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Information for Patients

NEUMEGA[®]
[nu-meg<a]
(oprelvekin)

Rx only

This patient package insert contains information and directions for patients and their caregivers who are getting or giving injections of Neumega at home. You should read this patient information each time you pick up your prescription in case new information has been added. This patient package insert does not take the place of talking with your doctor or other healthcare provider. If you have any questions about your treatment with Neumega you should talk to your doctor.

What is Neumega?

Neumega is a medicine that stimulates your body to make platelets, which are a type of blood cell. Neumega is for people who have received certain types of chemotherapy and is used to help prevent the number of platelets circulating in the blood from dropping dangerously low. Too few platelets can cause serious problems and even death. Platelets are needed to help clot your blood when you are cut or injured. People with very low platelet counts are more likely to bruise and may not be able to control their bleeding if they are cut or injured. Platelets that have been donated by other people (platelet transfusions) are often given to patients with very low platelet counts. Neumega may reduce the need for platelet transfusions after chemotherapy. If your platelet levels are still too low after taking Neumega, your doctor may recommend that you receive a platelet transfusion.

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

Neumega may have side effects; some of these side effects may be serious. The most serious possible side effects of treatment with Neumega include:

- **Allergic Reactions**

Neumega can cause serious allergic reactions in some patients. Signs that you are having a serious allergic reaction include: swelling of your face, tongue or throat; difficulty

breathing, swallowing or talking; shortness of breath; wheezing; chest pain; a tightness in your throat; feeling lightheaded; loss of consciousness; confusion; drowsiness; rash; itching; hives; flushing and/or fever. You or your caregiver should call your doctor immediately if you develop any of these signs or symptoms.

- **Heart Problems**

Neumega can cause heart problems in some patients. If you feel like your heart is pounding, beating fast or skipping a beat, or you have chest pains or are short of breath, you should call your doctor immediately. If you have ever had heart problems, you should tell your doctor before you start treatment with Neumega.

If you are taking a water pill (diuretic), you should tell your doctor, because the diuretic can cause your body to lose potassium. This is very important, because Neumega can cause heart problems and these heart problems could be more serious when the potassium in your blood is too low. Your doctor will be checking your blood for the amount of potassium in it. If your potassium level is low, your doctor may prescribe a potassium replacement medication to correct it.

- **Water Weight Gain**

Neumega may cause you to retain water and gain weight from the extra fluid in your body. For some patients, water weight gain may cause serious problems that require medicine or hospitalization. A small amount of water weight gain will usually go away within several days after you stop taking Neumega. But, if you have a rapid weight gain over a few days, swelling of the legs and feet, dizziness, shortness of breath or chest pain, it could mean that you have a serious condition with fluid around the lungs and heart. If you have ever had heart failure or are taking medicine that may cause you to retain water, you should tell your doctor before you start treatment with Neumega.

- **Eye Problem**

Neumega can cause or worsen an eye problem called papilledema. Papilledema is swelling of the optic (eye) nerve. Papilledema can cause changes in your eyesight from blurred vision to blindness.

- **Children Receiving Neumega**

Because Neumega is approved only for use in adults, you should talk to your child's doctor about the reasons why Neumega has been prescribed for your child. You should talk to your child's doctor about the risks and side effects of using this medication in children. One of the side effects seen in children taking Neumega is a serious eye condition called papilledema which is a form of swelling of the nerve that enters the back of the eye. Many children may not show any signs of papilledema. If your child complains that they have a headache or are having difficulty seeing, call your child's doctor right away. Other side effects that have been seen in children are fast heartbeat, redness of the eye, changes to the heart, and changes to bones that can be seen on x-ray.

