

JYNNEOS

STN: 125678

Proper Name: Smallpox and Monkeypox Vaccine, Live, Non-Replicating

Tradename: JYNNEOS

Manufacturer: Bavarian Nordic

Indication:

- 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.

Product Information

- [Package Insert - JYNNEOS \(/media/131078/download\)](#)
- [Demographic Subgroup Information - JYNNEOS \(/media/131870/download\)](#)
Refer to Section 1.1 of the Clinical Review Memo for information about participation in the clinical trials and any analysis of demographic subgroup outcomes that is notable.

Supporting Documents

- [March 16, 2023 Approval Letter - JYNNEOS \(/media/166286/download\)](#)
- [March 14, 2023 Approval Letter - JYNNEOS \(/media/166224/download\)](#)
- [September 2, 2022 Approval Letter - JYNNEOS \(/media/161393/download\)](#)
- [June 16, 2021 Approval Letter - JYNNEOS \(/media/150240/download\)](#)
- [June 7, 2021 Approval Letter - JYNNEOS \(/media/149946/download\)](#)
- [September 24, 2019 Summary Basis for Regulatory Action - JYNNEOS \(/media/131802/download\)](#)
- [September 24, 2019 Approval Letter- JYNNEOS \(/media/131079/download\)](#)
- [Approval History, Letters, Reviews, and Related Documents - JYNNEOS \(/media/131869/download\)](#)