

Patient Information
RAPTIVA (Rap-TEE-vah)
(efalizumab)
for injection, subcutaneous

Read the Patient Information that comes with RAPTIVA[®] (efalizumab) before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. **See your healthcare provider regularly while using RAPTIVA. Do not miss your appointments. Do not change or stop treatment without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about RAPTIVA. **Please discuss with your doctor which vaccinations you may need to receive before undertaking a treatment course of RAPTIVA[®].**

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT RAPTIVA?

RAPTIVA can decrease the activity of your immune system. Therefore, people using RAPTIVA may have an increased chance of getting:

- **Serious infections.** Some infections could become serious and in rare cases have led to hospitalization or death. If you have any infection, tell your healthcare provider before you start using RAPTIVA. If you get an infection that does not go away or if you notice any new or worsening medical problems, such as a new or sudden change in thinking, balance, strength, talking, walking, or vision, tell your healthcare provider right away.
- **Cancers.** Many drugs that decrease the activity of the immune system can increase the risk of cancer. If you have had cancer you should tell your healthcare provider before you start taking RAPTIVA. The role of RAPTIVA in the development of cancer is not known.
- **Low platelet counts (thrombocytopenia).** Platelets help your blood clot. Low platelets give you a higher chance for bleeding. Call your doctor right away if you have increased bruising or bleeding. Your healthcare provider may do regular blood tests to check your platelets while you are taking RAPTIVA.
- **Low blood counts (anemia).** Some patients treated with RAPTIVA have developed very low red blood cell counts and have become anemic. Call your doctor right away if you feel weak and lightheaded, your skin and eyes turn yellow in color or your urine turns red or dark.
- **Worsening of psoriasis.** Some patients have had severe worsening or new forms of psoriasis while taking RAPTIVA or after stopping RAPTIVA. Tell your healthcare

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provider right away if your psoriasis gets worse or if you see any new rashes during or after treatment with RAPTIVA.

- **Arthritis.** Some patients have had worsening or new arthritis while taking RAPTIVA or after stopping RAPTIVA. Tell your health care provider if you have severe redness, pain, swelling, or stiffness of joints such as hands, knees, ankles, etc.
- **Nervous system disorders.** Cases of disorders that affect the nervous system have been reported in people taking RAPTIVA. Signs that you could be experiencing a problem affecting your nervous system include: sudden onset of numbness or tingling, weakness in arms, legs, or face, or a new or sudden change in thinking, balance, strength, talking, walking, or vision. Tell your healthcare provider right away if these types of symptoms develop.

Talk to your healthcare provider if you need to receive a vaccine while using RAPTIVA.

RAPTIVA may reduce the effectiveness of vaccinations given during RAPTIVA therapy.

You should not receive live (including live-attenuated) vaccines while using RAPTIVA.

WHAT IS RAPTIVA?

RAPTIVA is a medicine used to treat adult patients with moderate to severe plaque psoriasis who can be treated with medicines that affect the whole body (systemic therapy) or with phototherapy.

RAPTIVA is a man-made protein that is like proteins made in the body called antibodies. Antibodies fight disease in the human body. RAPTIVA may decrease the skin changes in the body that are the main problems of moderate to severe plaque psoriasis.

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.

Before using RAPTIVA, tell your healthcare provider

1. about the following medical conditions:

- **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, notify your healthcare provider immediately. You and your healthcare provider will have to decide if RAPTIVA is right for you during pregnancy. If you use RAPTIVA when you are pregnant,

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call 1-877-RAPTIVA (1-877-727-8482) to ask how you can be included in the RAPTIVA Pregnancy Registry.

- **If you are 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 may not do both.
 - **If you have any infections (see WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT RAPTIVA?).**
 - **If you have immune system problems**
2. **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 healthcare provider if you are using:**
- **Other medicines or treatments for your psoriasis**
 - **Medicines called immunosuppressives or any medicine that affects your immune system.** Ask your healthcare provider or pharmacist if you are not sure if any of your medicines are immunosuppressives.

HOW SHOULD I USE RAPTIVA?

