

# AMGEVITA<sup>®</sup> (adalimumab)

Tumour Necrosis Factor alpha (TNF  $\alpha$ )  
blocker

## Patient Reminder Card for your child

This card has important safety information about AMGEVITA. Please be sure to:

- Show this card to all of your child's doctors and other healthcare providers. This is so they know your child is taking AMGEVITA.
- Keep this card with you at all times while your child is taking AMGEVITA and for 5 months after your child's last injection of AMGEVITA.
- In the notes section on the back of this card, write down information about any tuberculosis tests or treatment your child has had.

It is important to know that the possible side effects listed on this card are not the only possible side effects of AMGEVITA. For more comprehensive information, please read the AMGEVITA package leaflet given to you by your doctor or available on [www.medicines.ie](http://www.medicines.ie), or talk with your child's doctor.

## What is AMGEVITA?

The immune system normally protects the body from infection, but in some disease states (autoimmune diseases) this system doesn't work the way it should. AMGEVITA is a medicine that is used to treat certain autoimmune diseases. The purpose of this card is to provide information to you and your child's doctors about the safety issues associated with this medication.

Side effects that could happen with AMGEVITA include:

- Infections (including tuberculosis)
- Cancer
- Problems with your child's nervous system

These are not all of the possible side effects of AMGEVITA. In addition, certain vaccines may cause infections and should not be given while receiving AMGEVITA. Please check with your child's doctor before your child receives any vaccines.

## What should I know before my child starts treatment with AMGEVITA?

The benefits and risks of taking AMGEVITA vary from person to person. Before your child starts treatment with AMGEVITA, you should talk with his or her doctor about the benefits and risks for your child. Before your child starts treatment, you should tell his or her doctor:

- About any health problems your child has
- About any medicines your child takes (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
- If your child:
  - Has an infection or symptoms of an infection (such as fever, non-healing sores, wounds, feeling tired, dental problems)
  - Has tuberculosis currently or has had it in the past or has been in close contact with someone who has tuberculosis
  - Has cancer or has had it in the past
  - Ever feels any numbness or tingling
  - Has a problem that affects his or her nervous system, such as multiple sclerosis

*(continued)*



- Resides or travels in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic

Your doctor will check your child for signs and symptoms of tuberculosis before starting treatment with AMGEVITA. This will include a medical evaluation including medical history and appropriate screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on this card. Your child may need to be treated for tuberculosis before he/she starts treatment with AMGEVITA.

## **Vaccination advice**

Certain vaccines may cause infections and should not be given while receiving AMGEVITA. Please check with your child's doctor before your child receives any vaccines. It is recommended that children, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating AMGEVITA therapy. If your daughter received AMGEVITA while pregnant, her baby may be at higher risk for getting such an infection for up to approximately five months after the last dose she received during pregnancy. It is important that you tell the baby's doctors and other health care professionals about your daughter's AMGEVITA use during her pregnancy so they can decide when the baby should receive any vaccine.

## What should I do during my child's treatment with AMGEVITA?

During your child's treatment, you should:

- Tell your doctor if AMGEVITA is working.
- **Call your doctor right away about any side effects your child has.** Your child's doctor can help you try to manage them.
  - If your child does have a side effect, his or her doctor will decide if your child should keep taking AMGEVITA.
- Tell your doctor about any side effects your child has up to 4 months after the last injection of AMGEVITA. This is because side effects can happen after the last dose of AMGEVITA.
- Tell your child's doctor about:
  - Any new medical conditions that your child has
  - New medicines your child is taking (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
  - Any surgery or operation that your child is having

Some people taking AMGEVITA may get serious side effects. Some of the serious side effects are shown in the box below. Note that these are not the only possible side effects that might occur. Please read the AMGEVITA package leaflet for more information. Tell your child's doctor right away if your child has side effects during treatment with AMGEVITA. Your child's doctor may be able to help manage the side effects and stop them from getting worse.

**Infections** — People treated with AMGEVITA are more likely to get infections and, when they do, the infections are more severe. This risk of getting an infection may increase if your child's lung function is impaired. Some of these infections are relatively minor, such as a common cold. Others are more serious and potentially fatal, such as tuberculosis.

---

**Cancer** — The risk of getting certain types of cancer may be higher in people treated with AMGEVITA.

If your child takes AMGEVITA, the risk of getting lymphoma (a cancer that affects the lymph system), leukaemia (a cancer that affects the blood and bone marrow) or other cancers may increase.

*(continued)* 

On rare occasions, a specific and severe type of lymphoma has been observed in patients taking adalimumab. Some of those patients were also treated with azathioprine or 6-mercaptopurine. There have been cases of cancers, other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If your child has COPD, or is a heavy smoker, you should discuss with your child's doctor whether treatment with a TNF blocker is appropriate for your child. Cases of non-melanoma skin cancer have been observed in patients taking adalimumab.

---

**Nervous system problems** — Some people treated with AMGEVITA can develop new or worsening nervous system problems like multiple sclerosis.

Call your child's doctor or get medical care right away if your child has any of the following symptoms that might indicate serious side effects. These are not all of the possible symptoms of side effects. Tell your child's doctor right away if your child feels anything unusual during treatment with AMGEVITA. Your child's doctor may be able to help manage symptoms of side effects and stop them from getting worse.

*(continued)* 

### ***Infection:***

- Fever
- Chills
- Unusual sweating
- Feeling unwell or feeling more tired than normal
- Throwing up (vomiting) or feeling like he or she is going to throw up (nausea)
- Diarrhea
- Stomach pain
- Not feeling hungry the way he or she usually does (loss of appetite)
- Losing weight
- Coughing or coughing up blood or mucus
- Feeling like he or she can't catch his or her breath (shortness of breath)
- Problems peeing (urinating)
- Sores on his or her skin
- Nonhealing sores and wounds on his or her skin
- Sore muscles
- Problems with his or her teeth or gums

---

### ***Cancer:***

- Night sweats
- Swollen glands in his or her neck, armpits, groin, or other areas
- Weight loss
- New skin lesions or a change in skin lesions (such as moles or freckles) he or she already had
- Severe itchiness

---

### ***Nervous system***

- Feeling numbness or tingling anywhere in his or her body
- Changes in vision
- Muscle weakness
- Dizziness



## Patient information

Your child's name: \_\_\_\_\_

Your child's doctor's name: \_\_\_\_\_

Your child's doctor's telephone number: \_\_\_\_\_

Date of your child's first AMGEVITA injection: \_\_\_\_\_

Date of your child's last AMGEVITA injection  
if their treatment has finished: \_\_\_\_\_



## Tuberculosis tests and treatment

Date of your child's last tuberculosis test: \_\_\_\_\_

Has your child ever tested positive for tuberculosis?

Yes  No

Did your child receive treatment for having a positive  
tuberculosis test?

Yes  No

How long was your child treated  
for tuberculosis? \_\_\_\_\_

**AMGEN**<sup>®</sup>



## Information about any tuberculosis tests or treatment my child has had:

---

---

---

---

---

### **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 card. You can also report side effects directly via the HPRA Pharmacovigilance.

website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.