Generic Name:
Testosterone undecanoate
Trade Name:
Jatenzo
Company:
Clarus Therapeutics
Notes:

FDA approved testosterone undecanoate, an oral testosterone capsule to treat men with certain forms of hypogonadism. These men have low testosterone levels due to specific medical conditions, such as genetic disorders like Klinefelter syndrome or tumors that have damaged the pituitary gland.

Testosterone undecanoate should not be used to treat men with age-related hypogonadism, in which testosterone levels decline due to aging, even if these men have symptoms that appear to be related to low testosterone. The drug's benefits do not outweigh its risks for that use, according to FDA.

Efficacy was demonstrated in a 4-month clinical trial involving 166 men with hypogonadism. Study participants initially were given 237 mg of testosterone undecanoate twice per day, and the dose was adjusted downward or upward to a maximum of 396 mg twice per day on the basis of testosterone levels.

Eighty-seven percent of men treated with the drug achieved an average testosterone level within the normal range, which was the primary study endpoint.

Testosterone undecanoate contains a boxed warning stating that the drug can cause blood pressure to rise, increasing the risk of heart attack, stroke, and cardiovascular death. Health care providers should consider a patient?s individual heart disease risks and ensure that blood pressure is adequately controlled before prescribing the agent. They should also periodically monitor patient blood pressure during treatment.

The drug is currently one of two testosterone products that have this boxed warning. FDA is requiring all testosterone product manufacturers to conduct blood pressure postmarketing trials to more clearly address whether these products increase blood pressure.

Common adverse effects, occurring in more than 2% of patients in the clinical trial, included headache, an increase in red blood cell count, a decrease in HDL-C, high blood pressure, and nausea. An increase in prostate specific antigen (PSA) was also observed. Patients should have their hematocrit, cholesterol, and PSA monitored regularly to check for changes. Those with benign prostate hyperplasia should be monitored for worsening of symptoms.

Medication Monitor Categories:
New Drug Approvals