

**MEDICATION GUIDE**  
**OMONTYS® (O-mon-tis)**  
**(peginesatide)**  
**Injection**

Read this Medication Guide:

- before you start OMONTYS.
- if you are told by your healthcare provider that there is new information about OMONTYS.
- if you are told by your healthcare provider that you may inject OMONTYS at home, read this Medication Guide each time you receive a new supply of medicine.

This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Talk with your healthcare provider regularly about the use of OMONTYS and ask if there is new information about OMONTYS.

**What is the most important information I should know about OMONTYS?**

Using OMONTYS or other erythropoiesis-stimulating agents (ESAs) can lead to serious side effects including death.

- If you decide to take OMONTYS, your healthcare provider should prescribe the smallest dose of OMONTYS that is needed to reduce your chance of needing red blood cell transfusions.
- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with OMONTYS to reach a normal or near-normal hemoglobin level.
- You may get blood clots while receiving OMONTYS. If you are receiving OMONTYS and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Call your healthcare provider or get medical help right away if you have any of these symptoms of blood clots:

- Chest pain
- Trouble breathing or shortness of breath
- Pain in the legs, with or without swelling
- A cool or pale arm or leg
- Sudden confusion, trouble speaking, or understanding others' speech

- Sudden numbness or weakness of the face, arm, or leg, especially on one side of your body
- Sudden trouble seeing
- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working.

See **“What are the possible side effects of OMONTYS?”** below.

### **What is OMONTYS?**

OMONTYS is a prescription medicine that works like the human protein erythropoietin. OMONTYS is given to treat anemia (low red blood cells) in adults with chronic kidney disease (CKD) who are on dialysis.

OMONTYS stimulates your bone marrow to make more red blood cells. Having more red blood cells raises your hemoglobin level. If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen even if you take OMONTYS and do not have an increase in your hemoglobin level.

OMONTYS should not be used for the treatment of anemia:

- if you have chronic kidney disease (CKD) and are not on dialysis,
- if you are receiving treatment for cancer and your anemia is not caused by CKD,
- in place of emergency treatment for anemia (red blood cell transfusions).

OMONTYS has not been proven to improve the quality of life, fatigue, or well-being.

It is not known if OMONTYS is safe and effective in children.

### **Who should not use OMONTYS?**

Do not use OMONTYS if you have high blood pressure that is not controlled (uncontrolled hypertension).

### **What should I tell my healthcare provider before using OMONTYS?**

Before using OMONTYS tell your healthcare provider if you:

- have heart disease
- have or develop cancer
- have high blood pressure
- have any history of stroke, blood clot or seizure (convulsion)
- have blood disorders (such as sickle cell anemia or clotting disorders)
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if OMONTYS will harm your unborn baby.

- are breastfeeding or plan to breastfeed. It is not known if OMONTYS passes into your breast milk.

**Tell your healthcare provider about all of the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider when you get a new medicine.

### **How should I use OMONTYS?**

- Continue to follow your healthcare provider's instructions for diet, dialysis, and medicines, including medicines for high blood pressure, while using OMONTYS.
- Have your blood pressure checked as instructed by your healthcare provider.
- Your healthcare provider should do blood tests to check your hemoglobin and iron levels before and during your treatment with OMONTYS.
- OMONTYS is given one time a month into the vein, through your hemodialysis vascular access (intravenous), or under your skin (subcutaneous).
- OMONTYS should be given by your healthcare provider. In some cases, your healthcare provider may allow you or your caregiver to give the injections at home.
- If you or your caregiver has been trained to give the injections at home, it is important that you:
  - Carefully follow the instructions that your healthcare provider gives you. **Be sure that you read, understand, and follow the "Instructions for Use" that come with OMONTYS.**
  - Use OMONTYS exactly as your healthcare provider tells you to. Do not change the dose of OMONTYS unless told to do so by your healthcare provider.
  - Your healthcare provider will show you or your caregiver how much OMONTYS to use, how to inject it, how often it should be injected and how to safely dispose of the used containers, needles and syringes.
  - If you miss a dose of OMONTYS, call your healthcare provider right away for instructions on what to do.
  - If you inject more than the prescribed amount of OMONTYS, call your healthcare provider right away for instructions on what to do.

## What are the possible side effects of OMONTYS?

OMONTYS may cause serious side effects, including:

- See “What is the most important information I should know about OMONTYS?”
- **High blood pressure.** High blood pressure is a common side effect of OMONTYS in people with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine while taking OMONTYS. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often. If your blood pressure does increase, your healthcare provider may prescribe new or more blood pressure medicine.
- **Antibodies to OMONTYS.** Your body may make antibodies to OMONTYS. These antibodies can block or lessen your body’s ability to make red blood cells and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking OMONTYS.

The most common side effects of OMONTYS include:

- shortness of breath
- diarrhea
- nausea
- vomiting
- cough
- problems with your hemodialysis access
- headache
- muscle spasms
- joint, back, leg, or arm pain
- low blood pressure (hypotension)
- fever
- increase in blood potassium level
- upper respiratory infection

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

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

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 OMONTYS?

- Keep OMONTYS in the original package.
- Protect OMONTYS from light.
- Store OMONTYS in the refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- If a refrigerator is not available, OMONTYS vials and pre-filled syringes can be stored at 77 °F or less (25 °C or less) for up to 30 days.
- Throw away multiple use vials of OMONTYS no later than 28 days from the first day that you put a needle into the vial.

- OMONTYS single use vials and pre-filled syringes should be used only one time. Dispose of the single use vial and the pre-filled syringe after use even if there is medicine left in the container.

**Keep OMONTYS and all medicines out of the reach of children.**

### **General Information about the safe and effective use of OMONTYS**

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

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

For more information go to [www.omontys.com](http://www.omontys.com) or call 1-855-466-6689.