- **Stop taking Neumega and call your doctor or healthcare provider immediately if you develop any of these symptoms:**

- Shortness of breath or trouble breathing
- Chest pains
- Swelling in your face, hands, or feet
- Rapid weight gain over a few days
- You feel like your heart is pounding or beating out of your chest or skipping a beat, also referred to as palpitations
- Changes in your eyesight including blurred vision and blindness

Before you start taking Neumega, you should tell your doctor the names of all of the medications you are taking including prescription and non-prescription drugs, vitamins, and nutritional supplements. If you have any of the following conditions or medical problems, tell your doctor or healthcare provider:

- You are pregnant or planning to become pregnant
- Breast feeding
- You have heart problems
- You have kidney disease
- You have eye problems

Who should not take Neumega?

Do not take Neumega if you have ever had or think you have had an allergic reaction to Neumega. Talk to your doctor if you have any questions about this information.

What are the other possible side effects of Neumega?

The most common, but less serious side effects, are:

- Slight water weight gain
- Some swelling in the arms and/or legs
- Shortness of breath when walking or moving around
- Anemia (low red blood cell count)

These side effects may be caused by water retention. For most people, the water weight gain will go away a few days after the last injection of Neumega. Make sure you have read and understand the section called “**What is the most important information I should know about Neumega?**”, because many of these side effects could develop into a more serious condition.

Other side effects that you should tell your doctor about are:

- Blurred vision, headaches, or redness of the eyes
- Any swelling or bruising that doesn't go away in the location where you have injected Neumega

If you have any other problems, whether or not you think they are related to Neumega, you should call your doctor.

What important information do I need to know about taking Neumega at home?

To see if Neumega is working, your doctor will ask you to have blood tests done to measure the number of platelets in your body. After starting Neumega, it may take 10 to 21 days for your platelet numbers to increase. The amount of time it takes to increase the number of platelets varies from patient to patient. Neumega may not work for everyone and you may still need platelet transfusions or have bleeding even if you take Neumega as directed by your doctor. **You should always follow your doctor's instructions.**

If your doctor has recommended that you receive Neumega at home, then you and/or your caregiver should be instructed on how to prepare Neumega, how much Neumega to use, how to inject it, how often it should be injected, and how to dispose of the unused portions of each bottle. Do not inject Neumega until you are comfortable with the steps to prepare and inject Neumega at home.

It is important that you do not take any more or less of the amount of Neumega that your doctor prescribed. Too much Neumega might put you at risk for irregular heartbeats and water retention (including fluid around the heart and lungs). If you accidentally take too much Neumega, you should call your doctor immediately.

You should always change the site of your injections each day to avoid soreness at any one site. Your injections should be given about the same time each day. If you miss an injection on one day, you should not try to add it on the next day. Tell your doctor that you missed a dose and continue as usual with your next scheduled dose. The section “**How Do I Give Myself Neumega?**” gives you step-by-step instructions for preparing and injecting your dose of Neumega.

How Do I Give Myself Neumega?

Please read all the instructions carefully to be sure you understand the procedure before you prepare and give the injection.

Preparing the Neumega for Injection

1. First, make sure that you have all of the supplies that you will need:
 - a. Four alcohol wipes. [picture]
 - b. Two cotton balls. [picture]
 - c. One 1 mL (1 cc) syringe (plastic tube with lines on it) for giving the injection. [picture]

- d. Two needles. [picture]

One needle to use with the pre-filled syringe of Sterile Water for Injection, USP: 23 to 25 gauge, $\frac{3}{4}$ to 1 inch needle

