

MEDICATION GUIDE
RAPTIVA® (Rap-TEE-vah)
(efalizumab)
for injection, subcutaneous

Read the Medication Guide that comes with RAPTIVA® (efalizumab) before you start using it and before each injection. There may be new information. This information does not take the place of talking with your doctor about your condition or your treatment with RAPTIVA. Ask your doctor if you have any questions about this Medication Guide or RAPTIVA.

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

RAPTIVA has serious side effects that can lead to death:

- **Progressive Multifocal Leukoencephalopathy (PML).** PML is a serious brain infection caused by a virus. PML results in death or severe disability. Using RAPTIVA will increase your risk for PML. Your risk of PML may rise even more the longer you use RAPTIVA. Some patients who took RAPTIVA for 3 years died from PML and patients on RAPTIVA for less time could develop PML. There is no way to know ahead of time who will get PML. There is no treatment or cure for PML, and it almost always causes death. People who do live with PML are severely disabled.

Symptoms of PML include a new or sudden change in:

- thinking
- balance
- strength
- talking
- walking
- vision

Call your doctor right away if you have any of these symptoms or if anyone close to you notices a new or sudden change in your thinking.

Taking RAPTIVA increases your chances of PML because RAPTIVA weakens the ability of your immune system to fight the virus that causes PML. Your chance of getting PML may even be higher if you are also being treated with other medications that can weaken your immune system. You can still get PML even if you use RAPTIVA alone.

- **Serious infections.** Some of these infections have led to hospitalization or death and have been caused by bacteria, fungi, and viruses.

Symptoms of a serious infection include:

- fever
- cough
- flu-like symptoms
- feeling especially tired
- chills
- muscle aches
- stiff neck

Before you start using RAPTIVA, tell your doctor if you have an infection. During your RAPTIVA treatment, tell your doctor right away if you get an infection. Do not use RAPTIVA if you have a serious infection.

Stopping treatment with RAPTIVA. Stopping RAPTIVA may lead to serious side effects, such as severe worsening of your psoriasis, that can lead to hospitalization. Tell your doctor if you want to stop using RAPTIVA so that you and your doctor can carefully plan how to change to another psoriasis medicine.

What is RAPTIVA?

RAPTIVA is a prescription medicine used to treat adults with the type of psoriasis that is not adequately treated with medicines that go on the skin.

RAPTIVA has not been studied in children under 18 years of age.

Who should not use RAPTIVA?

- Do not use RAPTIVA if you have ever had an allergic reaction to RAPTIVA.
- Do not use RAPTIVA if you have been diagnosed with PML.

What should I tell my doctor before using RAPTIVA?

- **Vaccinations.** Ask your doctor whether you need any vaccinations **before** you start using RAPTIVA. Some vaccinations should not be given or will not work while you use RAPTIVA. Talk to your doctor about whether anyone in your household needs a vaccination. Some types of vaccines can spread to people with weakened immune systems, causing serious problems.

Tell your doctor about all of your medical conditions, including:

- **If you have any infections or a weakened immune system.** See “What is the most important information I should know about RAPTIVA?”
- **If you have or have had cancer.**
- **If you are pregnant, planning to become pregnant, or become pregnant while using RAPTIVA.** It is not known if RAPTIVA can harm your unborn baby. If you become pregnant while taking RAPTIVA, call your doctor right away. You and your doctor will decide if RAPTIVA is right for you during pregnancy. If you use RAPTIVA when you are pregnant, call 1-877-RAPTIVA (1-877-727-8482) to be included in the RAPTIVA Pregnancy Registry. This registry collects information to help understand the effects of RAPTIVA during pregnancy.
- **Breast feeding.** It is not known if RAPTIVA passes into your milk. It may harm your baby. You will need to decide whether to use RAPTIVA or breast feed, but you should not do both.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. It is not known if RAPTIVA and other medicines affect each other.