### **What are the ingredients in OMONTYS?**

Active ingredient: peginesatide

Inactive ingredients:

- Single Use Vials and Single Use Pre-filled Syringes: sorbitol, sodium phosphate monobasic (dihydrate), sodium phosphate dibasic, polysorbate 20, and sodium hydroxide in Water for Injection.
- Multiple Use Vials: sorbitol, phenol, L-methionine, glacial acetic acid, and sodium hydroxide in Water for Injection.

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

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**Instructions for Use**  
**OMONTYS® (O-mon-tis)**  
**(peginesatide)**  
**Injection**  
**Single use vials**  
**Multiple use vials**

Use these instructions if you or your caregiver has been trained to give OMONTYS injections at home. Do not give yourself the injection unless you have received training from your healthcare provider. If you are not sure about giving the injection or if you have questions, ask your healthcare provider for help.

Before reading these Instructions for Use, read the Medication Guide that comes with OMONTYS for the most important information you need to know.

**When you receive your OMONTYS vial and syringes, make sure that:**

- The name OMONTYS appears on the carton and vial label.
- The tamper evident seal on the carton is not damaged. Do not use if the tamper evident seal on carton is broken or missing.
- OMONTYS is used before the expiration date on the vial label. Do not use OMONTYS on or after the expiration date on the label.
- The dose strength of the OMONTYS vial (number of mg (milligrams) per mL (milliliter) on the vial label) is the same as your healthcare provider prescribed.
- You understand what the dose strength of OMONTYS means. OMONTYS vials come in different dose strengths. For example, the dose strength may be described as 10 mg/mL on the vial label. This means that there is 10 mg of medicine in each 1 mL of liquid. Your healthcare provider may also refer to a mL as a "cc". One mL is the same as one "cc".
- The OMONTYS liquid in the vial is clear and colorless to slightly yellow. Do not use OMONTYS if the liquid in the vial looks discolored or cloudy, or if the liquid has lumps, flakes or particles.
- The OMONTYS vial has a colored cap on the top of the vial of OMONTYS. Do not use the vial of OMONTYS if the colored cap has been removed or is missing.
- Use only the type of disposable syringe and needle that your healthcare provider has prescribed.
- Keep OMONTYS away from light. Store OMONTYS vials in their cartons in the refrigerator between 36 °F to 46 °F (2 °C to 8 °C) until time of use.
- Single-use vials of OMONTYS should be used only one time. Dispose of the vial after one use even if there is medicine left in the vial.

- After removing a dose from the multiple use vial, store the vial in the refrigerator (but not in the freezer) in its carton to protect from light. Do not store the vial for more than 28 days.
- Store unused portion of OMONTYS in the multiple use vials in the refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- Throw away the multiple use vial as directed by your healthcare provider if it has been more than 28 days since you first put a needle into the multiple use vial.

### **How should I prepare for an injection of OMONTYS?**

Your healthcare provider should show you how to give the correct dose of OMONTYS:

- Always keep an extra syringe and needle on hand.
- Follow your healthcare provider's instructions on how to measure your dose of OMONTYS.
- Only use disposable syringes and needles that your healthcare provider prescribed. If you do not use the correct syringe, you could inject too much or too little OMONTYS.
- Be sure you know which line on the syringe matches the dose of OMONTYS that your healthcare provider prescribed. Use a syringe and needle only one time and then dispose of them as instructed by your healthcare provider.

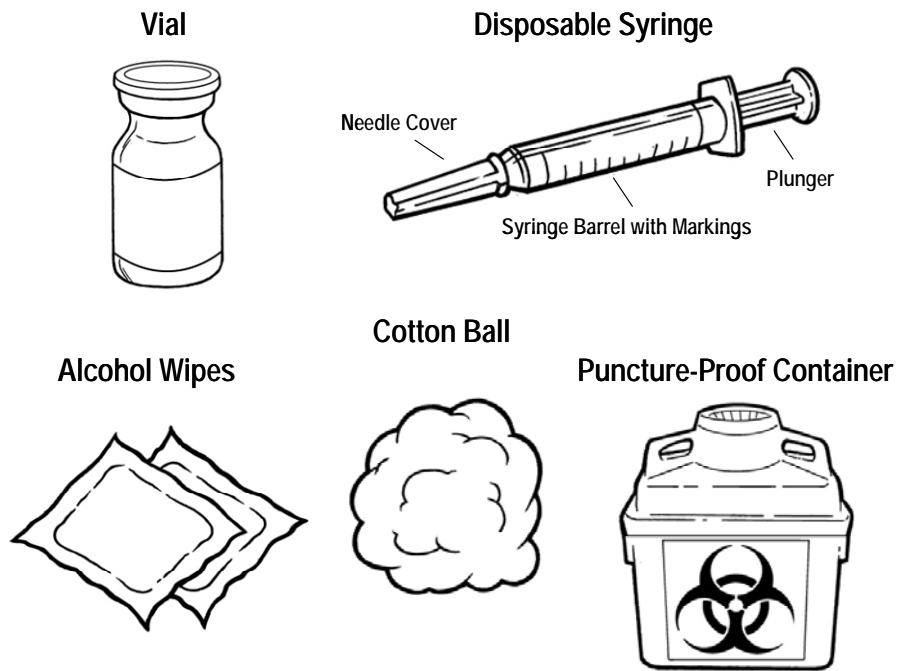
### **What do I need to know about the different types of OMONTYS vials?**

OMONTYS comes in two different types of vials.

