

CSL Behring

EVOGAM[®]

Information for patients



evogam

Human Normal Immunoglobulin 16% (16g/100ml) – Subcutaneous

Information for patients and caregivers about EVOGAM

This booklet is designed to help you follow the training you will have been given by your doctor, nurse or other healthcare professional to administer EVOGAM at home. For additional information, please review the Consumer Medicine Information leaflet included with each vial of EVOGAM. If you have any questions or concerns after reading this booklet, please ask your doctor or nurse.

What is in this booklet?

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What EVOGAM is and what it is used for

EVOGAM is a subcutaneous immunoglobulin (SCIg) therapy. It is made from human plasma that is collected by the New Zealand Blood Service and then sent to CSL Behring to be manufactured into EVOGAM.

EVOGAM contains human immunoglobulins (Ig), also known as antibodies, which are a type of protein found in the blood. Immunoglobulins are produced by your body's immune system to fight infections caused by pathogens such as bacteria and viruses. If you don't have enough antibodies, you may not be able to fight off diseases. EVOGAM can be used as antibody replacement therapy to correct this lack of antibodies. EVOGAM has been shown to keep Ig levels stable with weekly self-administration. This results in a consistent level of protection against infection.

The logo for EVOGAM, featuring the word "e" in black and "vogam" in blue, with a stylized blue shape above the "o".

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What you need to know before you start EVOGAM

Starting EVOGAM

Your EVOGAM treatment should be started and supervised by a health professional such as your doctor or nurse.

If your doctor decides you should receive EVOGAM at home, they will ensure you receive detailed instructions and training on how to use it. This will include the dosage and how often you need EVOGAM, as well as how to administer it.

If you don't understand the instructions, ask your doctor or nurse to explain them again.

Before you use EVOGAM

When you must not use it

Do not use EVOGAM if you are allergic to:

- human immunoglobulin products
- glycine

If you are not sure whether you should be using EVOGAM talk to your doctor.

Before you are given EVOGAM

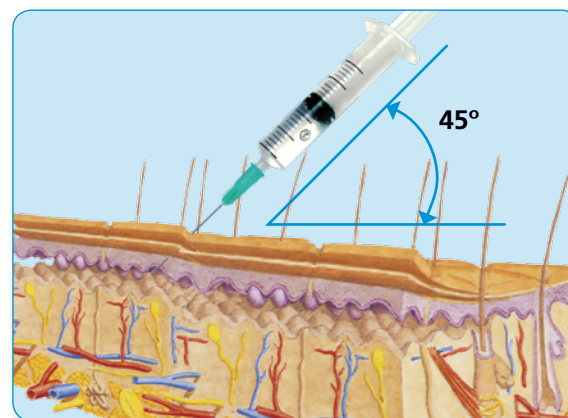
Tell your doctor if you:

- are pregnant or breastfeeding
- have had any vaccination within the last two weeks
- are allergic to any medicine or food
- have IgA deficiency
- have any other medical conditions.

How to use EVOGAM

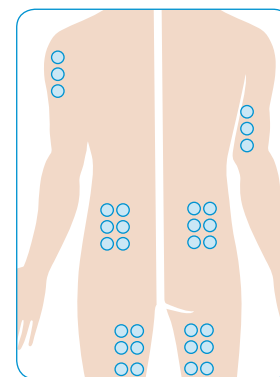
How EVOGAM is given

EVOGAM is infused subcutaneously through small needles inserted into the fatty tissue just below the skin's first layer. EVOGAM must not be delivered into your vein.



Suitable subcutaneous injection sites include lower abdomen, thighs, upper arms and hips. EVOGAM may be administered using one or more injection sites simultaneously, depending on the volume of fluid to be given.

Your doctor or nurse will advise you on this.



