AMGEVITA® (adalimumab)

Tumour Necrosis Factor alpha (TNF α) blocker

Patient Reminder Card

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

- Show this card to all of your doctors and other healthcare providers. This is so they know you are taking AMGEVITA.
- Keep this card with you at all times while you are taking AMGEVITA and for 5 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 possible side effects of AMGEVITA. For more comprehensive information, please read the AMGEVITA package leaflet given to you by your doctor or available on www.medicines.ie, or talk with your doctor.

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

Side effects that could happen with AMGEVITA include:

- Infections (including tuberculosis)
- Cancer
- Problems with your nervous system

These are not all of the possible side effects of AMGEVITA. In addition, certain vaccines may cause infections and should not be given while receiving AMGEVITA. Please check with your doctor before you receive any vaccines.

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 doctor about the benefits and risks for you.

Before starting treatment, you should tell your doctor:

- 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, non-healing 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 cancer or have had it in the past
  - Ever feel any numbness or tingling
  - Have a problem that affects your nervous system, such as multiple sclerosis

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- Reside or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic

Your doctor will check you for signs and symptoms of tuberculosis before you start treatment with AMGEVITA. This will include a medical evaluation including your medical history and appropriate screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on this card. You may need to be treated for tuberculosis before you start treatment with AMGEVITA.

Vaccination advice

Certain vaccines may cause infections and should not be given while receiving AMGEVITA. Please check with your doctor before you receive any vaccines. If you received AMGEVITA while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your AMGEVITA use during your pregnancy so they can decide when your baby should receive any vaccine.

What should I do during my treatment with AMGEVITA?

During your treatment, you should:

- Tell your doctor if AMGEVITA is working for you.
- **Call your doctor right away about any side effects you have.** Your doctor can help you try to manage them.
  - If you do have a side effect, your doctor will decide if you should keep taking AMGEVITA.
- Tell your doctor about any side effects you have 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 doctor 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 possible side effects that might occur. Please read the AMGEVITA package leaflet for more information. Tell your doctor right away if you have side effects during treatment with AMGEVITA. Your doctor 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. This risk of getting an infection may increase if your lung function is impaired. Some of these infections are relatively minor, such as a common cold. Others are more serious and potentially fatal, such as tuberculosis.

Cancer — The risk of getting certain types of cancer may be higher in people treated with AMGEVITA.
If you take AMGEVITA, the risk of getting lymphoma (a cancer that affects the lymph system), leukaemia (a cancer that affects the blood and bone marrow) or other cancers may increase.

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On rare occasions, a specific and severe type of lymphoma has been observed in patients taking adalimumab. Some of those patients were also treated with azathioprine or 6-mercaptopurine. There have been cases of cancers, other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you. Cases of non-melanoma skin cancer have been observed in patients taking adalimumab.

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

Call your doctor 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 doctor right away if you feel anything unusual during treatment with AMGEVITA. Your doctor may be able to help you manage symptoms of side effects and stop them from getting worse.

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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

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

Patient information

Your name: _____

Your doctor's name: _____

Your doctor's telephone number: _____

Date of your first AMGEVITA injection: _____

Date of your last AMGEVITA injection
if your treatment has finished: _____

Tuberculosis tests and treatment

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? _____

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Information about any tuberculosis tests or treatment you have had:

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this card. You can also report side effects directly via the HPRA Pharmacovigilance.

website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.