- Single use vials
- Multiple use vials

### **Important: Follow these instructions exactly to help avoid infections.**

1. Prepare a clean, flat work surface.
2. Gather the supplies you will need for an injection (see Figure A). You will need:
  - OMONTYS vial and the correct disposable syringe and needle
  - Alcohol wipes and cotton ball or gauze
  - Puncture-proof disposable container for safely disposing of the needle and syringe after injection



**Figure A**

3. Take a carton of OMONTYS from the refrigerator.
4. Take the vial of OMONTYS out of its carton and place it on your flat work surface.
5. Check the date on the OMONTYS vial to be sure that the medicine has not expired.
6. Do not use a single use vial of OMONTYS more than one time.
7. Wash your hands well with soap and warm water before preparing the dose (see Figure B).



**Figure B**



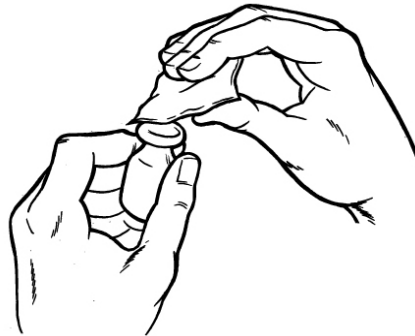
## Preparing the dose of OMONTYS

1. Remove the protective flip-off colored cap from the vial. Leave the rubber stopper on the vial (see Figure C).



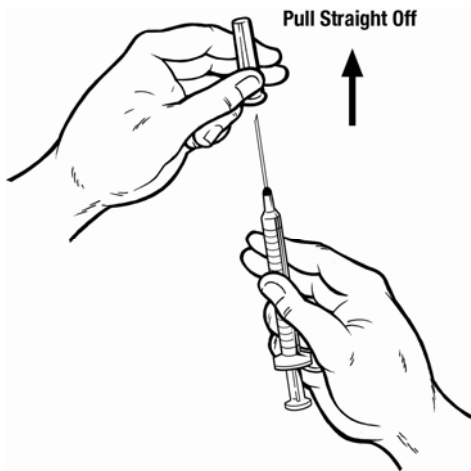
**Figure C**

2. Clean the rubber stopper with one alcohol wipe and put the vial on your flat work surface (see Figure D).



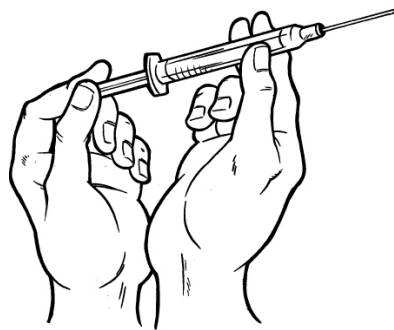
**Figure D**

3. Check the package containing the disposable syringe. If the syringe package is not damaged, open it and take out the syringe. If the package is damaged or has already been opened, do not use that syringe. Dispose of the syringe in the puncture-proof disposable container and get a new one.
4. Pull off the needle cover carefully (see Figure E). Always use the syringe and needle that has been recommended by your healthcare provider.



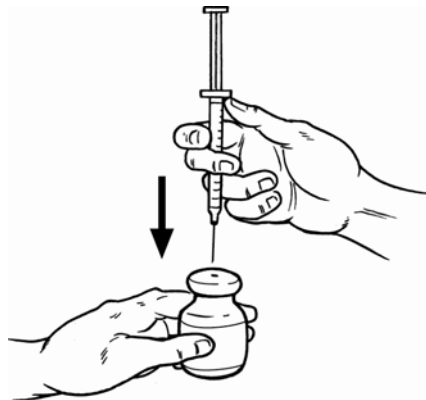
**Figure E**

5. Pull back on the plunger to the line on the syringe that matches the dose instructions of OMONTYS that your healthcare provider has given you (see Figure F).



**Figure F**

6. Keep the vial on your flat work surface and insert the needle straight through the center of the rubber stopper of the OMONTYS vial (see Figure G).



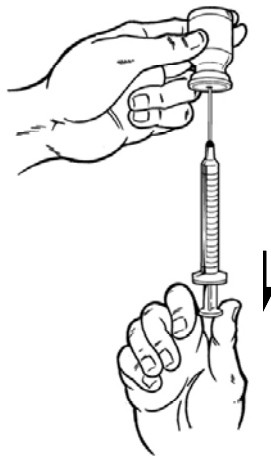
**Figure G**

7. Push down on the plunger of the syringe to inject the air from the syringe into the vial. The air injected into the vial will allow OMONTYS to be easily withdrawn into the syringe (see Figure H).



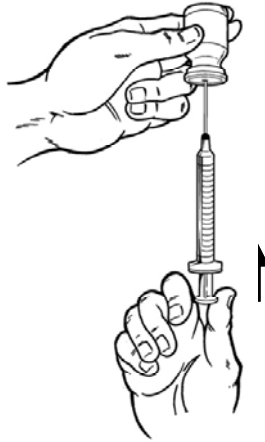
**Figure H**

8. Keep the needle inside the vial. Turn the vial upside down. Keep the vial upside down and make sure that the tip of the needle remains below the surface of the OMONTYS liquid. Slowly pull back on the plunger to fill the syringe with OMONTYS liquid to the number (mL or cc) on the syringe that matches the dose your healthcare provider has given you (see Figure I).



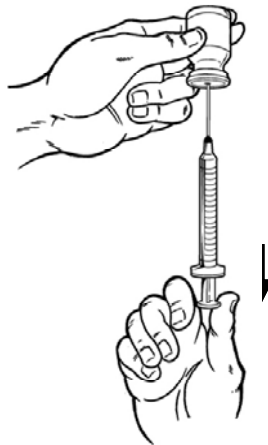
**Figure I**

9. Keep the needle in the vial. Check for air bubbles in the syringe. Small air bubbles are harmless, but too large an air bubble will not let you draw up the right amount of OMONTYS.
  - a. To remove air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe.
  - b. Slowly push on the plunger to push the air bubbles out of the syringe and back into the vial (see Figure J).