Especially, tell your doctor if you use:

- **Medicines that weaken your immune system.** Ask your doctor or pharmacist if you are not sure.
- **Other medicines or treatments for your psoriasis.**

How should I use RAPTIVA?

See the **Instructions for Use** at the end of this Medication Guide for how to prepare and inject RAPTIVA. Ask your doctor or pharmacist if you have any questions about using RAPTIVA.

- **Use RAPTIVA exactly as prescribed by your doctor.** Tell your doctor if you want to stop using RAPTIVA so that they can plan for other psoriasis treatment. Your psoriasis can worsen to severe levels quickly when RAPTIVA is stopped.
- RAPTIVA is an injection (shot) that you give yourself once a week. Your dose of RAPTIVA is based on your body weight. Tell your doctor if your weight changes. Do not change your dose without talking to your doctor.
- RAPTIVA is injected under the skin of your upper leg (thigh), upper arm, abdomen, or buttocks once a week. Use a different skin injection site (rotate) each time you give yourself an injection.
- Use RAPTIVA the same day each week. If you miss your dose of RAPTIVA, call your doctor to find out when to take your next dose of RAPTIVA and what schedule to follow after that.
- If you take more than your regular dose of RAPTIVA, call your doctor right away.
- Do not take light treatments for your psoriasis (UVB, PUVA, phototherapy) unless directed by your doctor.

What are the possible side effects of RAPTIVA?

Serious side effects with RAPTIVA include:

- **Progressive Multifocal Leukoencephalopathy (PML).** See “What is the most important information I should know about RAPTIVA?”
- **Serious infections.** See “What is the most important information I should know about RAPTIVA?”
- **Nervous system disorders.** People who use RAPTIVA can have serious disorders that affect the brain and nervous system. Symptoms of a nervous system disorder include:
 - sudden numbness or tingling
 - weakness in your arms, legs, or face
 - new or sudden change in thinking, balance, strength, talking, walking, or vision
- **Worsening of psoriasis.** Some people have severe worsening or a new psoriasis rash while taking RAPTIVA or after stopping RAPTIVA. Tell your doctor right away if your psoriasis gets worse or if you see any new rashes during or after treatment with RAPTIVA.
Call your doctor right away if you have any of these symptoms.
- **Cancer.** RAPTIVA weakens your immune system. When your immune system is weakened, you may have a higher chance of getting new cancer or making your cancer worse.
- **Low platelet counts (thrombocytopenia).** Platelets are cells that help your blood clot. Low platelets give you a higher chance for bleeding. Call your doctor right away if you have bleeding including your gums, a red rash, or more bruises than usual. Your doctor may do blood tests to check your platelets while you take RAPTIVA.

- **Low blood counts (anemia).** Some people who use RAPTIVA develop very low red blood cell counts. Call your doctor right away if you are:
 - weak
 - dizzy
 - lightheaded
 - out of breath
 - your skin or eyes turn yellow
 - your urine turns red or dark
- **Arthritis.** Some people have worsening or new arthritis while taking RAPTIVA or after stopping RAPTIVA. Tell your doctor if you get redness, pain, swelling, or stiffness of your joints.

The most common side effects of RAPTIVA usually happen within the first 48 hours after your RAPTIVA injection. Common side effects include:

- headache
- chills
- fever
- nausea
- muscle aches

Call your doctor if you are not sure if these problems are from an infection. See “What is the most important information I should know about RAPTIVA?”

These are not all the side effects of RAPTIVA. Talk to your doctor for medical advice about any signs and symptoms that bother you. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RAPTIVA?

- Store RAPTIVA vials in the refrigerator at 36° to 46°F (2° to 8°C) until you are ready to prepare your injection.
- Do not freeze or store at room temperature.
- Once RAPTIVA has been mixed with sterile water, you should use it right away to inject yourself. If you are unable to inject the RAPTIVA after mixing, the mixture can stay at room temperature for up to 8 hours. Do not use RAPTIVA that was mixed for more than 8 hours.
- If you are traveling, be sure to store RAPTIVA at the right temperature. If you have any questions, ask your doctor or pharmacist.
- Store RAPTIVA vials away from light.
- Throw away RAPTIVA vials that are out of date. The expiration date is marked on each vial of RAPTIVA.

