Patient Information ENFLONSIA™ (en-flahn-see-ah) (clesrovimab-cfor) injection, for intramuscular use

What is ENFLONSIA?

ENFLONSIA is a prescription medicine to help prevent lung disease, including severe lung disease, caused by Respiratory Syncytial Virus (RSV) in newborns and babies who are born during or entering their first RSV season.

ENFLONSIA contains antibodies to help prevent RSV disease.

It is not known if ENFLONSIA is safe and effective in children older than 12 months of age.

Your child should not receive ENFLONSIA if your child has a history of serious allergic reactions to any of the ingredients in ENFLONSIA. See the end of this Patient Information leaflet for a complete list of ingredients in ENFLONSIA.

Before your child receives ENFLONSIA, tell their healthcare provider about all of your child's medical conditions, including if your child:

• is scheduled to have heart surgery during or entering their first RSV season.

Tell your child's healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How is ENFLONSIA given?

- ENFLONSIA is given as an injection, in the thigh muscle, by your child's healthcare provider.
- Your child should get ENFLONSIA before the start of or during the RSV season. RSV season is the time of year when RSV infections are most common, usually occurring fall through spring. Your child's healthcare provider can tell you when the RSV season starts in your area.
- Your child may still get RSV disease after receiving ENFLONSIA. Talk to your child's healthcare provider about what symptoms to look for.
- If your child has heart surgery, your child's healthcare provider may need to give your child an additional ENFLONSIA injection soon after surgery.
- Your child can get ENFLONSIA at the same time as routine childhood vaccines.

What are the possible side effects of ENFLONSIA?

- Serious allergic reactions have happened with other medicines like ENFLONSIA. Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction, including:
 - swelling of the face, mouth, or tongue
 - o difficulty swallowing or breathing
 - unresponsiveness

- bluish color of skin, lips or under fingernails
- o muscle weakness
- severe rash, hives or itching

The **most common** side effects of ENFLONSIA are:

- redness and swelling at the site of your child's injection
- rash

These are not all the possible side effects of ENFLONSIA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ENFLONSIA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or child's healthcare provider for information about ENFLONSIA that is written for health professionals.

What are the ingredients in ENFLONSIA?

Active ingredient: clesrovimab-cfor

Inactive ingredients: arginine hydrochloride, histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection.

Issued: 06/2025

Manufactured by: Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA. U.S. License No. 0002

For patent information: www.msd.com/research/patent.

Copyright © 2025 Merck & Co., Inc., Rahway, NJ, USA, and its affiliates.

All rights reserved. usppi-mk1654-i-2506r000

For more information, go to www.ENFLONSIA.com or call 1-877-888-4231.

This Patient Information has been approved by the U.S. Food and Drug Administration