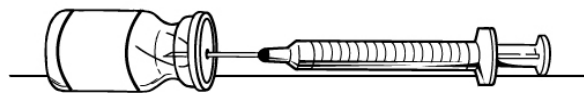
**Figure J**

- c. If you have pushed any liquid back into the vial, pull the plunger back slowly to the line on the syringe that matches your dose while making sure the tip of the needle is below the surface of the liquid. Check again for air bubbles. If there are still air bubbles, remove them by repeating Step 8 (see Figure K).



**Figure K**

10. Check again to make sure you have the right dose. Put the vial on its side with the needle still in it. This will keep the needle from touching anything before you use it (see Figure L).



**Figure L**

### Selecting and preparing the injection site:

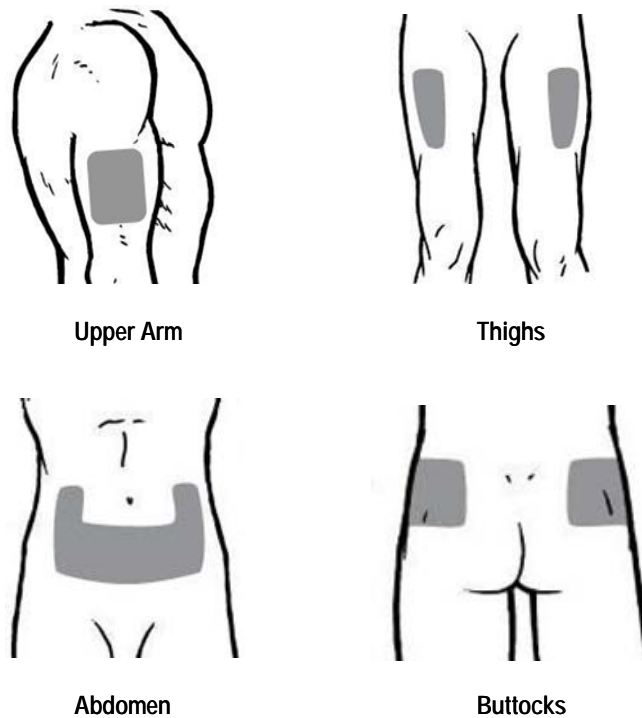
OMONTYS can be injected into your body using two different ways (routes) as described below. Follow your healthcare provider's instructions about how you should inject OMONTYS.

#### Subcutaneous Route:

OMONTYS can be injected under your skin. This is called a subcutaneous injection. When giving subcutaneous injections, follow your healthcare provider's instructions about changing the site for each injection.

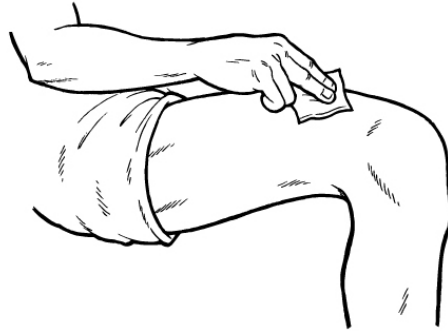
1. Choose one injection site from those shown in Figure M. The four sites where you can inject OMONTYS include:
  - The outer area of the upper arms
  - The front of the middle thighs
  - The abdomen (except for the two inch area around the navel)
  - The upper outer area of the buttocks

**Do not inject OMONTYS into an area on your body that is tender, red, bruised, hard, or that has scars or stretch marks.**



**Figure M**

2. Clean the injection site with an alcohol wipe. Do not touch this area again before giving the injection (see Figure N).



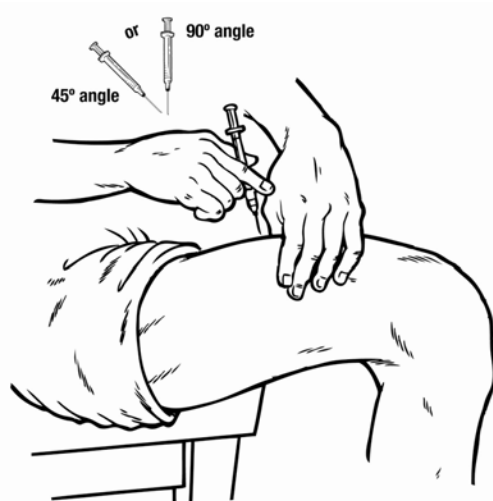
**Figure N**

3. Check that the correct amount of OMONTYS is in the syringe.
4. Remove the prepared syringe and needle from the vial of OMONTYS and hold it in the hand that you will use to inject the medicine. Use the other hand to pinch a fold of skin at the cleaned injection site. Do not touch the cleaned area of skin (see Figure O).



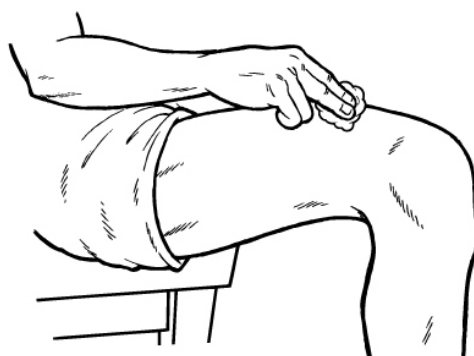
**Figure O**

5. Hold the syringe like you would hold a pencil. Insert the needle in a quick “dart like” motion. Insert the needle either at a slight angle (45 degree angle) or straight up and down (90 degree angle) into the skin. Inject the prescribed dose by pushing the plunger all the way down as directed by your healthcare provider, nurse or pharmacist (see Figure P).