Keep RAPTIVA and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT RAPTIVA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RAPTIVA for a condition for which it was not prescribed. Do not give RAPTIVA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about RAPTIVA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RAPTIVA that is written for health professionals. For more information, you can also call 1-877-RAPTIVA (toll free).

What are the ingredients in RAPTIVA?

Active ingredient: efalizumab

Inactive ingredients: sucrose, L-histidine hydrochloride monohydrate, L-histidine, polysorbate 20, and sterile water for injection.

Instructions for use

How do I prepare and give a RAPTIVA injection?

If your dose is more than 1.25 mL, you will need to use 2 RAPTIVA blister trays, and you will give yourself 2 injections of RAPTIVA.

Setting Up the Equipment

1. Take the RAPTIVA (efalizumab) blister tray out of the refrigerator, and place it on a flat, well-lit, clean work surface.
2. Wash your hands with soap and water before opening the blister tray.

3. Open the tray and lay out the contents. Allow the contents to come to room temperature.



As shown below, the tray contains:

- One RAPTIVA vial
- One 1.3-mL prefilled syringe of sterile water
- Two 25-gauge needles
- Two alcohol prep pads

Contact your doctor or pharmacist if you are missing any of the items listed above.



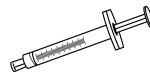
RAPTIVA Vial



Alcohol Prep Pads (2)



Needles (2)



Prefilled Syringe

4. Check the expiration date on the RAPTIVA vial label and prefilled syringe label. If the expiration date has passed, do not use the RAPTIVA vial or the prefilled syringe containing the sterile water. Contact your doctor.
5. Partially peel open the needle pack and place it on a clean surface. Be sure to grasp the needle by the plastic cover and avoid touching the end of the syringe and the needle.



6. Remove the plastic cap protecting the rubber stopper of the RAPTIVA vial. Open one alcohol prep pad package and wipe the rubber stopper with an alcohol prep pad. Do not touch the top of the vial after wiping.
7. Remove the cap covering the prefilled syringe tip. Remove one of the 25-gauge needles from its package by grasping the needle by the plastic cover and without touching the end of the needle. Carefully place the capped 25-gauge needle onto the syringe tip. Twist needle to secure.

Mixing RAPTIVA

1. Remove the needle cap. **Do not touch the needle.** Keep the RAPTIVA vial upright on a firm surface, and slowly puncture the rubber stopper with the needle. Slowly push down on the syringe plunger to inject all of the 1.3 mL of sterile water onto the side wall of the vial to cause less foaming. Some foaming may happen; this is normal.



2. With the needle and syringe still in the vial stopper, gently swirl the vial to mix. Wait 5 minutes for the medicine to completely dissolve. To avoid excess foaming, **do not shake the vial.** The RAPTIVA solution should be clear to pale yellow. **Do not use the solution if it is discolored or cloudy or if particles (solid matter) are in the solution.**



Preparing the RAPTIVA Dose for Injection

If you need more than one vial of RAPTIVA for the correct dose (dose amount is greater than 1.25 mL), repeat Steps 1–6 of this section using a second RAPTIVA blister tray, and divide your dose between two syringes.

1. Turn the vial upside down, keeping the needle in the vial. (The needle will now be pointing upward.) Make sure the tip of the needle is covered all the way by the medicine in the vial. Pull back the syringe slightly if necessary. This will make it easier to get the medicine into the syringe.
2. Pull back on the plunger to fill the syringe. Withdraw the correct dose of medicine by reading the numbers on the syringe. Remove the syringe from the vial.



