

Neutralizing monoclonal antibody **mAb114** for Ebola virus disease (EVD)



mAb114 is also known by the commercial name Ebanga™ and molecular name ansuvimab.

Guidance for health care workers

Both mAb114 and REGN-EB3 are recommended for use in EVD. The two drugs should not be given together. The choice of which monoclonal antibody to use depends on availability, including emerging information about effectiveness.

CLINICAL INDICATIONS

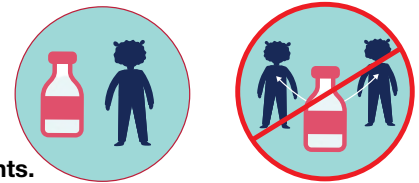
- All patients with RT-PCR confirmed EVD caused by Zaire ebolavirus, including children, pregnant women, breastfeeding women and older people.
- Neonates < 7 days, without EVD RT-PCR confirmation, born to mothers with RT-PCR confirmed EVD.

Patients should receive mAb114 as soon as possible after confirmation of RT-PCR diagnosis of EVD.



AVAILABLE FORMULATION

A vial contains: 400 mg off-white to white lyophilized powder. Upon reconstitution, one vial contains 8 mL of solution, containing 50 mg/mL of **mAb114**.



Note: Each vial is used for only one patient, it must not be used for multiple patients.

STORAGE

Prior to reconstitution

Store refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect from light. Do not freeze. Do not shake.



Expiry

The expiration date for the product is available via a product-specific website which is frequently updated. Access the website using the QR code provided on the product.

After reconstitution

The maximum storage time for reconstituted solution in the vial and the diluted solution in the IV bag is **4 hours**.

- If the infusion is stopped for any reason, it can be restarted on the same patient as long as the time from dilution to restarting and completing the infusion remains within 4 hours.
- If the timeframe has been exceeded the remaining dosage required for the patient should be calculated, new vials prepared, diluted then administered and the excess diluted drug should be safely disposed. Drugs should not be moved from high-risk to low-risk zones for temporary storage.

DOSAGE AND ROUTE

The dose of **mAb114** for adult and paediatric patients is **50 mg/kg (or 1 mL/kg)** reconstituted with sterile water for injection, further diluted and administered as a single intravenous (IV) infusion over 60 minutes.

EXAMPLE: Patient weighting 50 kg

- Recommended dose is 2500 mg mAb114 OR 50 mL of mAb114.
- The dosage requires 7 vials.
- Insert in each of the vials: 7.7 mL of sterile water for injection using a sterile 10-mL syringe and an 18-gauge needle. Holding horizontally, angle the needle down at an approximate 45° angle, above the lyophilized powder. Slowly inject the diluent along the wall of the vial and without any air to avoid foaming and bubbles. Swirl them gently for 10 seconds and leave them to rest for 10 seconds until all the powder is dissolved. Repeat until the powder is dissolved. This may take up to 20 minutes
- The total of the mAb114 vials should be 50 mL and should be added to 50 mL of dilution solution (0.9% sodium chloride or Ringer's lactate) to make a total of 100 mL diluted infusion solution.
- Invert 10 times (do not shake).
- Infuse the 100 mL of diluted infusion solution over 60 minutes.

