



Reminder Leaflet for AMGEVITA®

The purpose of this leaflet is to remind you and your healthcare providers (HCPs) about the safety issues associated with AMGEVITA.

This leaflet does not list all of the possible side effects of this medicine. Please read the AMGEVITA Consumer Medicine Information (CMI) or talk with your HCP for more information.

Please be sure to:

- Show this leaflet to all of your HCPs, such as your GP, specialist, nurse and/or pharmacist. This is so they know you are taking AMGEVITA.
- Keep this leaflet with you at all times while you are taking AMGEVITA and for 4 months after your last injection of AMGEVITA.
- Write down information about any tuberculosis (TB) tests or treatment you may have had in the notes section available on this leaflet.

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 (RA) and psoriasis (PsO).

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 have discussed with your HCP the benefits and risks for you.

Before you start 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 herbal supplements).
- **If you have:**
 - An infection or symptoms of an infection (such as fever, nonhealing sores, wounds, feeling tired, dental problems).
 - TB, or if you have been in close contact with someone who has had it.
 - Any type of cancer or have had it in the past.
 - Multiple sclerosis (MS) or other demyelinating diseases (conditions that affect the insulating layer around nerves).

As cases of TB have been reported in patients treated with AMGEVITA, your HCP will check you for signs and symptoms before starting this medicine. TB can develop during therapy even if you have received treatment for the prevention of TB.

Vaccination advice

Check with your HCP before you receive any vaccines. Patients receiving AMGEVITA should not receive live vaccines (for example, BCG or oral polio vaccine).

Pregnancy information: If you use this medicine during pregnancy, your baby may have a higher risk of getting an infection. Tell your baby's HCP that you used this medicine during your pregnancy and before your newborn baby receives any vaccine. If you become pregnant while using AMGEVITA, tell your HCP immediately.

What should I do during my treatment with AMGEVITA?

During your treatment, you should tell your HCP:

- **If AMGEVITA is not working for you.**
- **About any side effects that you have:**
 - All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.
 - There have been cases of certain kinds of cancer in patients using AMGEVITA or similar medicines.
- **About any:**
 - New medical conditions that you have.
 - New medicines you take (including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements).
 - Surgery you have planned.

Are there any side effects of treatment?

Some people taking AMGEVITA may get serious side effects.

Some of the serious side effects are shown in the boxes below. Other side effects not listed may occur in some people.

Please read the AMGEVITA CMI for more information, available at www.medsafe.govt.nz.

Infections - You might get infections more easily while you are receiving AMGEVITA treatment. These infections may be serious, such as TB. Your HCP may recommend you discontinue AMGEVITA if you develop an infection.

Cancer - There have been cases of certain kinds of cancer in patients using AMGEVITA or similar medicines. People with more serious RA that have had the disease for a long time may have a higher chance of getting a kind of cancer that affects the lymph system, called lymphoma, or that affects the blood, called leukaemia. If you take AMGEVITA your risk may increase.

Nervous system problems - Some people treated with AMGEVITA can develop nervous system problems like MS.

Tell your HCP as soon as possible if you do not feel well while you are taking AMGEVITA or if you have any other problems using it.

Do this even if you do not think the problems are connected to the medicine or are not listed in this leaflet.

Call your HCP or get medical care right away if you have any of the following symptoms that might indicate serious side effects.

Infection:

- Fever
- Wounds
- Burning on urination
- A bump or open sore that doesn't heal
- Dental problems
- Persistent cough
- Weight loss
- Listlessness (lack of energy).

Cancer:

- Appearance of new skin lesions or if existing lesions change appearance.

Nervous system problems:

- Numbness or tingling throughout your body
- Arm or leg weakness
- Problems with vision.

These are not all of the possible symptoms of side effects. Please read the full CMI for a list of all the possible side effects of AMGEVITA.

 **Tuberculosis tests and treatment**

Date of your last TB test: _____

Have you ever tested positive for TB?

Yes No

Did you receive treatment for having a positive TB test?

Yes No

How long were you treated for TB? _____

 **Information about any TB tests or treatment you have had:**

For more information on AMGEVITA, to report any side effects involving AMGEVITA or to request additional copies of this material please contact Amgen Medical Information on **0800 443 885** or email **medinfo.JAPAC@amgen.com**

AMGEVITA® (adalimumab) is a Prescription Medicine available as a pre-filled syringe or single-use pre-filled pen and may contain 20 mg or 40 mg of adalimumab.

Ask your doctor if AMGEVITA is right for you. Use strictly as directed. AMGEVITA has risks and benefits. Please read the safety information in the AMGEVITA Consumer Medicines Information (CMI), available at www.medsafe.govt.nz/Consumers/cmi/a/amgevita.pdf or telephone 0800 443 885 (free call). If you have any questions about using AMGEVITA, or if symptoms continue, or you have side effects, speak to your healthcare professional.

AMGEVITA is a fully funded medicine under Special Authority for most indications - normal pharmacy prescription charges apply. AMGEVITA is not funded for enthesitis-related arthritis and non-radiographic axial spondyloarthritis. Normal pharmacy and doctor's charges will apply.

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