

AMGEVITA[®]

(adalimumab injection)

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 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 possible side effects of AMGEVITA. For more comprehensive information, please read the AMGEVITA Patient Medication Information Leaflet that comes with the medication or talk with your child's HCP.

This material was developed by Amgen Canada Inc. as part of the risk minimization plan for AMGEVITA. This material is not intended for promotional use.



WHAT IS AMGEVITA?

AMGEVITA is a biosimilar biologic drug (biosimilar) to the reference biologic drug HUMIRA®.

AMGEVITA is a medicine that is used in children 2 years of age and older who have polyarticular juvenile idiopathic arthritis, children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments, adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa who have not responded to antibiotics, or in children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

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

Serious side effects that could happen with AMGEVITA include:

- Serious infections
- 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?

Like all medicines that affect the immune system, AMGEVITA can cause serious side effects. Before your child starts treatment with AMGEVITA you should talk with his or her HCP about the possible benefits and possible side effects, including serious side effects, of taking AMGEVITA. These can vary from person to person.

Before starting treatment with AMGEVITA, you should talk with his or her HCP about this therapy and any questions or concerns you may have.

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, minerals, natural supplements or alternative medicines)
- If your child:
 - Has an allergy to any of the ingredients in AMGEVITA
 - 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 cancer or has had it in the past
 - Ever feels any numbness or tingling
 - Has a problem that affects his or her nervous system or eyes, such as multiple sclerosis, Guillain-Barré syndrome, optic neuritis, or intermediate uveitis.
 - Has or have had liver disease, hepatitis B infection, or heart failure

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 you start treatment.

VACCINATION ADVICE

Tell your HCP if your child is scheduled to be vaccinated for anything. You may receive vaccinations except for live vaccines. It is recommended that pediatric Crohn's disease patients, if possible, be brought up to date with all immunizations according to current guidelines before starting AMGEVITA.

If your child receives AMGEVITA whilst pregnant, tell the infant's HCP before the infant receives any vaccination. It is not recommended to give live vaccines, such as BCG vaccine (usually given to prevent tuberculosis), to infants exposed to AMGEVITA in the womb until 5 months after the mother's last dose of AMGEVITA during her pregnancy. Other examples of live vaccines include vaccines used to protect against measles, mumps, rubella, and chickenpox. Always obtain advice from your HCP before any vaccination.

WHAT SHOULD I DO DURING MY CHILD'S TREATMENT WITH AMGEVITA?

During your child's treatment, you should:

- Keep your HCP informed about how your child is doing on AMGEVITA.
- **Call your HCP right away about any side effects your child may have.**
 - If your child gets a side effect, his or her HCP will decide if your child should continue or stop his or her AMGEVITA treatment. It is important to talk with your child's HCP to find out what is appropriate for your child.
- Tell your HCP 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 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, minerals, natural supplements or alternative medicines)
 - Any surgery or dental procedure 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 Patient Medication Information for more information. Tell your child's HCP right away if your child has side effects during treatment with AMGEVITA.

Serious infections - People treated with AMGEVITA are more likely to develop infections and, when they do, the infections are more severe. There have been rare cases where patients taking adalimumab or other tumour necrosis factor (TNF)-blocking agents have developed serious infections. Some of these cases have been life-threatening, such as tuberculosis.

Cancer - The risk of getting certain types of cancer may be 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. If your child gets a side effect, his or her HCP will decide if your child should continue or stop his or her AMGEVITA treatment. It is important to talk with your child's HCP to find out what is appropriate for your child.

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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

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

 **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? _____

PATIENT INFORMATION

Your child's name: _____

Name of your child's HCP:
(who prescribed AMGEVITA): _____

Your child's HCP's telephone number: _____

Dose of your child's AMGEVITA injection: _____

Date of your child's first AMGEVITA injection: _____

Date of your last AMGEVITA injection
if you are no longer taking AMGEVITA: _____



INFORMATION ABOUT ANY TUBERCULOSIS TESTS OR TREATMENT YOUR CHILD HAS HAD:

Version 3.0

March 2022

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