

Read all of this leaflet carefully before you start using NEUPOGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NEUPOGEN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

NEUPOGEN (Injection)

NEUPOGEN 30 MU Injection (in a pre-filled syringe)

NEUPOGEN 48 MU Injection (in a pre-filled syringe)

WHAT NEUPOGEN CONTAINS

NEUPOGEN syringes contain the active ingredient filgrastim.

Excipients for vials and pre-filled syringes: sorbitol, acetate, polysorbate 80, sodium, water for injection.

Each vial contains 30 MU of filgrastim per 1,0 ml.

Each pre-filled syringe contains 30 MU or 48 MU of filgrastim per 0,5 ml.

WHAT NEUPOGEN IS USED FOR

NEUPOGEN stimulates the bone marrow to produce more white blood cells. White cells are important as they help your body fight infection.

Your doctor has prescribed NEUPOGEN for you to help your body make more white blood cells.

NEUPOGEN is useful in several different conditions. Your doctor will tell why you are being treated with NEUPOGEN.

BEFORE USING NEUPOGEN

Before starting treatment take special care and make sure your doctor knows if you:

- have a liver or kidney condition,
- are suffering from other illnesses (especially if you think you may have an infection),
- have allergies.

NEUPOGEN must not be used if you are allergic to it or any of the inactive ingredients it contains.

You will need to have regular blood tests whilst being treated with NEUPOGEN to count the number of neutrophils and other white blood cells in your blood. This will tell your doctor how well the treatment is working and will also indicate if treatment needs to be continued.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while taking NEUPOGEN please consult your doctor, pharmacist or other healthcare professional for advice.

It is important to tell your doctor if you are pregnant, think you may be pregnant or plan to get pregnant.

You should not use NEUPOGEN if you are pregnant or breastfeeding your infant.

Taking NEUPOGEN with other medicines

If you are taking other medicines on a regular basis, including traditional or complementary medicines, using NEUPOGEN at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

NEUPOGEN should not be diluted with saline solutions.

NEUPOGEN vials and pre-filled syringes contain no preservatives and are for single dose use only.

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with NEUPOGEN. These medicines include

- lithium

- some chemotherapy medicines e.g. fluorouracil.

These medicines may be affected by NEUPOGEN or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

NEUPOGEN should not be used 24 hours before and 24 hours after having chemotherapy.

Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NEUPOGEN.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

HOW TO TAKE NEUPOGEN

NEUPOGEN is given once a day by injection, usually in to the tissue just under the skin. This is known as a subcutaneous injection.

Learning to give your own injections will mean that you will not have to wait at home for a nurse to call, nor will you have to go to the hospital or clinic every day to receive your injections.

You will need to have your injections at about the same time every day. The most suitable places for injection are:

- the back of the arms,
- the top of the thighs,
- the abdomen, except for the area around the navel.

It is better to change the injection site every day to avoid the risk of soreness at anyone site.

Always use NEUPOGEN exactly as your doctor tells you to. This medicine is given by injection, either through an intravenous infusion (drip) or into the tissue just under the skin. This is known as a subcutaneous (s.c.) injection. If you are receiving this medicine by s.c. injection, your doctor may suggest that you learn how to give yourself the injections. Your doctor or nurse will give you instructions on how to do this. Do not attempt to self-administer without this training. Some of the information you require is given at the end of this leaflet, but proper treatment of your disease requires close and constant co-operation with your doctor. The amount of NEUPOGEN you need will depend on the condition you are taking NEUPOGEN for and on your bodyweight.

Your doctor will prescribe the appropriate dose for your condition.

When and how does treatment with NEUPOGEN end?

Your doctor will tell you when to stop using NEUPOGEN. It is quite normal to have a number of courses of NEUPOGEN treatment.

Equipment required for administration

To give yourself a subcutaneous injection you will need the following items:

1. A new pre-filled syringe of NEUPOGEN.
2. Needle in needle guard.
3. Alcohol wipes.
4. A puncture-proof container for disposing of used syringes and needles safely.

What should I do when setting up to give myself a subcutaneous injection?

1. Try to self-inject at approximately the same time every day.
2. Remove your NEUPOGEN syringe from the refrigerator.
3. Check it is the medication your doctor prescribed (NEUPOGEN).
4. Check the dose that you have been prescribed.
5. Check the liquid has no discolouration, cloudiness or particles.
6. Check the expiry date on the syringe. Do NOT use if the date has expired.
7. Let the syringe stand for 30 minutes to reach room temperature.
8. Wash your hands thoroughly.
9. Find a comfortable, well-lit working place.
10. Place everything you need within easy reach: syringe, wipes and the disposal container.

How do I prepare my NEUPOGEN injection?

Follow these instructions to help avoid contamination and possible infection.

1. Set up the equipment you will need and remove the vial of NEUPOGEN from the refrigerator 20 to 30 minutes before the injection is due, to allow it to reach room temperature. Use each NEUPOGEN vial once only and DO NOT SHAKE THE VIAL.
2. Check that the syringe you are using is marked every tenth of a me (i.e. 0,1; 0,2 me, etc.) so

that you can accurately inject the prescribed dose. Use disposable syringes and needles, and use them once only.

