH) act synergistically in reproduction.

Indication

For women, follitropin is indicated for induction of ovulation and pregnancy in an ovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure. It is also indicated for the development of multiple follicles in the ovulatory patient participating in an assisted reproductive technology program. It is indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.



Patent Situation

Though there are second line patents, which are still valid, basic patents of the originator molecule have already been expired and biosimilars are on the market.

Market and Competitive Field

Follitropin beta was first approved by EMA in 1996, and by FDA in 1997. It was developed and marketed as Follistim® by MSD. Gonal F® from Merck KGaA got the approvals in 1995 by EMA and in 1997 by FDA. Sales in 2020 were 203 Mio € (MSD), and 630 million € (Merck KGaA).

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	FSH
	Follistim®, Gonal F®
	Bemfola®, Cinnal-f®, Elonva®, Folisurge, FostiRel®, Gonadopin®, Gonapure®, Ovaleap®
Clone selection / comparability	
Affinity to recombinant target – kinetics (Biacore)	FSH-R
Cell-based bioassay	cAMP
(Pre)clinical application	
Pharmacokinetics (ECL or ELISA)	
Immunogenicity (Biacore / ELISA / bioassay)	
Batch release EU	

Vela Portfolio

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