Neutralizing monoclonal antibody cocktail REGN-EB3 for Ebola virus disease (EVD)

REGN-EB3 is also known by the commercial name INMAZEB™ and molecular names atoltivimab, maftivimab, odesivimab.

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 REGN-EB3 as soon as possible after confirmation of RT-PCR diagnosis of EVD.

AVAILABLE FORMULATION

A vial of REGN-EB3 (14.5 mL) contains:

- 241.7 mg (16.67 mg per mL) of atoltivimab
- 241.7 mg (16.67 mg per mL) of maftivimab
- 241.7 mg (16.67 mg per mL) of odesivimab.

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

DOSAGE AND ROUTE

The recommended dosage of REGN-EB3 is 150 mg/kg (equivalent to 3 mL/kg):

- 50 mg of atoltivimab per kg
- 50 mg of maftivimab per kg
- 50 mg of odesivimab per kg

Diluted and administered as a single intravenous (IV) infusion.

Volume of REGN-EB3 needed (mL) = body weight (kg) x 3
Number of vials of REGN-EB3 needed = volume of REGN-EB3 / 14.5

STORAGE

Prior to dilution

Store REGN-EB3 vial refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect from light. Do not freeze or shake.

After dilution

The maximum duration between preparation of the diluted REGN-EB3 to completion of administration to the patient depends on the dilution solution used and the storage conditions within the times in table one.

- If the infusion is stopped for any reason, it can be restarted as long as the time from dilution to completing the infusion remains within the time stated in table one.
- 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.

<table>
<thead>
<tr>
<th>Dilution solution</th>
<th>Storage conditions</th>
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</thead>
<tbody>
<tr>
<td>0.9% sodium chloride</td>
<td>Store at room temperature up to 25 °C for no more than 8 hours or refrigerated at 2 °C to 8 °C for no more than 24 hours.</td>
</tr>
<tr>
<td>5% dextrose solution or Ringer's lactate solution</td>
<td>Store at room temperature up to 25 °C for no more than 4 hours or refrigerated at 2 °C to 8 °C for no more than 4 hours.</td>
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</tbody>
</table>

Expiry

The expiration date for the product is available via a product-specific website, which is frequently updated (www.regeneron.com).