3. Wash and dry your hands thoroughly, and find a clean, quiet place where you can inject undisturbed.
4. Flip the protective cap off the vial. Do NOT remove the rubber stopper.
5. Wipe the top of the rubber stopper with an alcohol swab.
6. With the needle cap on, carefully pull back on the plunger. This will draw air into the syringe. The amount of air should be the same as your NEUPOGEN dose.
7. Carefully remove the needle cap, taking care not to touch the exposed needle. Gently push the needle through the rubber top of the NEUPOGEN vial.
8. Carefully push the plunger down. The air injected into the vial will allow NEUPOGEN to be easily withdrawn from the vial into the syringe.
9. Turn the vial and syringe upside down. Make sure the tip of the needle is in the solution. Slowly pull back on the plunger to draw the correct dose of NEUPOGEN into the syringe.
10. Check the syringe for air bubbles. The air is harmless, but a large air bubble will reduce the NEUPOGEN dose. To remove the air bubbles, gently push the solution back into the vial and measure the correct dose of NEUPOGEN.
11. Check that the correct dose of NEUPOGEN has been drawn into the syringe. Remove the needle from the vial.

How do I give my injection?

1. Disinfect the skin by using an alcohol wipe and pinch the skin between the thumb and forefinger, without squeezing.
2. Insert the needle fully into the skin at an angle of approximately 45°. Pull slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and insert it in another place.
3. Inject the liquid slowly and evenly, always keeping the skin pinched.
4. After injecting the solution, remove the needle and release the skin. Disinfect the skin with a clean alcohol wipe.
5. Put the used syringe in the special disposal container.

Remember

Most people can learn to give themselves a subcutaneous injection, but if you are experiencing a lot of difficulty, please do not be afraid to ask for help and advice from your doctor or nurse.

Disposal of used syringes

- Do not put the cover back on used syringes.
- Put used syringes into the puncture-proof disposal container.
- Dispose of the full container as instructed by your doctor, nurse or pharmacist.

NEVER put used syringes into your normal household waste bin. If you take too much medicine or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

If you forget to take NEUPOGEN:

Do not take a double dose to make up for forgotten individual doses and discuss it with your doctor.

Do not share medicines prescribed for you with another person. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

POSSIBLE SIDE EFFECTS

NEUPOGEN can have side effects.

NEUPOGEN may cause bone and muscle pain. You may experience headache, backache or pain in the long bones of your arms and legs. Ask your doctor which medicine you can take to help with this. NEUPOGEN may also make it painful or difficult to pass urine. If this is a problem, speak to your doctor. You may experience redness, swelling or itching at the site of injection. If you notice a lump, swelling or bruising that does not go away, contact your doctor.

You may experience a serious, generalised allergy to NEUPOGEN, which could cause a rash over the whole body, shortness of breath, wheezing, feeling weak, fast pulse, or sweating. If you think you are having this type of reaction, stop your NEUPOGEN injection and get medical help *immediately*.

Other unwanted effects are headache, diarrhoea, nose-bleeding, hair thinning, joint pain and rash. You may develop an enlarged spleen or liver, loss of calcium from the bones and blood in the urine. Some chemical changes occur in the blood, but these will be detected on your routine blood tests. If you are concerned about these or any other unwanted effects talk to your doctor or pharmacist. It is also very important that you call your doctor if you think you may have an infection. There are many ways an infection may show itself. You should watch for a temperature of 37,8 °C or greater, chills or other signs of infection such as a rash, sore throat, diarrhoea, ear-ache, difficult or painful breathing or problems such as cough or wheezing. If you have a fever or any of these contact your doctor immediately and go straight to your hospital.

- **Others**

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. **Not all side effects reported for NEUPOGEN are included in this leaflet. Should your general health worsen while taking NEUPOGEN, consult your doctor, pharmacist or other health care professional for advice.**

STORAGE AND DISPOSAL INFORMATION

NEUPOGEN should be stored in the refrigerator at 2 – 8 °C. Accidental exposure to freezing temperature will not adversely affect the stability of NEUPOGEN. Always keep this medicine in the closed original pack.

- Keep this medicine out of the reach and sight of children.
- This medicine must not be used after the date (EXP) printed on the pack. Return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

PRESENTATION

NEUPOGEN (1 ml vials): Packs of 1 and 5.

NEUPOGEN 30 MU: (0,5 ml pre-filled syringes): Packs of 5.

NEUPOGEN 48 MU: (0,5 ml pre-filled syringes): Packs of 5.

IDENTIFICATION

NEUPOGEN 30 is a clear, colourless liquid, practically free from particles, supplied either in colourless glass vials with rubber stoppers or in colourless glass syringes with tip caps and plunger stoppers containing 30 million units, equivalent to 300 µg of filgrastim.

NEUPOGEN 48 is a clear, colourless liquid, practically free from particles, supplied in colourless glass syringes with tip caps and plunger stoppers containing 48 million units, equivalent to 480 µg of filgrastim.

REGISTRATION NUMBER

NEUPOGEN (1 ml vials): Z/30.4/190

NEUPOGEN 30 MU (0,5 ml pre-filled syringes): 32/30.4/0032

NEUPOGEN 48 MU (0,5 ml pre-filled syringes): 32/30.4/0033

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Registration: NEUPOGEN: September 1992

NEUPOGEN 30 MU and 48 MU: April 1998

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