

AMGEVITA[®] ▼ (adalimumab)

Patient Alert 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 healthcare providers (HCPs). 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 4 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 side effects of AMGEVITA. For more comprehensive information, please read the AMGEVITA patient information leaflet (PIL) given to you by your doctor or available on www.medicines.org.uk, or talk with your child's HCP.

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, such as rheumatoid arthritis and psoriasis. The purpose of this card is to provide information to you and your child's HCPs about the safety issues associated with this medication.

Side effects that could happen with AMGEVITA include:

- Infections
- Heart failure
- Cancer
- Problems with your child's nervous system

These are not all of the possible side effects of AMGEVITA.

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 HCP about the benefits and risks for your child.

Before your child starts treatment, you should tell his or her HCP:

- 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, nonhealing 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 a serious heart condition or heart failure currently or has had it in the past
 - Has cancer or has had it in the past
 - Ever felt any numbness or tingling
 - Has a problem that affects his or her nervous system, such as multiple sclerosis

Your child's HCP will check your child for signs and symptoms of tuberculosis before starting treatment with AMGEVITA. He or she may need to be treated for tuberculosis before starting treatment.

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

During your child's treatment, you should:

- Tell your HCP if AMGEVITA is working.
- **Call your HCP right away about any side effects your child has.** Your child's HCP can help you try to manage them.
 - If your child does have a side effect, his or her HCP will decide if your child should keep taking AMGEVITA.
- Tell your HCP about any side effects your child has for 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 HCP 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 side effects that might occur. Please read the AMGEVITA PIL for more information. Tell your child's HCP right away if your child has side effects during treatment with AMGEVITA. Your child's HCP 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. Some of these infections are relatively minor, such as a common cold. Others are more serious and potentially fatal, such as tuberculosis.

Heart failure — Some people can develop heart failure when treated with AMGEVITA. For some people who already have heart failure, it can get worse upon using AMGEVITA.

Cancer — The risk for getting certain types of cancer is higher in people treated with AMGEVITA.

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

Call your child's HCP 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 HCP right away if your child feels anything unusual during treatment with AMGEVITA. Your child's HCP 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
-

Heart failure:

- Feeling like he or she can't catch his or her breath (shortness of breath)
 - Swelling of his or her ankles or feet
 - Rapid weight gain
-

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 problems:

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



Patient information card

Your child's name: _____

Your child's HCP's name: _____

Your child's HCP's telephone number: _____

Name of the condition your child is being treated for:

Date of your child's first AMGEVITA injection: _____

Date of your child's last AMGEVITA injection

if treatment has finished: _____

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? _____



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



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. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

See www.mhra.gov.uk/yellowcard for how to report side effects. By reporting side effects you can help provide more information on the safety of this medicine.