

Monkeypox Fast Facts

TPOXX (tecovirimat)

If you have [monkeypox symptoms](#), talk to your healthcare provider even if you haven't had contact with someone who has monkeypox.

What you need to know:

- TPOXX is an antiviral drug approved by the FDA in 2018 to treat smallpox in adults and children.
- There are no FDA-approved or authorized treatment for monkeypox virus infections, and no data establishing the safety or effectiveness of using TPOXX to treat monkeypox in humans.
- TPOXX [may be used](#) for people with severe disease or who are more likely to get severely ill, like patients with weakened immune systems.

About the drug:

- The FDA approved TPOXX for smallpox under the FDA's [Animal Rule regulations](#), which allows for approval of certain drugs and biological products when human efficacy studies are not ethical and field trials to study the effectiveness of drugs or biological products are not feasible.
- Human efficacy studies of smallpox disease are not feasible because smallpox has been eradicated globally and exposing people to smallpox virus for the purpose of a clinical trial is not ethical. Due to scientific and logistical limitations with the use of smallpox virus in animal models, the efficacy of TPOXX was established in animal models using related viruses, specifically non-human primates infected with monkeypox virus and rabbits infected with rabbitpox virus. These studies demonstrated improved survival in animals that received TPOXX compared to animals that received placebo.
- There are currently no data demonstrating the effectiveness of TPOXX for the treatment of smallpox or monkeypox in humans. TPOXX has only been tested in healthy human volunteers, without smallpox or monkeypox infection, to assess safety.
- Drugs that are effective in animal studies are not always effective in humans. Conducting randomized, controlled trials to assess TPOXX's safety and efficacy in humans with monkeypox infections is essential.
- As monkeypox was endemic in other parts of the world (e.g., the Democratic Republic of Congo), it was not eligible for approval for the treatment of monkeypox disease under the FDA's Animal Rule regulations because it was both ethical and feasible to conduct clinical trials in humans.
- The [prescribing information](#) contains more information about the drug.

Additional information:

- The [CDC holds an expanded access Investigational New Drug protocol](#), sometimes referred to as "compassionate use", that allows for the use of TPOXX for treatment of monkeypox, and the product is only available from the Strategic National Stockpile. The FDA worked closely with the CDC to streamline the protocol to reduce data collection and reporting requirements. The revised protocol is now available for use.
- Information for healthcare professionals on treatment of monkeypox can be found on the CDC's page: [Treatment Information for Healthcare Professionals](#).

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