

MEDICATION GUIDE
AMEVIVE® (Am-ah-veev)
(alefacept)
for injection

Read this Medication Guide before your first treatment with AMEVIVE and if your doctor tells you that there is new information about AMEVIVE. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about AMEVIVE?

AMEVIVE can increase your risk of having serious side effects, including:

1. Cancers: AMEVIVE may decrease the activity of your immune system and increase your risk for certain types of cancer. Before receiving AMEVIVE, tell your doctor if you have ever had any type of cancer.

2. Serious Infections:

AMEVIVE lowers the number of certain white blood cells in your body. This can affect the ability of your immune system to fight infections and can increase your risk of getting serious infections. Some people get serious infections while receiving AMEVIVE, including infections caused by bacteria, fungi, or viruses. These infections may happen in your skin or a wound, lungs (pneumonia), stomach or intestine, gallbladder, or may spread throughout your body. Some people have to be treated in the hospital for their infection.

- Your doctor will do a blood test before you start receiving AMEVIVE and every 2 weeks during treatment to check your white blood cell counts.
- If your white blood cell counts are too low, your doctor will check your blood weekly. Your doctor may need to either delay or stop your treatment with AMEVIVE if your blood counts are too low.

You should not receive AMEVIVE if you have any kind of infection, unless your doctor says it is okay.

Before starting AMEVIVE, tell your doctor if you think you have an infection or have symptoms of an infection such as:

- swollen glands
- fever, sweats or chills
- cough
- muscle aches
- shortness of breath
- blood in your phlegm
- warm, red, or painful skin or sores on your body
- burning when you urinate or urinate more often than normal
- feel very tired
- get a lot of infections or have infections that keep coming back

After starting AMEVIVE, call your doctor right away if you have any symptoms of an infection (see above).

What is AMEVIVE?

AMEVIVE is a prescription medicine used to treat adults with moderate to severe plaque psoriasis that keeps coming back (chronic), who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills). **It is not known if AMEVIVE is safe and effective in children.**

Who should not use AMEVIVE?

Do not use AMEVIVE if you:

- have HIV infection

What should I tell my doctor before taking AMEVIVE?

Before receiving AMEVIVE, tell your doctor if you:

- have any of the conditions or symptoms listed in the section “What is the most important information I should know about AMEVIVE?”
- are receiving phototherapy for your psoriasis.
- are allergic to AMEVIVE or any of its ingredients. See the end of this Medication Guide for a list of the ingredients in AMEVIVE.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if AMEVIVE will harm your unborn baby. Tell your doctor right away if you become pregnant while receiving AMEVIVE or within 8 weeks after receiving your last dose of AMEVIVE.
- are breastfeeding or plan to breastfeed. It is not known if AMEVIVE passes into your breast milk. You and your doctor should decide if you will take AMEVIVE or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your doctor if you receive phototherapy or take any other medicines that affect your immune system, including other medicines for treatment of your plaque psoriasis.

How will I receive AMEVIVE?

- AMEVIVE is given as an injection into your muscle.
- AMEVIVE is usually given one time each week for 12 weeks.
- Talk with your doctor to find out when you will receive injections. Keep all of your injection and follow-up appointments. It is important for you to stay under your doctor’s care during treatment.
- After you finish 12 weeks of treatment, you will stop treatment for at least 12 weeks. Your doctor may then decide that you should receive another 12 week treatment course of AMEVIVE.

What are the possible side effects of AMEVIVE?

AMEVIVE can cause serious side effects, including:

- **See “What is the most important information I should know about AMEVIVE?”**
- **Serious allergic reactions** can happen during treatment with AMEVIVE.

Call your doctor right away if you get any of the following symptoms of an allergic reaction with AMEVIVE:

- red-itchy welts (hives) on your skin
- swelling or tingling of your lips, tongue, or inside your mouth
- **Serious Liver problems.** Some patients treated with AMEVIVE develop serious liver problems, including liver injury.

Call your doctor right away if you get any of the following signs and symptoms of serious liver problems:

- yellowing of your skin or the whites of your eyes
- you start to bruise easily
- tiredness
- loss of appetite or vomiting that does not go away, or abdominal pain
- dark urine
- pale stool

Common side effects of AMEVIVE include:

- sore throat
- dizziness
- cough
- nausea
- itching
- muscle aches
- chills
- injection site reactions such as pain, redness

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AMEVIVE. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about AMEVIVE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about AMEVIVE. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about AMEVIVE that was written for healthcare professionals.

What are the ingredients in AMEVIVE?

Active ingredient: alefacept

Inactive Ingredients: citric acid monohydrate, glycine, sodium citrate dehydrate, sucrose.

Sterile water for injection is provided as a diluent.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Astellas Pharma US, Inc.
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