**Figure P**

6. Pull the needle out of your skin. Do not recap the needle. Place a cotton ball or gauze over the injection site and press gently for several seconds. Do not rub (see Figure Q).



**Figure Q**

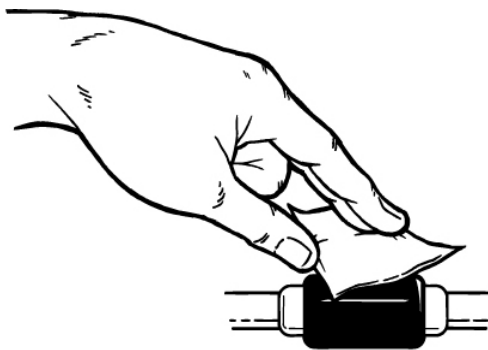
7. Dispose of the used syringe and needle as described below. Do not reuse the syringes and needles.

**Intravenous Route:**

- OMONTYS can be injected in your vein through a special access port on the dialysis tubing while dialysis is underway. This type of OMONTYS injection is called an intravenous injection. This route is usually for hemodialysis patients.
- If you have a hemodialysis vascular access, make sure it is working by checking it as your healthcare provider has shown you. Be sure to let your healthcare provider know right away if you are having any problems, or if you have any questions.

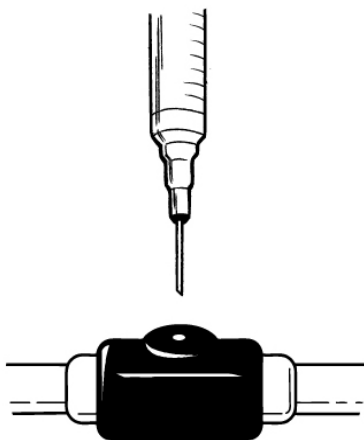
**Peritoneal Dialysis Patients: If you are a peritoneal dialysis patient, administer OMONTYS only by subcutaneous route under your skin (See Subcutaneous Route section above)**

1. Clean the venous port of the hemodialysis tubing with an alcohol wipe (see Figure R).



**Figure R**

2. Insert the needle of the syringe into the cleaned venous port and push the plunger all the way down to inject all the OMONTYS (see Figure S).



**Figure S**

3. Remove the syringe from the venous port. Do not recap the needle. Dispose of the syringe and needle as described below.

### **How should I dispose of vials, syringes and needles?**

**Do not reuse the single-use vials, syringes, or needles. Follow the required state and local laws for disposal of needles and syringes. Ask your healthcare provider or pharmacist about correct disposal of used vials, syringes and needles.**

Use the information below as a general guideline:



- Do not put the needle cover back on the needle.
- Place all used needle and syringes in the puncture-proof disposable container with a lid.
- Dispose of the full puncture-proof disposable container as instructed by your healthcare provider or pharmacist.
- Do not dispose of the vial, needle, syringe, or disposable container in the household trash or recycle.
- Do not use glass or clear plastic containers to dispose of the needle and syringe.
- Keep the puncture-proof disposable container out of the reach of children. Do not recycle.
- When the puncture-proof disposable container is full, tape around the cap or lid to make sure the cap or lid does not come off. Throw away the puncture-proof disposable container as instructed by your healthcare provider.

**Keep OMONTYS and all medicines out of reach of children.**

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

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Palo Alto, CA 94304

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**Instructions for Use**  
**OMONTYS® (O-mon-tis)**  
**(peginesatide)**  
**Injection**  
**Single Use Pre-filled Syringe**

Use these instructions if you or your caregiver has been trained to give OMONTYS injections at home. Do not give yourself the injection unless you have received training from your healthcare provider. If you are not sure about giving the injection or if you have questions, ask your healthcare provider for help.

Before reading these Instructions for Use, read the Medication Guide that comes with OMONTYS for the most important information you need to know.

**When you receive your OMONTYS pre-filled syringe, make sure that:**

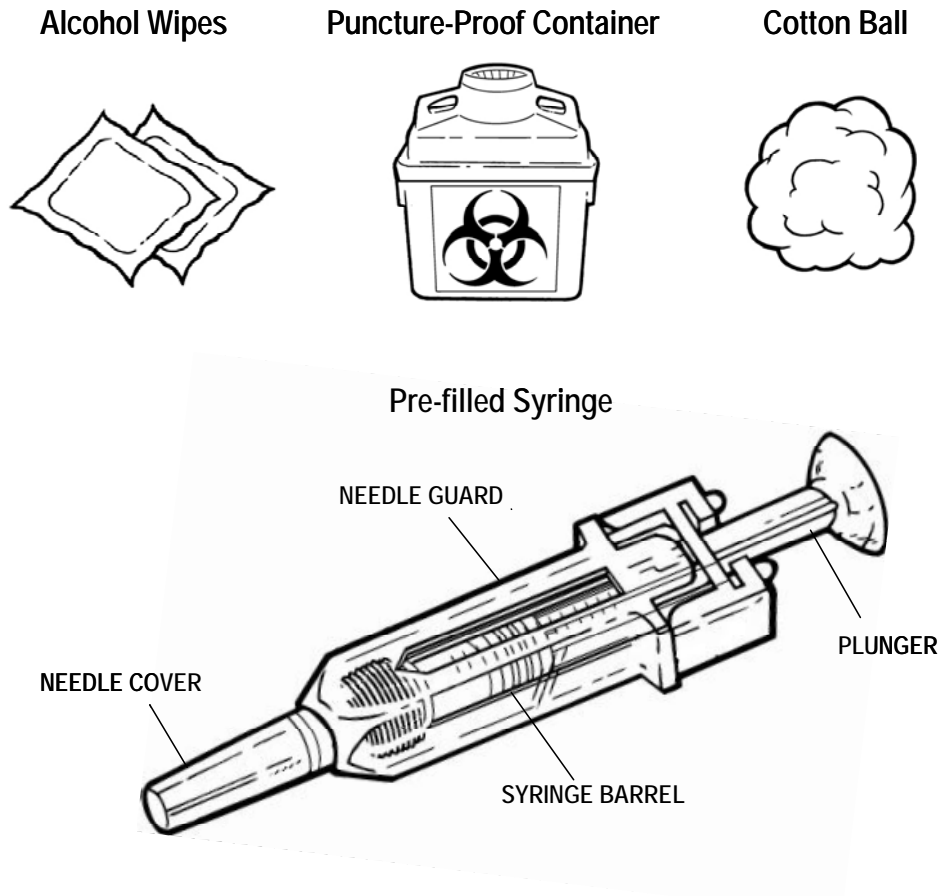
- The name OMONTYS appears on the carton and pre-filled syringe label.
- The tamper evident seal on the carton is not damaged. Do not use if the tamper evident seal on carton is broken or missing.
- OMONTYS is used before the expiration date on the pre-filled syringe label. Do not use OMONTYS on or after the expiration date on the label.
- The amount of OMONTYS on the pre-filled syringe label matches the amount prescribed (the number of mg (milligrams) per mL (milliliter)) by your healthcare provider.
- The OMONTYS liquid in the pre-filled syringe is clear and colorless to slightly yellow. Do not use OMONTYS if the liquid in the syringe looks discolored or cloudy, or if the liquid has lumps, flakes or particles.
- Store OMONTYS in the refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- Keep OMONTYS away from light. Store OMONTYS pre-filled syringes in their cartons until time of use.