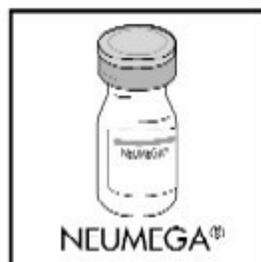
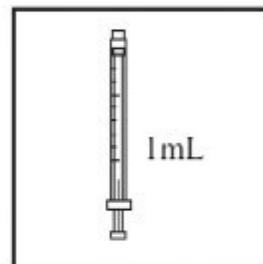
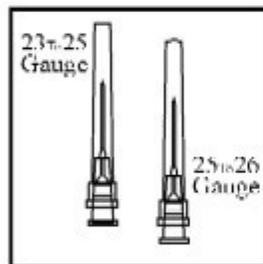
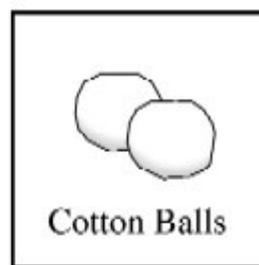
One needle to use with the 1 mL (1 cc) syringe: 25 to 26 gauge, $\frac{1}{2}$ to 1 inch needle

- e. A puncture-proof container (“Sharps Container”) for disposing of needles and syringes.

- f. One Neumega kit containing:

Bottle of Neumega powder. [picture]

Pre-filled syringe of Sterile Water for Injection, USP. [picture] (from this point on referred to as pre-filled syringe)



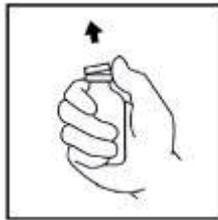
2. You must use a new bottle of Neumega powder and a new pre-filled syringe every time you give yourself a dose of Neumega.

Look for the expiration date printed on the Neumega bottle and pre-filled syringe. **Do not use** the Neumega powder or the pre-filled syringe if the current month and year is after the month and year on the bottle or pre-filled syringe; this means that the Neumega or pre-filled syringe have expired. Tell your doctor that the Neumega and/or the pre-filled syringe have expired and that you need replacements. If the Neumega powder and the pre-filled syringe have not expired, then continue with the steps that follow.

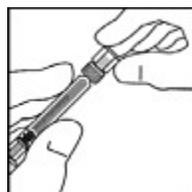
Wash your hands with soap and water. [picture]

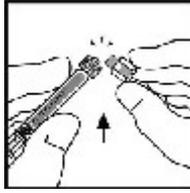


3. Pick up the bottle labeled “Neumega” and flip off the protective cap. [picture] Wipe the rubber stopper on the top of the bottle with a sterile alcohol wipe. Leave the wipe on top of the bottle. Place the vial upright on a clean, flat surface.

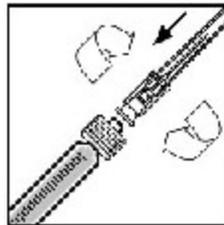


4. Remove the 23 to 25 gauge needle from its package, leaving the cap on the needle. Place the needle on the same clean, flat surface. Pick up the pre-filled syringe. To remove the tamper-resistant cap from the syringe tip, hold the syringe at an angle in one hand. [picture] With the other hand, move the tamper-resistant cap in an up and down motion until the seal is broken. [picture] The seal should break at the perforation marks and leave a portion of the white syringe tip in place. After the seal is broken, remove and discard the cap.





5. While still holding the pre-filled syringe, pick up the 23 to 25 gauge needle. With the cap still on this needle, attach it to the pre-filled syringe [picture] by turning the needle clockwise until completely secured. Remove and discard the cap of this needle by gently pulling it off, but do not touch the needle with your hand or let it touch anything else. It is important to keep this needle sterile in order to prevent infection.



6. Take the Neumega bottle and remove the alcohol wipe. Do not touch the cleaned rubber stopper with your hands. Holding the Neumega bottle with one hand, use the other hand to push the needle of the pre-filled syringe containing the Sterile Water for Injection, USP through the middle of the rubber stopper. Carefully aim the needle to the side of the Neumega bottle and press the plunger of the syringe **slowly**, so that the stream of Sterile Water for Injection, USP runs down the inside wall of the bottle. [picture]



7. After injecting all of the Sterile Water for Injection, USP from the syringe into the Neumega bottle, take the needle out of the rubber stopper. Dispose of this needle and syringe as described in [step 7](#) of the section “**Injecting Neumega**”. **Do not recap needle.**
8. **Gently swirl** the bottle until all of the Neumega powder has dissolved and the fluid in the bottle is clear. [picture] **Do not shake the bottle.** Shaking Neumega may damage the medicine so it does not work properly.