- **Your dose of RAPTIVA is based on your body weight. Depending on your body weight, you may need to use either less or more than one vial after mixing RAPTIVA. Use RAPTIVA exactly as prescribed by your healthcare provider.** Tell your healthcare provider if your weight changes. Do not change your dose without talking to your healthcare provider. Do not stop using RAPTIVA without talking to your healthcare provider.
- RAPTIVA is an injection that you give yourself once a week.
- **See the end of this leaflet for instructions on how to prepare and inject RAPTIVA (HOW DO I PREPARE AND GIVE A RAPTIVA INJECTION?).** Ask your healthcare provider or pharmacist if you have any questions about using RAPTIVA.
- RAPTIVA is injected under the skin (subcutaneous) of your upper leg (thigh), upper arm, abdomen, or buttocks once a week. Change (rotate) your skin injection site with each injection.
- Use RAPTIVA the same day each week. If you miss your dose of RAPTIVA, contact your healthcare provider 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 healthcare provider right away.
- See your healthcare provider regularly while using RAPTIVA. Do not miss your appointments. Your healthcare provider may do blood tests, including platelet counts, before and during treatment with RAPTIVA to check its affect on your body.

WHAT SHOULD I AVOID WHILE USING RAPTIVA?

Unless directed by your healthcare provider, do not:

- take other medicines called immunosuppressives.
- take treatments called phototherapy.

Talk to your healthcare provider if you need to receive a vaccine while you are taking RAPTIVA. You should also talk to your doctor if anyone in your household requires a live (including live-attenuated) vaccine, because of the potential risk for shedding and transmission. You should not receive live vaccines while using RAPTIVA. (see **WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT RAPTIVA?**)

WHAT ARE THE POSSIBLE SIDE EFFECTS OF RAPTIVA?

RAPTIVA can affect your immune system and might cause serious side effects including the following (see WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT RAPTIVA?):

- **Serious infections**
- **Cancers**
- **Low platelet counts (thrombocytopenia)**
- **Low blood counts (anemia)**
- **Worsening of psoriasis**
- **New or worsening arthritis**
- **Nervous system disorders**

The most common side effects of RAPTIVA include headache, chills, fever, nausea, and muscle aches. These reactions usually happen within the first 48 hours following RAPTIVA injection, and often decrease after the first few weeks of use of RAPTIVA.

Other side effects that can also happen with RAPTIVA include back pain or swelling of the arms or legs (peripheral edema). Talk to your healthcare provider about any symptoms that bother you.

If you get any side effect that concerns you or if you get an infection, call your healthcare provider.

These are not all the side effects of RAPTIVA. For more information, ask your healthcare provider or pharmacist.

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 drug after mixing, the mixture can stay at room temperature for up to 8 hours. Do not use RAPTIVA that was mixed more than 8 hours earlier.

If you are traveling, be sure to store RAPTIVA at the right temperature. If you have any questions, ask your healthcare provider or pharmacist.

- Protect RAPTIVA vials from light while stored.
- Throw away RAPTIVA vials that are out of date.
- **Keep RAPTIVA and all medicines out of the reach of children.**

GENERAL INFORMATION ABOUT RAPTIVA

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. 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.

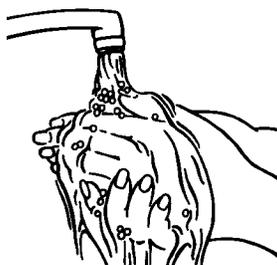
This leaflet summarizes the most important information about RAPTIVA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about RAPTIVA that is written for health professionals. For more information, you can also call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

HOW DO I PREPARE AND GIVE A RAPTIVA INJECTION?

If your dose amount 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

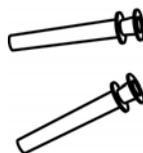
Contact your healthcare provider or pharmacist if you are missing any of the items listed above.



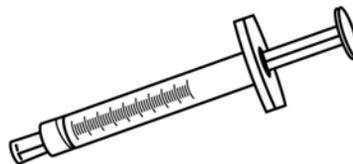
RAPTIVA
Vial



Alcohol Prep
Pads (2)



Needles (2)



Prefilled Syringe

4. Check the expiration (Exp.) 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 healthcare provider.

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- 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.



- 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.
- 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

- 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.