**How should I prepare for an injection of OMONTYS?**

- Your healthcare provider should show you how to give the correct dose of OMONTYS.
- Use the pre-filled syringe only one time and dispose of it as instructed by your healthcare provider.

**Important: Follow these instructions exactly to help avoid infections.**

1. Prepare a clean, flat work surface.
2. Gather the supplies you will need for an injection (see Figure A). You will need:
  - OMONTYS pre-filled syringe
  - Alcohol wipes and cotton ball or gauze
  - Puncture-proof disposable container for safely disposing of the pre-filled syringe after injection



**Figure A**

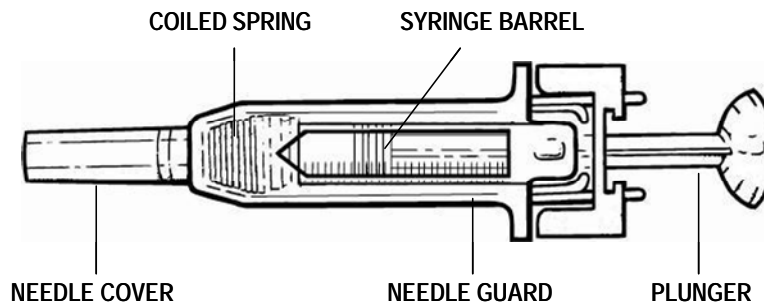
3. Take a carton of OMONTYS from the refrigerator.
4. Take the pre-filled syringe of OMONTYS out of its carton and place it on your flat work surface. Do not remove from wrapper at this point.
5. Use a pre-filled syringe only one time.
6. Wash your hands well with soap and warm water before preparing the dose (see Figure B).



**Figure B**

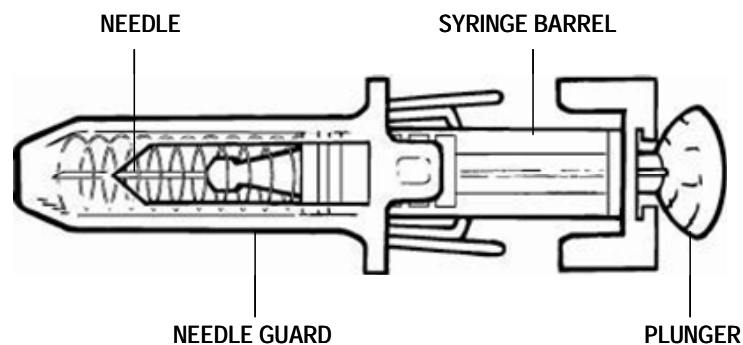
### Preparing the dose of OMONTYS

1. Open the wrapper and remove the pre-filled syringe from the tray.
  - Check to see that the needle cover is on and the needle guard is covering only the barrel of the syringe (see Figure C).



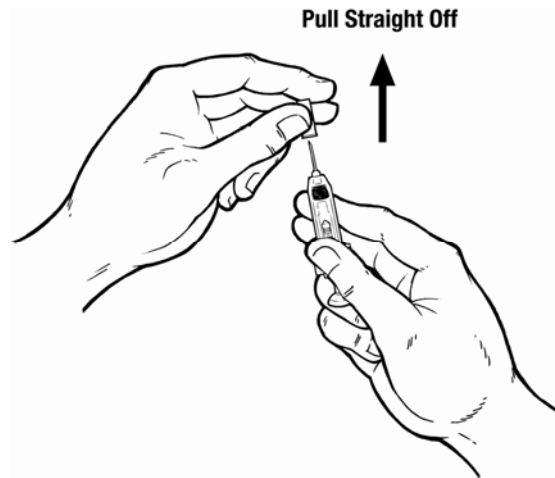
**Figure C**

- If the needle guard is covering the needle, then it has already been activated (see Figure D). **Do not** use that syringe. Dispose of the syringe in the puncture-proof disposable container. Use a new pre-filled syringe.