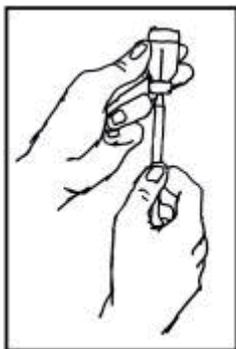
Check the fluid inside the bottle. It should be clear and colorless without any powder or specks. **Do not** inject the Neumega if the fluid is cloudy or colored or if you see any particles. Call your doctor, nurse or pharmacist for instructions on what to do with a bottle of Neumega that you cannot use.

You should use the Neumega mixed with the Sterile Water for Injection, USP as soon after mixing it as possible. Do not let more than three (3) hours go by between the time you mix the Neumega and the water, and the time that you use it. The mixed Neumega and Sterile Water for Injection, USP can be stored in the Neumega bottle for up to three (3) hours either at room temperature or in the refrigerator. Remember to keep the bottle out of the light. **Do not store the Neumega and Sterile Water for Injection, USP mixture in a syringe.**

9. After the Neumega powder is dissolved, wipe the rubber stopper on the top of the bottle again with a new sterile alcohol wipe, leaving the alcohol wipe on top.
10. Take the 1 mL (1 cc) syringe and the 25 to 26 gauge needle and remove them from their packages. Attach this needle to the 1 mL (1 cc) syringe as described in steps 4-6. This is the needle and syringe that you will use to inject the Neumega into your skin.

Fill the syringe with air by pulling the plunger back to the line or number on the syringe that your doctor or nurse has told you is the right one for the amount of Neumega that you are supposed to take.

11. Take the bottle of Neumega liquid and remove the alcohol wipe from the top. Do not touch the cleaned rubber stopper with your hands. Hold the bottle with one hand and push the needle through the center of the rubber stopper. Inject the air from the syringe into the bottle.
12. Turn the bottle and syringe upside down. Keep the tip of the needle in the fluid and slowly pull the plunger back [picture]. Stop when the fluid reaches the line or number that your doctor or nurse has told you is the right one for the amount of Neumega that you are supposed to take.



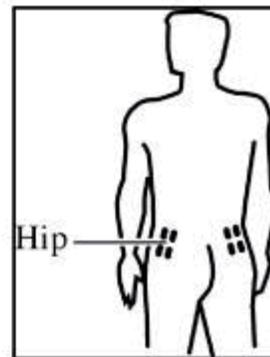
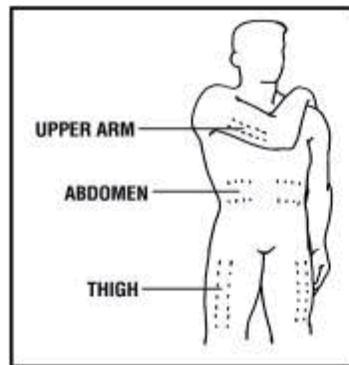
13. Check the syringe for bubbles. If you see bubbles in the syringe, push them back into the bottle by pushing in on the plunger. The fluid that is in the syringe should be clear and colorless, without any particles or bubbles.

Check to be sure that the fluid is still at the line or number that your doctor or nurse has told you is the right one for the amount of Neumega that you are supposed to take. If it is too little, pull the plunger back to the mark. If it is too much, push the plunger in to the mark. Once you are sure you have the right amount, you can go on to step 14.

