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Generic Name:

Smallpox and monkeypox vaccine

Trade Name:

Jynneos

Company:

Bavarian Nordic A/S

Notes:

FDA has approved [Jynneos](#), a live, nonreplicating smallpox and monkeypox vaccine that prevents smallpox and monkeypox disease in adults ages 18 years and older who are at high risk for smallpox or monkeypox infection. It is the only currently FDA-approved vaccine for prevention of monkeypox disease.

Jynneos is made from a vaccinia virus, which is closely related to but less harmful than variola or monkeypox viruses and can protect against both of these diseases. Jynneos contains a modified form of the vaccinia virus that does not cause disease in humans and is nonreplicating.

Its effectiveness for prevention of smallpox was determined in a clinical study comparing the immune responses in study participants who received either Jynneos or ACAM2000, an FDA-approved vaccine for prevention of smallpox. The study included approximately 400 healthy adults ages 18 through 42 years who had never been vaccinated for smallpox. Half of the study participants received two doses of Jynneos administered 28 days apart, and half received one dose of ACAM2000.

The group vaccinated with Jynneos had an immune response that was not inferior to immune responses to ACAM2000. Vaccine effectiveness for prevention of smallpox was also inferred from supportive animal studies, which showed that prior vaccination with Jynneos protected nonhuman primates who were exposed to viruses related to the smallpox virus.

Effectiveness of Jynneos for prevention of monkeypox disease is inferred from the antibody responses in the smallpox clinical study participants and from studies in nonhuman primates that showed protection of animals vaccinated with Jynneos who were exposed to the monkeypox virus.

Safety was assessed in more than 7,800 individuals who received at least one dose of the vaccine. The most commonly reported adverse effects were pain, redness, swelling, itching, firmness at the injection site, muscle pain, headache, and fatigue. No safety concerns that would require a Medication Guide have been identified.

Jynneos is administered in two doses given 4 weeks apart.

The vaccine is part of the Strategic National Stockpile (SNS), the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency that is severe enough to cause local supplies to be depleted. The availability of this vaccine in the SNS will help ensure that the vaccine is accessible in the United States if needed.

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