

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor, nurse or pharmacist.

▼ This medicine is new. Please report side effects that you may experience with this medicine. See the [full CMI](#) for further details.

1. Why is my child being given ENFLONSIA?

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

For more information, see Section [1. Why is my child being given ENFLONSIA?](#) in the full CMI.

2. What should I know before my child is given ENFLONSIA?

Your child should not be given ENFLONSIA if they have had a serious allergic reaction to any of the ingredients in ENFLONSIA.

Talk to your child's doctor if your child has any other medical conditions or any allergies or takes any other medicines.

For more information, see Section [2. What should I know before my child is given ENFLONSIA?](#) in the full CMI.

3. What if my child is taking other medicines?

Your child can get ENFLONSIA at the same time as routine childhood vaccines.

For more information, see Section [3. What if my child is taking other medicines?](#) in the full CMI.

4. How is ENFLONSIA given?

ENFLONSIA is given as an injection, usually in the thigh muscle, by your child's healthcare provider.

More instructions can be found in Section [4. How is ENFLONSIA given?](#) in the full CMI.

5. What should I know after my child is given ENFLONSIA?

Things you should do	• Remind any doctor, nurse or pharmacist you visit that your child has been given ENFLONSIA. • Tell your child's doctor and seek medical care right away if your child has any signs or symptoms of a serious allergic reaction, as these reactions have happened with other medicines like ENFLONSIA. Signs and symptoms of serious allergic reactions may include: • Swelling of face, mouth or tongue • Difficulty swallowing or breathing • Unresponsiveness • Bluish color of skin, lips or under fingernails • Muscle weakness • Severe rash, hives or itching • Your child may still get RSV disease after receiving ENFLONSIA. Talk to your child's healthcare provider about what symptoms to look for.
Looking after your medicine	• It is unlikely that you will be asked to store ENFLONSIA. If you are, follow the instructions in the carton on how to take care of your medicine properly. • Keep it where young children cannot reach it.

For more information, see Section [5. What should I know after my child is given ENFLONSIA?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are redness and swelling where your child got the injection, and rash.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ENFLONSIA

Clesrovimab

Consumer Medicine Information (CMI)

This leaflet provides important information about getting ENFLONSIA. **You should also speak to your child's doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about being given ENFLONSIA.**

Where to find information in this leaflet:

1. [Why is my child being given ENFLONSIA ?](#)
2. [What should I know before my child is given ENFLONSIA ?](#)
3. [What if my child is taking other medicines?](#)
4. [How is ENFLONSIA given?](#)
5. [What should I know after my child is given ENFLONSIA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why is my child being given ENFLONSIA?

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

RSV season is the time of year when RSV infections are most common, with peak cases usually occurring between autumn and winter. RSV infection can lead to serious lung disease.

ENFLONSIA contains antibodies (proteins the body uses to fight harmful germs) to help prevent RSV disease.

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

Anyone can become infected by RSV and 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 bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs) that may lead to hospitalization and even death. Children at greatest risk include newborns and babies up to 12 months of age, especially those 6 months and younger, or those with heart or lung problems.

2. What should I know before my child is given ENFLONSIA?

Warnings

Your child should not be given ENFLONSIA if they:

- Have had a serious allergic reaction to any of the ingredients in ENFLONSIA.
- Always check the ingredients listed at the end of this leaflet to make sure your child can be given this medicine.

Tell your child's healthcare provider:

- If your child has a low number of blood platelets (which help blood clotting), a bleeding problem or bruises easily, or is taking a medicine to prevent blood clots (anticoagulant).
- About any medical conditions or allergies your child has or had.
- Any medicine your child is given for any other condition.

After being given ENFLONSIA, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

ENFLONSIA is a medicine for newborns and babies and should not be given to females who could become pregnant or are breast-feeding.

Children

It has not yet been established if ENFLONSIA can be used in children who are older than 12 months of age.

3. What if my child is taking other medicines?

Your child can be given ENFLONSIA at the same time as routine childhood vaccines.

Tell your child's doctor, nurse or pharmacist if your child is taking, has recently taken or might take any other vaccines or medicines, including any medicines, vitamins or supplements (including herbal supplements) that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect ENFLONSIA.

4. How is ENFLONSIA given?

How will my child be given ENFLONSIA?

ENFLONSIA is given as an injection, usually in the thigh muscle, by your child's healthcare provider.

When will my child be given ENFLONSIA?

- Your child should be given ENFLONSIA before the start of or during the RSV season.
- Your child's healthcare provider can tell you when the RSV season starts in your area.
- If your child has surgery for certain types of heart disease, your child's healthcare provider may need to give your child an additional ENFLONSIA injection after surgery.

5. What should I know after my child is given ENFLONSIA?

Things you should do

Call your doctor straight away, and seek medical help immediately, if you notice any signs or symptoms of a serious allergic reaction such as:

- swelling of the face, mouth or tongue
- difficulty swallowing or breathing
- unresponsiveness
- bluish color of skin, lips or under fingernails
- muscle weakness
- severe rash, hives, or itching

Serious allergic reactions have happened with other medicines like ENFLONSIA. Remind any doctor, nurse or pharmacist you visit that your child has been given ENFLONSIA.

Your child may still get RSV disease after receiving ENFLONSIA. Talk to your child's healthcare provider about what symptoms to look for.

Looking after your medicine

It is unlikely that you will be asked to store ENFLONSIA. If you are, follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your child's doctor, nurse or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Skin: • Redness and swelling where your child got the injection • Rash	Speak to your doctor if you have any of these less serious side effects and they worry you.

Tell your child's doctor, nurse or pharmacist if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some children.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

This medicine is only available with a doctor's prescription.

What ENFLONSIA contains

Active ingredient (main ingredient)	clesrovimab 105 mg
Other ingredients	arginine hydrochloride histidine histidine hydrochloride monohydrate polysorbate 80 sucrose water for injections

ENFLONSIA does not contain any preservatives.

Your child should not be given this medicine if they are allergic to any of these ingredients.

What ENFLONSIA looks like

ENFLONSIA is a colourless to slightly yellow, clear to slightly opalescent solution for injection.

ENFLONSIA is available as a prefilled syringe for intramuscular injection.

AUST R 478965

Who distributes ENFLONSIA

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113

CCPPI-MK1654-I-102024

RCN: 000027481-AU

CCPPI-MK1654-122025

RCN: 000028784

This leaflet was prepared in March 2026.

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