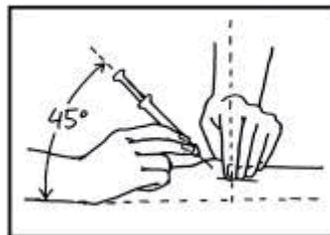
14. Take the needle out of the bottle. Hold the syringe with the needle pointing straight up and gently tap the side of the syringe with your fingers to bring remaining air bubbles to the top of the syringe.
15. Still holding the syringe and needle pointing up, gently press the plunger in a little to push any air out through the needle. If a small drop of fluid comes out, that's okay. **Do not recap needle.** Do not lay the syringe down or allow it to touch a surface.

Injecting Neumega

1. Neumega can be injected into the skin of your upper legs (thighs), your abdomen (stomach), your hip, or your upper arms if not self-injecting. [picture] You should inject the Neumega into one of these different places of your body every time you use it.



2. Once you have decided where you will inject yourself, use your free hand to clean the skin with an alcohol wipe.
3. Take the 1 mL (1 cc) syringe containing the Neumega. Hold the syringe like a dart between the thumb and first finger just above the place where the needle attaches to the syringe. With your other hand, pinch your skin with your thumb and forefinger. This mound of skin is the place where you will inject the Neumega. Push the needle into the skin at a 45-degree angle. [picture] Gently let go of the pinched skin with one hand and keep holding the needle in the skin with the other hand.



4. **Gently** pull back on the plunger with your free hand. If you see blood come into the syringe, do not inject the Neumega. If this happens, take the syringe out of your skin, and discard this needle and syringe in a puncture proof container as outlined below in [step 7](#) of this section. You will need to repeat all the above steps using a new bottle of Neumega, a new pre-filled syringe of Sterile Water for Injection, USP, a new 1 mL (1 cc) syringe, and new needles. Inject the Neumega at a new site.
5. If you do not see blood when you pull back the plunger, inject Neumega by slowly pushing the plunger all the way in.
6. Hold a cotton ball near the needle and pull the needle out of the skin. Press the cotton ball over the place where you made the injection for three to five seconds. **Do not rub the site.**
7. **Do not recap needles.** Dispose of the syringes with the needles on them into the puncture-proof container (“Sharps Container”). The “Sharps Container” is a special box or other container for disposal of syringes and needles that your doctor or pharmacist has provided for you.

Always keep the Sharps Container out of the reach of children.

Ask your doctor, nurse, or pharmacist for instructions on how to properly dispose of a full container. There may be special state and local laws for disposal of used needles and syringes.

Do not dispose of the Sharps Containers in household trash. Do not recycle.

How should I store Neumega?

The kit containing the bottle of powdered Neumega and the pre-filled syringe should be kept in a refrigerator. **Do not freeze.** The Neumega powder must be protected from light.

Every time you give yourself a dose of Neumega, you must use a new bottle of Neumega powder and a new pre-filled syringe of Sterile Water for Injection, USP. There is an expiration date printed on the bottle of the Neumega powder and on the pre-filled syringe. Do not use the Neumega or the pre-filled syringe if it is past the expiration date (month and year).

After you mix the Neumega with the Sterile Water for Injection, USP, you must use it as soon as possible. Do not let more than three (3) hours go by between the time you mix the Neumega and the water, and the time that you use it. The Neumega and Sterile Water for Injection, USP mixture can be stored in the Neumega bottle for up to three (3) hours either at room temperature or in the refrigerator. Remember to keep the bottle out of the light. **Do not store the Neumega and Sterile Water for Injection, USP mixture in a syringe.**

After you give yourself an injection of Neumega, discard the Neumega bottle and syringe with the needle attached into the “Sharps Container”.

Do not dispose of the Sharps Containers in household trash. Do not recycle.

General Advice About Prescription Medicines

Medicines are sometimes prescribed for purposes other than those listed here. If you have any questions or concerns about Neumega talk to your doctor. Do not use Neumega for a condition or person other than for whom it is prescribed.



This product's label may have been updated. For current package insert and further product information, please visit www.pfizer.com or call our medical communications department toll-free at 1-800-934-5556.



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