



HUMAN GROWTH HORMONE

(Trade Names: Genotropin®, Humatrope®, Norditropin®, Nutropin®, Saizen®, Serostim®)

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DEA/OD/ODE

Introduction:

Human growth hormone (hGH) is a naturally occurring polypeptide hormone secreted by the pituitary gland and is essential for body growth. Daily secretion of hGH increases throughout childhood, peaking during adolescence, and steadily declining thereafter. In 1985, synthetic hGH was developed and approved by the FDA for specific uses. However, it is commonly abused by athletes, bodybuilders, and aging adults for its ability to increase muscle mass and decrease body fat, as well as its purported potential to improve athletic performance and reverse the effects of aging.

Licit Uses:

Several FDA-approved injectable hGH preparations are available by prescription from a supervising physician for clearly and narrowly defined indications. In children, hGH is approved for the treatment of poor growth due to Turner's syndrome, Prader-Willi syndrome, and chronic renal insufficiency, hGH insufficiency/deficiency, for children born small for gestational age, and for idiopathic short stature. Accepted medical uses in adults include the treatment of the wasting syndrome of AIDS and hGH deficiency. The recommended dosage is 40 µg/kg/day for children and 25 µg/kg/day for adults. The FDA-approved injectable formulations are available as liquid preparations, or as powder with a diluent for reconstitution.

Chemistry and Pharmacology:

Using recombinant DNA technology, two forms of synthetic hGH were developed, somatropin and somatrem. Somatropin is identical to the endogenous pituitary-derived hGH, whereas somatrem has an extra amino acid on the N-terminus. Both synthetic forms have similar biological actions and potencies as the endogenous hGH polypeptide. Synthetic hGH also is chemically indistinguishable from the naturally occurring hormone in blood and urine tests.

hGH binds to growth hormone receptors present on cells throughout the body. hGH functions to regulate body composition, fluid homeostasis, glucose and lipid metabolism, skeletal muscle and bone growth, and possibly cardiac functioning. Sleep, exercise, and stress all increase the secretion of hGH.

The use of hGH is associated with several adverse effects including edema, carpal tunnel syndrome, joint pain, muscle pain, and abnormal skin sensations (e.g., numbness and tingling). It may also increase the growth of pre-existing malignant cells, and increase the possibility of developing diabetes.

hGH is administered by subcutaneous or intramuscular injection. The circulating half-life of hGH is relatively short half-life (20-30 minutes), while its biological half-life is much longer (9-17 hours) due to its indirect effects.

Illicit Uses:

Human growth hormone is illicitly used as an anti-aging agent, to improve athletic performance, and for bodybuilding purposes. It is marketed, distributed, and illegally prescribed off-label to aging adults to replenish declining hGH levels and reverse age-related bodily deterioration. It is also abused for its ability to alter body composition by reducing body fat and increasing skeletal muscle mass. It is often used in combination with other performance enhancing drugs, such as anabolic steroids. Athletes also use it to

improve their athletic performance, although the ability of hGH to increase athletic performance is debatable.

Abuser Population:

Athletes, bodybuilders, and aging adults are the primary abusers of hGH. Because the illicit use of synthetic hGH is difficult to detect, its use in sports is believed to be widespread. Over the past few years, numerous professional athletes have admitted to using hGH. Bodybuilders, as well as celebrities also purportedly use it for its ability to alter body composition. Aging adults looking to reverse the effects of aging are increasingly using synthetic hGH.

Illicit Distribution:

The illicit distribution of hGH occurs as the result of physicians illegally prescribing it for off-label uses, and for the treatment of FDA-approved medical conditions without examination and supervision. Illicit distribution also involves diverted hGH obtained through theft, smuggled hGH illegally imported from other countries, and counterfeit hGH.

The illicit distribution of injectable synthetic hGH formulations is thought to be primarily through Internet pharmacies, as well as wellness and anti-aging clinics and websites. Internet pharmacies are often partnered with a physician willing to write prescriptions for a fee without a physical examination. Individuals may also obtain hGH without a prescription through the black market. hGH is often marketed with other performance enhancing drugs (e.g., anabolic steroids).

According to the National Forensic Laboratory Information System (NFLIS), law enforcement officials submitted 30 hGH items/exhibits to state and local forensic laboratories between 2005 and 2010. Various oral preparations (e.g., sprays and pills) purported to contain hGH are also marketed and distributed. However, hGH is only available in the injectable form. The hGH molecule is too large for absorption across the lining of the oral mucosa and the hormone is digested by the stomach before absorption can occur.

Control Status:

Human growth hormone is not controlled under the Controlled Substances Act (CSA). However, as part of the 1990 Anabolic Steroids Control Act, the distribution and possession, with the intent to distribute, of hGH "for any use...other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services...and pursuant to the order of a physician..." was criminalized as a five-year felony under the penalties chapter of the Food, Drug, and Cosmetics Act of the FDA.

hGH is listed by the World Anti-Doping Agency and the International Olympic Committee as a performance enhancing drug barring athletes from using it.

Comments and additional information are welcomed by the Office of Diversion Control, Drug and Chemical Evaluation Section.
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