

# **Monkeypox Fast Facts**

# JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating)

If you have <u>monkeypox symptoms</u>, talk to your healthcare provider even if you haven't had contact with someone who has monkeypox.

When properly administered, vaccines can be effective tools at protecting people against monkeypox illness.

# What you need to know:

- <u>JYNNEOS</u> is a vaccine approved (licensed) by the FDA for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. This vaccine, which was approved in 2019, is the only vaccine approved for the prevention of monkeypox in the U.S.
- JYNNEOS is approved as a two-dose vaccination series. The Centers for Disease Control and Prevention considers
  people fully vaccinated about two weeks after their second shot, and it is not yet clear how well people are
  protected after only one dose. The CDC recommends vaccinated individuals should continue to take steps
  to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with
  someone who has monkeypox.
- The FDA evaluation of this licensed product helps ensure the safety, effectiveness, and quality of the vaccine.

#### About the vaccine:

- The vaccine **does not** contain the contain the viruses that cause smallpox or monkeypox.
- The effectiveness of JYNNEOS against monkeypox is supported studies in both humans and animals. For more
  information on the clinical studies see: <u>FDA approves first live, non-replicating vaccine to prevent smallpox and
  monkeypox.</u>
- JYNNEOS is made from a vaccinia virus, a virus that is closely related to, but less harmful than, smallpox or monkeypox viruses, and can protect against both diseases.
- It is given as two subcutaneous injections (shots under the skin) four weeks apart.
- The most commonly reported side effects from patients in the clinical study were pain, redness, swelling, itching, firmness at the injection site, muscle pain, headache, chills and fatigue.
- The prescribing information contains more information about the product.

## About the Emergency Use Authorization (EUA):

- On August 9, 2022, the FDA issued an EUA for the JYNNEOS vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection. This will increase the total number of doses available for use by up to five-fold. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk of monkeypox infection; in these individuals JYNNEOS is administered by subcutaneous injection.
- In issuing this EUA, the FDA determined that the known and potential benefits of JYNNEOS outweigh the known and potential risks for the authorized uses.
- Additional information on the FDA's decision to authorize the vaccine for these uses may be found here.

### **Additional information:**

- JYNNEOS is available from the Strategic National Stockpile and can be <u>requested in consultation with CDC</u>. In the U.S., there is currently a limited supply of the vaccine although more is expected in coming weeks and months.
- The CDC has recommended approaches for vaccination of certain individuals in the <u>CDC Vaccine Strategies to</u>

  <u>Prevent Monkeypox</u>, in particular to people following exposure to monkeypox and certain higher risk individuals.