



AMGEVITA® Reminder Leaflet for your Child

The purpose of this leaflet is to remind you and your child's 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 child's HCP for more information.

Please be sure to:

- Show this leaflet to all of your child's HCPs. This is so they know your child is taking AMGEVITA.
- Keep this leaflet with you at all times while your child is taking AMGEVITA and for 4 months after your child's last injection of AMGEVITA.
- Write down information about any tuberculosis (TB) tests or treatment your child 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 juvenile idiopathic arthritis (JIA) and psoriasis (PsO).

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 started treatment with AMGEVITA, you should have discussed with their HCP the benefits and risks for your child.

Before your child starts treatment, you should tell their HCP:

- About any health problems your child has.
- About any medicines your child takes (including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements).
- **If your child has:**
 - An infection or symptoms of an infection (such as fever, nonhealing sores, wounds, feeling tired, dental problems).
 - TB, or has been in close contact with someone who has had it.
 - Any type of cancer or has had it in the past.
 - A problem that affects their nervous system, such as multiple sclerosis (MS).

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

Vaccination advice

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

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

During your child's treatment, you should tell your child's HCP:

- **If AMGEVITA is not working for them.**
- **About any side effects that your child has:**
 - All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. Your child may need medical attention if they experience any side effects.
- **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 herbal supplements).
 - Surgery that your child is having soon.

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. **Note** that these are not the only possible side effects that might occur.

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

Infections - People on AMGEVITA might get infections more easily while receiving treatment. These infections may be serious, such as TB. Your HCP may recommend your child discontinues AMGEVITA if they 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 your child takes AMGEVITA their risk may increase.

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

Tell your child's HCP as soon as possible if your child doesn't feel well while taking AMGEVITA or if they 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 child's HCP or get medical care right away if your child has 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 the 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 child's last TB test: _____

Has your child ever tested positive for TB?

Yes No

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

Yes No

How long was your child treated for TB? _____

 **Information about any TB tests or treatment my child has 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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NZL-501-0923-80010. TAPS MR9747.

Date of preparation: November 2023. AMG11695.

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