3. Slide the needle into the cap on a flat surface to pick up the needle cap. To lower the chance of a needlestick injury, do not touch the cap until it covers the needle all the way. Push the cap all the way down over the needle



4. Hold the syringe upright and tap the side of the syringe to let air bubbles rise to the top. Gently push in the plunger of the syringe to push the air bubbles out.
5. After removing the bubbles, recheck the dose of medicine in the syringe. If necessary, push the plunger again to remove any amount of medicine beyond the line that indicates your dose. Make sure you have the right dose as instructed by your doctor. Twist the capped needle off the syringe and discard it in a puncture-resistant container (see **DISPOSAL OF THE SYRINGE, NEEDLES, AND SUPPLIES**). **Never reuse a needle or syringe.**
6. Remove the other 25-gauge needle from its package by grasping **the needle by the plastic cover and** without **touching the end of the needle**. Carefully place the capped 25-gauge needle onto the syringe tip. Twist to secure. Put the syringe down while preparing your skin for injection.

Selecting and Preparing the Injection Site

1. Wash your hands well with soap and water.



2. Choose an area of the body for the injection. Avoid, if possible, skin involved with psoriasis. Possible injection sites include the following:
- Outer area of the upper legs (thighs)
 - Stomach area around the belly button



If someone else is giving you an injection, you can also use:

- Back of upper arms
- Buttocks



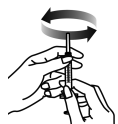
3. It is important to change (rotate) the injection site each time you take RAPTIVA to lower your chances of soreness and redness at the injection site. Changing the injection site will also improve absorption of the medication. Repeat injections given in the same area should be at least 1 inch apart. **Do not give an injection close to a vein that you can see under the surface of your skin.**
4. Wash the skin at the site of injection with soap and water. Let it air dry.
5. Cleanse the skin at the injection site with an alcohol prep pad using a circular motion. Let the area air dry all the way. **Do not touch this area again before giving the injection.**



Giving the RAPTIVA Injection under the Skin

Your doctor will teach you how to inject RAPTIVA. Do not inject RAPTIVA unless you have been taught the right way to give the injection.

1. Hold the syringe and remove the needle cover. Twisting the needle cover while pulling will help in the removal. **Do not touch the needle or allow the needle to touch anything.**



2. Hold the syringe in the hand you use to inject yourself. Use your other hand to pinch a patch of skin at the clean injection site. **Do not** lay the syringe down or allow the needle to touch anything.

3. Hold the syringe firmly between your thumb and fingers so that you have steady control. Insert the needle straight down at a 90-degree angle. This is important to make sure the medicine is injected into fatty tissue.



4. After the needle is inserted all the way into the skin, you can gently let go of the pinched skin. Be sure the needle stays in your skin. Slowly and smoothly push the plunger down into the syringe until it stops.
5. When all of the medicine has been injected, remove the needle and do not re-cap it. Discard the used syringe with the attached needle into a puncture resistant container (see **DISPOSAL OF THE SYRINGE, NEEDLES, AND SUPPLIES**). **Never reuse a needle or syringe.** Press a dry, sterile gauze (not provided) over the injection site. Do not use the alcohol prep pad. A small bandage may be put over the injection site.



6. If your dose amount is more than 1.25 mL, you will need to give a second injection. Choose the second injection site at least 1 inch from the first injection site.

DISPOSAL OF THE SYRINGE, NEEDLES, AND SUPPLIES

1. As stated earlier, place the used syringe with the attached needle in a puncture-resistant container, like a sharps container. You can buy a sharps container at your local pharmacy.



2. Talk to your doctor about how to properly dispose of a filled container of your used syringes and needles. There may be special local and state laws for disposing of used needles and syringes. **Do not throw the filled container in the household trash and do not recycle.**
3. The needle cap, alcohol prep pads, and other used supplies can be thrown out with your regular trash.
4. **Always keep syringes, injection supplies, and disposal containers out of the reach of children.**
5. **Do not reuse these single-use syringes or needles.**

Rx Only

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



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4826404
FDA Approval October 2003
Code revision March 2009
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