Growth hormone composition

The present invention relates to dry compositions of rhGH polymer prodrugs, methods for their manufacture as well as containers and kits of parts comprising said compositions.

Growth hormone (GH) is a hormone that stimulates growth and cell reproduction in humans and other animals. It is a 191-amino acid, single-chain polypeptide hormone which is synthesized, stored, and secreted by the somatotroph cells within the lateral wings of the anterior pituitary gland. The hormone is also known as somatotropin when referring to human growth hormone (hGH) produced by recombinant DNA technology, and is abbreviated "rhGH".

Growth hormone has a variety of functions in the body, the most noticeable of which is the increase of height throughout childhood, and there are several diseases which can be treated through the therapeutic use of GH.

Growth hormone deficiency is caused by insufficient production of growth hormone which causes various negative effects. During infancy and childhood the most prominent feature is growth failure, resulting in short stature, whereas in adults it causes diminished lean body mass, poor bone density and other physical and psychological effects. The standard treatment of growth hormone deficiency is daily injections with recombinant human growth hormone (rhGH) under the skin or into the muscle.

To free the pediatric patient group from the burden of daily injections, long-acting growth hormone compositions are intended to provide therapy of growth hormone deficiency in children. Various compositions of long-acting or sustained release human growth hormone are described. Growth hormone depots of the first generation were based on slow-release compositions of the human growth hormone in highly viscous liquid such as sucrose acetate isobutyrate (WO 01/78683, Genentech) or biodegradable PLGA (polylactide/polyglycolide) gel. US 5,645,010, Alkermes, describes a composition of zinc-complexed hGH in PLGA. A corresponding marketed product (Nutropin Depot) was offered as single-dose injectable composition. For various reasons, Nutropin Depot did not show significant market uptake and was discontinued.

DRY GROWTH HORMONE COMPOSITION TRANSIENTLY LINKED TO A POLYMER CARRIER

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