Front

Back

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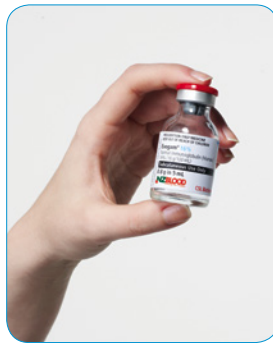
How to administer EVOGAM

Step 1: Prepare EVOGAM and equipment

- a) **Remove** the vial of EVOGAM from the refrigerator and allow it to reach room temperature prior to use.
- b) **Gather** what you need for administration. This may include an infusion pump, administration tubing, subcutaneous needle or catheter sets, Y-site connectors, alcohol wipes, syringes, transfer device, gauze or transparent dressing, tape, sharps disposal container and treatment diary.



- c) **Check** EVOGAM vials. Carefully check the liquid in each vial, but do not shake it. The liquid should be clear or slightly cloudy. Do not use it if the liquid contains particles, is missing the protective cap, or is past the expiry date.



- d) **Remove** the protective cap from the vial, and wipe the rubber stopper with an alcohol wipe.



Step 2: Wash hands

Wash hands with soap and water and dry hands thoroughly with a clean towel.



Step 3: Prepare vial adaptor

- a) **Remove** the top cover of the vial adaptor, leaving the adaptor inside the blister pack.
- b) **Place** the EVOGAM vial on a flat surface.
- c) **Place** the vial adaptor over the top of the vial, using the blister pack to handle the vial adaptor. Press down firmly until the vial adaptor snaps into place, so that it pierces the rubber stopper.
- d) **Remove** the outer package of the vial adaptor and discard. Take care not to touch the exposed end of the device.



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Step 4: Prepare syringe

Pull back the plunger of the syringe to fill the syringe with air. The amount of air should be the same as the amount of EVOGAM you will transfer from the vial.



Step 5: Connect to vial

a) **Attach** the syringe to the vial adaptor, by twisting the syringe onto the connection.



b) **Push** the plunger of the syringe down. This will inject the air from the syringe into the vial.



Step 6: Withdraw EVOGAM from vial

a) **Turn** the vial and syringe upside down whilst holding the plunger in, leaving the syringe and vial attached.



b) **Release** pressure on the plunger and pull back slowly on the plunger of the syringe to fill the syringe with EVOGAM.



c) **Detach** the syringe from the vial adaptor with a twist, leaving the vial adaptor attached to the vial.

Repeat steps 3 to 6 if multiple vials are required to achieve the prescribed dose of EVOGAM. The same syringe may be used (to a maximum of 20mL) but use a new vial adaptor for each vial.

Step 7: Prepare the infusion tubing

To prime (fill) the tubing, connect the syringe filled with EVOGAM to the infusion tubing and gently push on the syringe plunger to fill the tubing with EVOGAM, until you see a drop of EVOGAM come out of the needle.



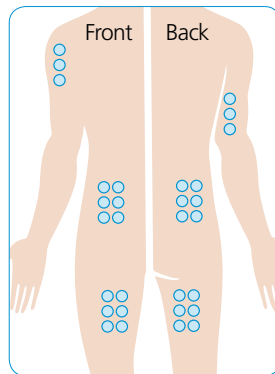
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Step 8: Insert needle

- a) **Select** an appropriate infusion site. This may be the abdomen, thigh, upper arm, or side of the hip.

The number and location of injection sites depends on the volume of the total dose. When a dose of more than 20mL is given, it is advisable to give it in divided doses at different sites, which can be infused at the same time.



- b) **Clean** the injection site(s) as directed by your health care professional.

- c) **Pinch** together the skin around the injection site with two fingers, and insert the needle under the skin.



- d) **Place** sterile gauze and tape or a transparent dressing over the injection site. This will keep the needle from coming out.



Step 9: Check needle placement

Make sure you are not injecting EVOGAM into a blood vessel. To test for this, pull the plunger back gently.

If there is blood in the tubing, which would appear as red or pink fluid entering the tubing from the injection site, remove and discard the needle and tubing. Repeat steps beginning with step 7 using a new needle and tubing, and a new infusion site.



