Package leaflet: Information for the user

ENFLONSIA® 105 mg solution for injection in pre-filled syringe
clesrovimab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child is given this medicine because it contains important information for you and your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ENFLONSIA is and what it is used for

ENFLONSIA contains the active substance clesrovimab. This is an antibody (a protein that the body uses to fight harmful germs) that helps prevent lung disease caused by *respiratory syncytial virus* (RSV) disease.

It is given to newborns and babies up to 12 months of age who are born during or entering their first RSV season.

RSV season is the time of year when RSV infections are most common, usually occurring autumn through spring of the next year.

RSV is a common respiratory virus that usually causes symptoms similar to the common cold but can also affect the lungs. Signs of RSV infection may include a runny nose, trouble feeding, difficulty breathing, coughing, sneezing, wheezing (whistling sound during breathing) or fever.

Anyone can become infected by RSV. Almost all children get an RSV infection by the time they are 2 years old. While most recover quickly, RSV can cause severe illness including inflammation of the small airways in the lung (bronchiolitis) and infection of the lungs (pneumonia) that may lead to hospitalisation and even death. Children at greatest risk include newborns and babies up to 12 months of age, especially those 6 months and younger, or with medical vulnerabilities, for example being born too soon or with heart or lung problems.

2. What you need to know before your child is given ENFLONSIA

Do not give ENFLONSIA
Your child must not be given ENFLONSIA if they are allergic to clesrovimab or any of the other ingredients of this medicine (listed in section 6).

Tell your child's doctor, pharmacist or nurse about any medical conditions or allergies your child has or had.

Warnings and precautions
Serious allergic reactions may happen with ENFLONSIA. Tell your child's doctor or seek medical care right away if your child has any of the following signs and symptoms of a serious allergic reaction, which may include:

- swelling of the face, mouth, or tongue
- difficulty swallowing or breathing
- unresponsiveness
- blue tint to the colour of skin, lips or under fingernails
- muscle weakness
- severe rash, hives or itching

Talk to your child's healthcare professional before your child is given ENFLONSIA if they have any bleeding problems, bruises easily, or are taking medicines to prevent blood clots.

Children and adolescents
Do not give this medicine to children between the age of 1 and 18 years of age. This is because it has not yet been studied in this group.

Other medicines and ENFLONSIA
Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

ENFLONSIA may be given at the same time as vaccines that are part of the national immunisation programme.

ENFLONSIA contains polysorbate 80
This medicine contains 0.14 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell your doctor if your child has any known allergies.

3. How and when ENFLONSIA is given

ENFLONSIA is given by a healthcare professional as an injection in the muscle. It is usually given in the thigh.

The recommended dose is 105 mg given as a single injection. This is given before the start of or during the RSV season.

Your child's healthcare professional can tell you when the RSV season starts in your area.

If your child is scheduled to have surgery for certain types of heart disease, your child's healthcare professional may need to give your child an additional injection of ENFLONSIA after surgery.

Your child may still get RSV disease after receiving this medicine. Talk to your child's healthcare professional about what signs to look for.

If you have any further questions on the use of this medicine, ask your child's doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your child's doctor, pharmacist or nurse if your child has any of the following side effects:

Common (may affect up to 1 in 10 children)
- pain, redness (erythema), or swelling where your child got the injection
- rash

Uncommon (may affect up to 1 in 100 children)
- red, itchy swollen bumps on the skin; also called hives

Reporting of side effects
If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ENFLONSIA

Your child's doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

Keep this medicine out of reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. After removal from the refrigerator, the medicine must be used within 48 hours or discarded.

Keep the pre-filled syringe in the outer carton in order to protect from light.
Do not shake.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What ENFLONSIA contains
- The active substance is clesrovimab. One pre-filled syringe of 0.7 mL contains 105 mg of clesrovimab.
- The other ingredients are histidine, histidine hydrochloride monohydrate, arginine hydrochloride, sucrose, polysorbate 80 (E433) (see section 2 "ENFLONSIA contains polysorbate 80") and water for injections.

What ENFLONSIA looks like and contents of the pack
ENFLONSIA is a clear to slightly opalescent, colourless to slightly yellow solution for injection.

ENFLONSIA is available in the following pack sizes:
- 1 pre-filled syringe
- 1 pre-filled syringe + 1 needle
- 1 pre-filled syringe + 2 needles
- 10 pre-filled syringes
- 10 pre-filled syringes + 10 needles
- 10 pre-filled syringes + 20 needles
- Multipacks comprising 5 cartons, each containing 10 pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, United Kingdom

Manufacturer:
Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

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New MAA

The following information is intended for healthcare professionals only:

- Before injection, remove the carton from the refrigerator and allow the pre-filled syringe to come to room temperature for approximately 15 minutes.
- Visually inspect the medicinal product for particulate matter and discolouration. The medicinal product is a clear to slightly opalescent, colourless to slightly yellow solution. It should not be used if particulate matter or discolouration is found.
- Do not use ENFLONSIA if the pre-filled syringe has been dropped or damaged, the security seal on the carton has been broken, or the expiry date has passed.
- Hold the syringe barrel in one hand to unscrew the tip cap by twisting it counter-clockwise with the other hand. Do not remove the Luer lock adaptor or the finger flange extender.
- Attach a sterile Luer lock needle by twisting in a clockwise direction until the needle fits securely on the pre-filled syringe. If not provided, due to the viscosity of the medicinal product, use a 25 gauge or larger needle.
- Inject the entire contents of the pre-filled syringe intramuscularly in the anterolateral aspect of the thigh. The medicinal product should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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