- 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 1–7 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

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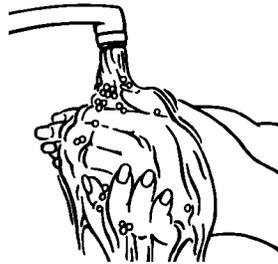
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healthcare provider. Twist the capped needle off the syringe and discard it in a puncture-resistant container (see **DISPOSAL OF THE SYRINGE, NEEDLES, AND SUPPLIES**). **Never reuse a needle or syringe.**

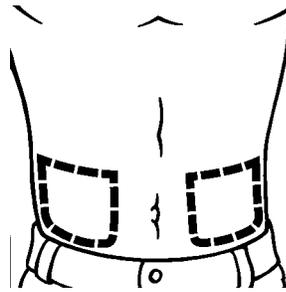
6. Remove the other 25-gauge needle from its package by grasping **the needle by the plastic cover and** without **touching the end of the needle**. Carefully place the capped 25-gauge needle onto the syringe tip. Twist to secure. Put the syringe down while preparing your skin for injection.

Selecting and Preparing the Injection Site

1. Wash your hands well with soap and water.

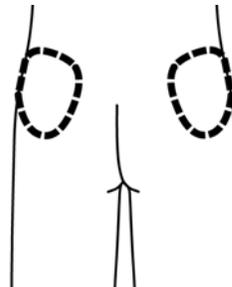
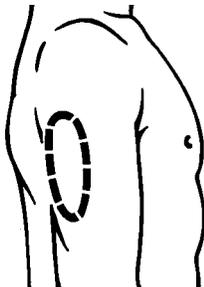


2. Choose an area of the body for the injection. Avoid, if possible, skin involved with psoriasis. Possible injection sites include the following:
 - Outer area of the upper legs (thighs)
 - Stomach area around the belly button



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

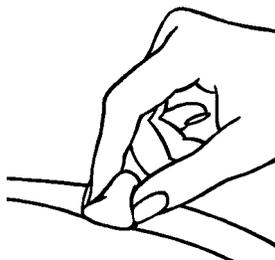
- Back of upper arms
- Buttocks



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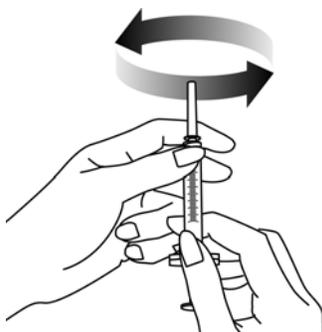
3. It is important to change (rotate) the injection site each time you take RAPTIVA to lower your chances of soreness and redness at the injection site. Changing the injection site will also improve absorption of the medication. Repeat injections given in the same area should be at least 1 inch apart. **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 healthcare provider will teach you how to inject RAPTIVA. Do not inject RAPTIVA unless you have been taught the right way to give the injection.

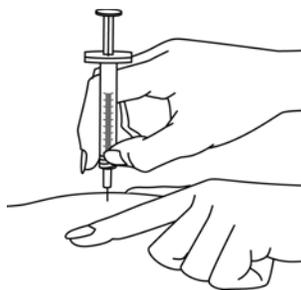
1. Hold the syringe and remove the needle cover. Twisting the needle cover while pulling will help in the removal. **Do not touch the needle or allow the needle to touch anything.**



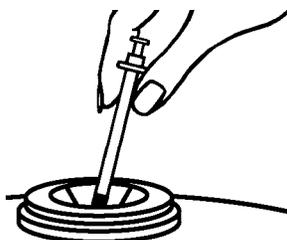
2. Hold the syringe in the hand you use to inject yourself. Use your other hand to pinch a patch of skin at the clean injection site. **Do not** lay the syringe down or allow the needle to touch anything.
3. Hold the syringe firmly between your thumb and fingers so that you have steady control. Insert the needle straight down at a 90-degree angle. This is important to make sure the medicine is injected into fatty tissue.

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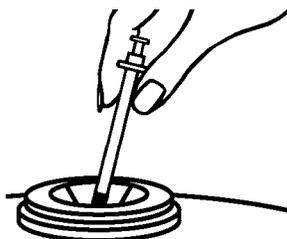
4. After the needle is inserted all the way into the skin, you can gently let go of the pinched skin. Be sure the needle stays in your skin. Slowly and smoothly push the plunger down into the syringe until it stops.
5. When all of the medicine has been injected, remove the needle and do not re-cap it. 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 healthcare provider about how to properly dispose of a filled container of your used syringes and needles. There may be special local and state laws for

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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

RAPTIVA[®] [efalizumab]

Manufactured by:

Genentech, Inc.

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South San Francisco, CA 94080-4990

4826402

FDA Approval Month YYYY~~June 2005~~

Code revision June 2005

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