If there is no blood in the tubing, continue to step 10.

Step 10: Start infusion

Follow the instructions that you have been given by your doctor or nurse to start the infusion, which may be with an infusion pump, or by using a slow push technique, and infuse at the rate you have been instructed.



Or



The recommended initial infusion rate is 10mL/hr per injection site, with subsequent infusion rate increased as tolerated to a maximum of 20mL/hr per site.

Step 11: After the infusion

- a) **Take off** the dressing and take the needle out of the injection site, applying light pressure to the injection site.
- b) **Throw away** the EVOGAM single-use vial, along with the needle and tubing, in the sharps container. Throw away dressing and tapes in the household waste.
- c) **Record** your treatment. Peel off the removable part of the label of the EVOGAM vial, and put this label in your treatment diary or logbook. Document the date and time of your infusion, the amount of EVOGAM that you infused, and the rate of infusion.



While you are using EVOGAM

Recording your EVOGAM treatment

Use your *EVOGAM Patient Diary*, provided by your healthcare professional, to record details of each EVOGAM treatment as well as any other information you wish to capture. This will provide important information for discussion at your regular check ups.

Other things to keep in mind

Tell your doctor if you are planning to have a vaccination. EVOGAM may impair the effect of some virus vaccines such as measles, mumps, rubella and chicken pox for a period of at least six weeks, and up to three months.

Tell your doctor if you are about to have any blood tests. EVOGAM may interfere with the results of some tests, resulting in misleading results.

Inform other doctors, dentists, and pharmacists who treat you that you have been given this medicine. It is important for them to know if they are starting you on any other new medicines.

Other possible side effects

Important safety information

All medicines can have side effects. Sometimes they are serious, most of the time they're not. If you do have any side effects that concern you, please discuss these with your doctor or nurse. You may need medical treatment if you experience some side effects.

Common side effects experienced by patients in the EVOGAM clinical trial included injection site reactions, headache, nausea and vomiting, fever, pain and fatigue.

EVOGAM is derived from human plasma. Whilst processes are included in EVOGAM's manufacture to inactivate or remove infectious agents, including viruses, the risk of transmission cannot be completely eliminated. However, the measures taken are considered effective against known viruses.

If you have a history of anaphylactic or severe response to immune globulin preparations or selective immunoglobulin A deficiency, check with your doctor or nurse, as EVOGAM should not be used.

Tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital if you notice any of the following symptoms:

- Signs of an allergic reaction, which may include swelling of the lips, tongue or eyes, loss of consciousness, difficulty in breathing, or hives.
- Chest pain.
- Tingling, numbness or weakness on one side of the body.
- Severe headache with neck stiffness, painful eye movements, and inability to withstand bright light.

For further important safety information regarding EVOGAM, please refer to the Consumer Medicine Information included with each vial of EVOGAM.



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Injection site reactions

Injection site reactions are common following subcutaneous infusion of EVOGAM. These are mostly mild to moderate and usually diminish within 24–48 hours. These reactions include local redness, swelling, discomfort and itching, with some examples of these pictured below.

Injection site reactions over time



* Images of injection sites following SCIg administration. CSL Behring.

If you have any concerns about reactions at the injection site please discuss them with your doctor or nurse.

How to Store EVOGAM

Store EVOGAM in the refrigerator (2°C to 8 °C). Do not freeze. Once removed from refrigeration, store below 25°C and use within 2 weeks.

Leave EVOGAM in its carton until ready to use.

Do not use EVOGAM after the expiry date.

Keep EVOGAM out of the reach and sight of children.

Contents of the pack and other information

EVOGAM is clear and pale-yellow to light-brown, and may be cloudy in appearance. It is packaged in single-use, clear glass vials with a vial adaptor.

EVOGAM does not contain any preservatives, so any unused portion should be discarded immediately.

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Date of preparation: August 2013