

AMGEVITA[®] ▼ (adalimumab)

Patient Alert Card

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

- Show this card to all of your healthcare providers (HCPs). This is so they know you are taking AMGEVITA.
- Keep this card with you at all times while you are taking AMGEVITA and for 4 months after your last injection of AMGEVITA.
- In the notes section on the back of this card, write down information about any tuberculosis tests or treatment you have 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 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 HCPs about the safety issues associated with this medication.

Side effects that could happen with AMGEVITA include:

- Infections
- Heart failure
- Cancer
- Problems with your nervous system

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

What should I know before I start treatment with AMGEVITA?

The benefits and risks of taking AMGEVITA vary from person to person. Before starting treatment with AMGEVITA, you should talk with your HCP about the benefits and risks for you.

Before starting treatment, you should tell your HCP:

- About any health problems you have
- About any medicines you take (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
- If you:
 - Have an infection or symptoms of an infection (such as fever, nonhealing sores, wounds, feeling tired, dental problems)
 - Have tuberculosis currently or have had it in the past or have been in close contact with someone who has tuberculosis
 - Have a serious heart condition or heart failure or have had it in the past
 - Have cancer or have had it in the past
 - Ever felt any numbness or tingling
 - Have a problem that affects your nervous system, such as multiple sclerosis

Your HCP will check you for signs and symptoms of tuberculosis before you start treatment with AMGEVITA. You may need to be treated for tuberculosis before you start treatment.

What should I do during my treatment with AMGEVITA?

During your treatment, you should:

- Tell your HCP if AMGEVITA is working for you.
- **Call your HCP right away about any side effects you have.**
Your HCP can help you try to manage them.
 - If you do have a side effect, your HCP will decide if you should keep taking AMGEVITA.
- Tell your HCP about any side effects you have for up to 4 months after your last injection of AMGEVITA. This is because side effects can happen after your last dose of AMGEVITA.
- Tell your HCP about:
 - Any new medical conditions that you have
 - New medicines you are taking (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
 - Any surgery or operation that you are 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 HCP right away if you have side effects during treatment with AMGEVITA. Your HCP may be able to help you 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 HCP or get medical care right away if you have any of the following symptoms that might indicate serious side effects. These are not all of the possible symptoms of side effects. Tell your HCP right away if you feel anything unusual during treatment with AMGEVITA. Your HCP may be able to help you 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 you're going to throw up (nausea)
 - Diarrhea
 - Stomach pain
 - Not feeling hungry the way you usually do (loss of appetite)
 - Losing weight
 - Coughing or coughing up blood or mucus
 - Feeling like you can't catch your breath (shortness of breath)
 - Problems peeing (urinating)
 - Sores on your skin
 - Nonhealing sores and wounds on your skin
 - Sore muscles
 - Problems with your teeth or gums
-

Heart failure:

- Feeling like you can't catch your breath (shortness of breath)
 - Swelling of your ankles or feet
 - Rapid weight gain
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Cancer:

- Night sweats
 - Swollen glands in your neck, armpits, groin, or other areas
 - Weight loss
 - New skin lesions or a change in skin lesions (such as moles or freckles) you already have
 - Severe itchiness
-

Nervous system problems:

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



Patient information card

Your name: _____

Your doctor's name: _____

Your doctor's telephone number: _____

Name of the condition you are being treated for:

Date of your first AMGEVITA injection: _____

Date of your last AMGEVITA injection

if treatment has finished: _____

Date of your last tuberculosis test: _____

Have you ever tested positive for tuberculosis?

Yes No

Did you receive treatment for having a positive tuberculosis test?

Yes No

How long were you treated for tuberculosis? _____



Information about any tuberculosis tests or treatment you have 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.