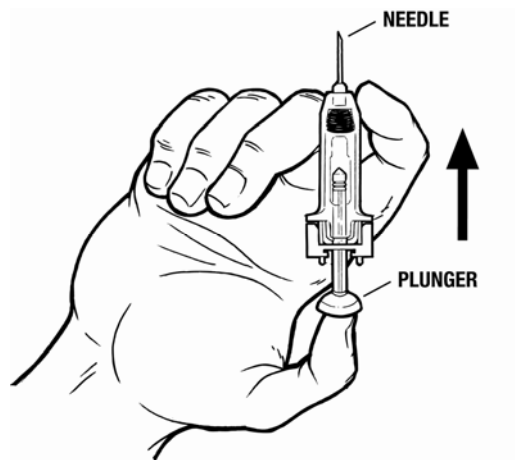
**Figure D**

2. Hold the syringe with the needle pointing up to prevent the OMONTYS from leaking out of the needle. Pull the needle cover straight off (see Figure E).



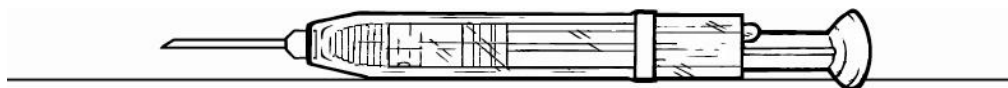
**Figure E**

3. Check the syringe for air bubbles. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe (see Figure F).



**Figure F**

4. When you put the syringe down on your flat work surface, be careful not to let the needle touch anything (see Figure G).



**Figure G**

## Selecting and preparing the injection site

OMONTYS can be injected into your body using two different ways (routes) as described below. Follow your healthcare provider's instructions about how you should inject OMONTYS.

### Subcutaneous Route:

OMONTYS can be injected under your skin. This is called a subcutaneous injection. When giving subcutaneous injections, follow your healthcare provider's instructions about changing the site for each injection.

1. Choose one injection site from those shown in Figure H. The four sites where you can inject OMONTYS include:
  - The outer area of the upper arms
  - The front of the middle thighs
  - The abdomen (except for the two-inch area around the navel)
  - The upper outer area of the buttocks

**Do not inject OMONTYS into an area on your body that is tender, red, bruised, hard, or that has scars or stretch marks.**

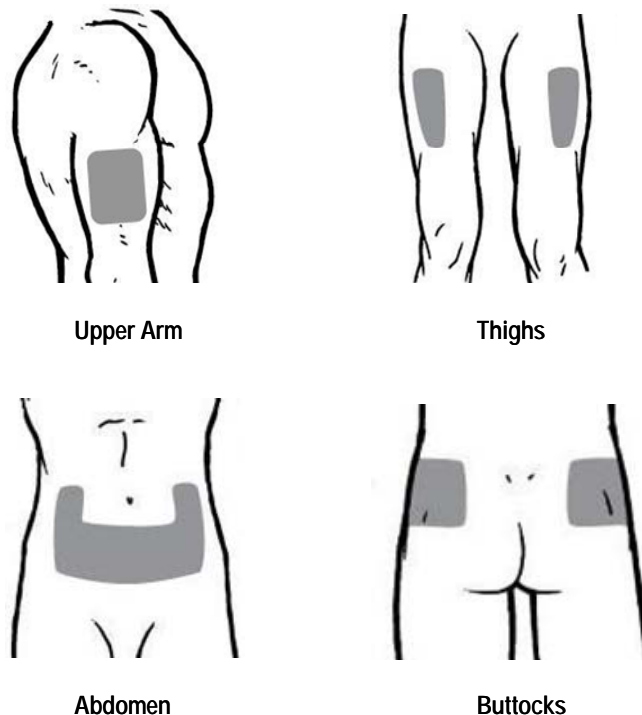
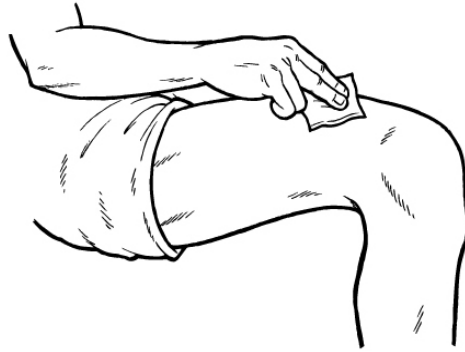


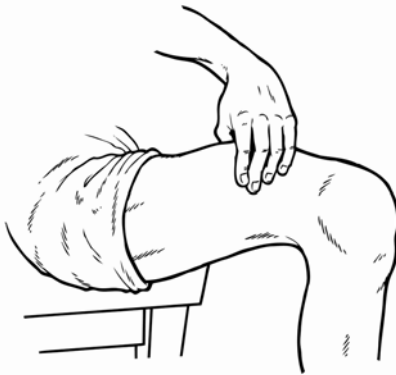
Figure H

2. Clean the injection site with an alcohol wipe. Do not touch this area again before giving the injection (see Figure I).



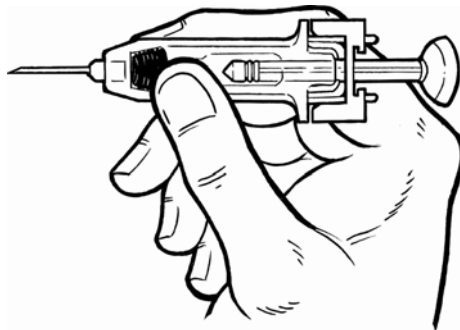
**Figure I**

3. Hold the pre-filled syringe in the hand that you will use to inject OMONTYS. Use the other hand to pinch a fold of skin at the cleaned injection site. Do not touch the cleaned area of skin (see Figure J).



