

Jatenzo approved for men with low testosterone

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(HealthDay)—Jatenzo (testosterone undecanoate) has been approved by the U.S. Food and Drug Administration to treat men with low testosterone, medically called hypogonadism.

The approval covers men with low levels of the male hormone due to specific medical conditions, including genetic disorders such as Klinefelter syndrome or tumors that have damaged the pituitary gland, the agency said in a news release.

Jatenzo should not be used to treat men with "age-related hypogonadism," in which testosterone levels drop due to aging, the agency warned. The FDA added that the drug's effectiveness hadn't been established for treating age-related hypogonadism, and that the drug's effects on raising blood pressure could increase older men's risks of heart attack, stroke and cardiovascular death.

"Jatenzo's oral route of administration provides an important addition to current treatment options available for men with certain hypogonadal conditions who up until now have most commonly been treated with testosterone products that are applied to the skin or injected," said Dr. Hylton Joffe, director of the agency's Division of Bone, Reproductive and Urologic Products. "But it's important to emphasize that this drug should not, like other testosterone treatments, be used to treat older men with 'age-related hypogonadism.'"

Jatenzo's effectiveness was demonstrated in a clinical study involving

166 men with hypogonadism. Study participants initially were given the drug at a dose of 237 milligrams 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 Jatenzo-treated men achieved an average testosterone level within the normal range, the FDA said.

The drug's label includes a boxed warning that it can cause blood pressure to spike. Doctors should consider a patient's heart disease risks and ensure that blood pressure is adequately controlled before prescribing Jatenzo, the agency said.

The medication's most common side effects include headache, high red blood cell count, a decrease in [high-density lipoprotein](#) ("good") cholesterol, high [blood pressure](#), a spike in prostate specific antigen (PSA) and nausea.

Jatenzo is produced by Clarus Therapeutics, based in Northbrook, Ill.

More information: Visit the FDA [to learn more](#).

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