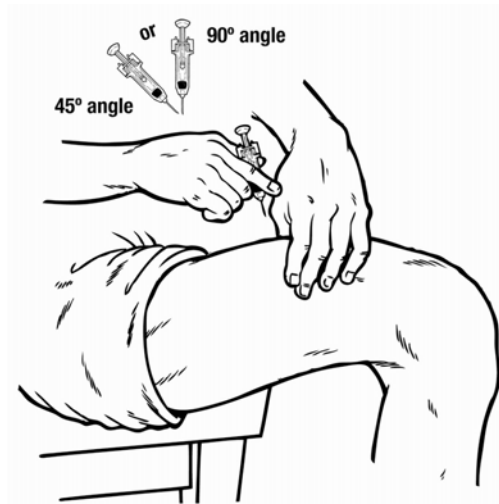
**Figure J**

4. Hold the pre-filled syringe like you would hold a pencil between the thumb and fore finger with the syringe resting on the middle finger (see Figure K).



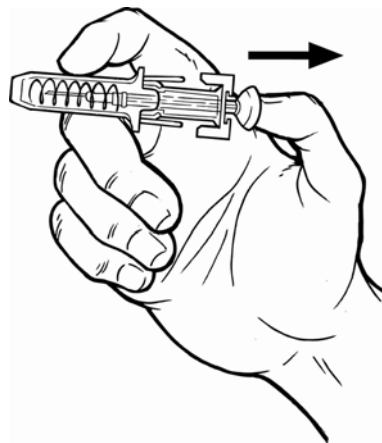
**Figure K**

5. Insert the needle in a quick “dart like” motion. Insert the needle either at a slight angle (45 degree angle) or straight up and down (90 degree angle) into the skin. Inject the prescribed dose subcutaneously as directed by your healthcare provider, nurse or pharmacist (see Figure L). The plunger must be fully depressed during injection in order for the needle guard (a safety mechanism to prevent accidental needle sticks) to activate.



**Figure L**

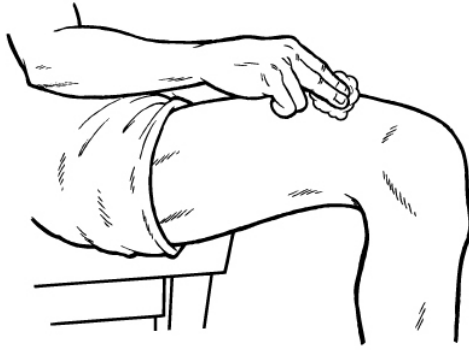
6. Take the needle out of the skin without releasing the plunger. Let go of the plunger after removing the needle from the skin to allow the syringe to move up until the entire needle is guarded and locks into place (see Figure M).



**Figure M**

7. Place a cotton ball or gauze over the injection site and press gently for several seconds. Do not rub (see Figure N).





**Figure N**

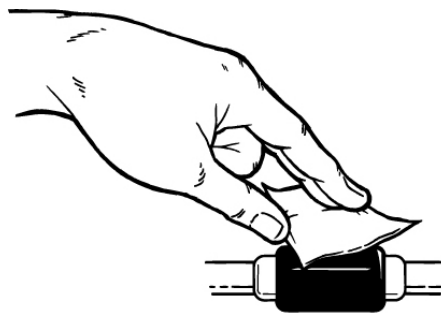
8. Dispose of the used pre-filled syringe as described below. Use the pre-filled syringe one time only.

**Intravenous Route:**

- OMONTYS can be injected in your vein through a special access port on the dialysis tubing while dialysis is underway. This type of OMONTYS injection is called an intravenous injection. This route is usually for hemodialysis patients.
- If you have a hemodialysis vascular access, make sure it is working by checking it as your healthcare provider has shown you. Be sure to let your healthcare provider know right away if you are having any problems, or if you have any questions.

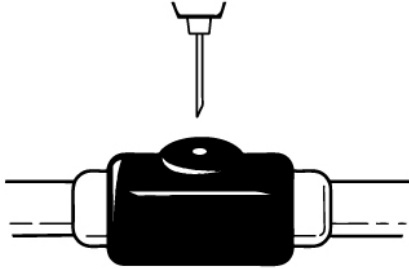
**Peritoneal Dialysis Patients: If you are a peritoneal dialysis patient, administer OMONTYS only by subcutaneous route under your skin (See subcutaneous route section above)**

1. Clean the venous port of the hemodialysis tubing with a new alcohol wipe (see Figure O).



**Figure O**

2. Insert the needle of the pre-filled syringe into the cleaned venous port and push the plunger all the way down to inject all the medicine (see Figure P). The plunger must be fully depressed during injection in order for the needle guard (a safety mechanism to prevent accidental needle sticks) to activate.



**Figure P**

3. Remove the syringe from the venous port without releasing the plunger. Then, let go of the plunger to allow the syringe to move up until the entire needle is guarded and locks into place.
4. Dispose of the used pre-filled syringe as described below. Use the pre-filled syringe one time only.

### **How should I dispose of pre-filled syringes?**

Do not reuse the single use pre-filled syringe. Follow the required state and local laws for disposal of needles and syringes. Ask your healthcare provider or pharmacist about correct disposal of used pre-filled syringes.

Use the information below as a general guideline:

- Do not put the needle cover back on the needle.
- Place all used pre-filled syringes in the puncture-proof disposable container with a lid.
- Dispose of the full puncture-proof disposable container as instructed by your healthcare provider or pharmacist.
- Do not dispose of the pre-filled syringe or disposable container in the household trash or recycle.
- Do not use glass or clear plastic containers to dispose of pre-filled syringes.
- Keep the puncture-proof disposable container out of the reach of children. Do not recycle.
- When the puncture-proof disposable container is full, tape around the cap or lid to make sure the cap or lid does not come off. Throw away the puncture-proof disposable container as instructed by your healthcare provider.

**Keep OMONTYS and all medicines out of reach of children.**

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

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