ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. **NAME OF THE MEDICINAL PRODUCT**

Neulasta 6 mg solution for injection.

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

6 mg of pegfilgrastim in 0.6 ml (10 mg/ml*) solution for injection.

Pegfilgrastim is produced by r-DNA technology in *E. coli* (K12).

For excipients, see 6.1.

* Based on protein only. The concentration is 20 mg/ml if the PEG moiety is included.

3. **PHARMACEUTICAL FORM**

Solution for injection.

4. **CLINICAL PARTICULARS**

4.1 **Therapeutic indications**

Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

4.2 **Posology and method of administration**

One 6 mg dose (a single pre-filled syringe) of Neulasta is recommended for each chemotherapy cycle, administered as a subcutaneous injection approximately 24 hours following cytotoxic chemotherapy. There are insufficient data to recommend the use of Neulasta in children and adolescents under 18 years of age.

Neulasta therapy should be initiated and supervised by physicians experienced in oncology and/or haematology.

4.3 **Contraindications**

Hypersensitivity to pegfilgrastim, filgrastim, *E. coli* derived proteins, or to any excipients.

4.4 **Special warnings and special precautions for use**

The safety and efficacy of Neulasta have not been investigated in patients with acute leukaemia and should not be used in such patients receiving myelosuppressive chemotherapy.

The safety and efficacy of Neulasta have not been investigated in patients receiving high dose chemotherapy.

The onset of pulmonary signs such as cough, fever, and dyspnoea in association with radiological signs of pulmonary infiltrates, and deterioration in pulmonary function along with increased neutrophil count may be preliminary signs of Adult Respiratory Distress Syndrome (ARDS). In such circumstances Neulasta should be discontinued at the discretion of the physician and the appropriate treatment given.
There have been isolated cases of splenic rupture following administration of granulocyte-colony stimulating factors. A diagnosis of splenic rupture should be considered in patients reporting left upper abdominal pain or shoulder tip pain.

Treatment with Neulasta alone does not preclude thrombocytopenia and anaemia because full dose myelosuppressive chemotherapy is maintained on the prescribed schedule. Regular monitoring of platelet count and haematocrit is recommended.

Neulasta should not be used to increase the dose of cytotoxic chemotherapy beyond established dosage regimens.

Publications have reported that high leucocyte counts are disadvantageous prognostic factors in patients with sickle-cell anaemia. Therefore, physicians should exercise caution when administering Neulasta in patients with sickle cell disease, should monitor appropriate clinical parameters and laboratory status and be attentive to the possible association of Neulasta with splenic enlargement and vaso-occlusive crisis.

White blood cell counts of 100 x 10^9/l or greater have been observed in less than 1% of patients receiving Neulasta. No adverse events directly attributable to this degree of leucocytosis have been reported. Such elevation in White blood cells is transient, typically seen 24 to 48 hours after administration and is consistent with the pharmacodynamic effects of Neulasta.

The safety and efficacy of Neulasta for the mobilisation of blood progenitor cells in patients or healthy donors has not been adequately evaluated.

4.5 Interactions with other medicinal products and other forms of interaction

Due to the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, Neulasta should be administered approximately 24 hours after administration of cytotoxic chemotherapy. In clinical studies, Neulasta has been safely administered 14 days before chemotherapy. Concomitant use of Neulasta with any chemotherapy agent has not been evaluated in patients. In animal models concomitant administration of Neulasta and 5-fluorouracil (5-FU) or other antimetabolites has been shown to potentiate myelosuppression.

Possible interactions with other haematopoietic growth factors and cytokines have not been specifically investigated in clinical studies.

The potential for interaction with lithium, which also promotes the release of neutrophils, has not been specifically investigated. There is no evidence that such an interaction would be harmful.

The safety and efficacy of Neulasta have not been evaluated in patients receiving chemotherapy associated with delayed myelosuppression eg, nitrosoureas.

Specific interaction or metabolism studies have not been performed, however, clinical studies have not indicated an interaction of Neulasta with any other medicinal products.

4.6 Pregnancy and lactation

There are no adequate data from the use of pegfilgrastim in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

Neulasta should not be used during pregnancy unless clearly necessary.

There is no clinical experience with lactating women, therefore Neulasta should not be administered to women who are breast-feeding.
4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

In randomised clinical studies in patients with malignancy receiving Neulasta after cytotoxic chemotherapy, most adverse events were caused by the underlying malignancy or cytotoxic chemotherapy.

The most frequently reported study-drug related undesirable effect was bone pain (26%). Bone pain was generally of mild-to-moderate severity, transient and could be controlled in most patients with standard analgesics.

Reversible, mild to moderate elevations in uric acid, alkaline phosphatase and lactate dehydrogenase, with no associated clinical effects, occurred in 7%, 10% and 20% respectively of patients receiving Neulasta following cytotoxic chemotherapy. Nausea was observed in healthy volunteers (11%) and < 1% of patients receiving chemotherapy.

Very common (> 10%) and common (> 1%, < 10%) undesirable effects in clinical studies were:

<table>
<thead>
<tr>
<th>Body system</th>
<th>Undesirable effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculo skeletal</td>
<td><strong>Very common</strong></td>
</tr>
<tr>
<td></td>
<td>Skeletal pain</td>
</tr>
<tr>
<td>Application site</td>
<td><strong>Common</strong></td>
</tr>
<tr>
<td>Body as a whole</td>
<td>Injection site pain</td>
</tr>
<tr>
<td>CNS/PNS</td>
<td>Chest pain (non-cardiac), pain</td>
</tr>
<tr>
<td>Musculo-skeletal</td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Arthralgia, myalgia, and back, limb,</td>
</tr>
<tr>
<td></td>
<td>musculo-skeletal, and neck pain</td>
</tr>
</tbody>
</table>

4.9 Overdose

There is no experience with overdose of Neulasta in humans.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cytokines, ATC Code: L03AA13

Human granulocyte colony stimulating factor (G-CSF) is a glycoprotein, which regulates the production and release of neutrophils from the bone marrow. Pegfilgrastim is a covalent conjugate of recombinant human G-CSF (r-metHuG-CSF) with a single 20 kd polyethylene glycol (PEG) molecule. Pegfilgrastim is a sustained duration form of filgrastim due to decreased renal clearance. Pegfilgrastim and filgrastim have been shown to have identical modes of action, causing a marked increase in peripheral blood neutrophil counts within 24 hours, with minor increases in monocytes and/or lymphocytes. Similarly to filgrastim, neutrophils produced in response to pegfilgrastim show normal or enhanced function as demonstrated by tests of chemotactic and phagocytic function. As with other haematopoietic growth factors, G-CSF has shown in vitro stimulating properties on human endothelial cells. G-CSF can promote growth of myeloid cells, including malignant cells, in vitro and similar effects may be seen on some non-myeloid cells in vitro.

In two randomised, double-blind, pivotal studies in patients undergoing myelosuppressive chemotherapy consisting of doxorubicin and docetaxel, use of pegfilgrastim, as a single once per cycle dose, reduced the duration of neutropenia and the incidence of febrile neutropenia similarly to that...
observed with daily administrations of filgrastim (a median of 11 daily administrations). In the absence of growth factor support, this regimen has been reported to result in a mean duration of grade 4 neutropenia of 5 to 7 days, and a 30-40% incidence of febrile neutropenia. In one study (n=157), which used a 6mg fixed dose of pegfilgrastim the mean duration of grade 4 neutropenia for the pegfilgrastim group was 1.8 days compared with 1.6 days in the filgrastim group (difference 0.23 days, 95% CI -0.15, 0.63). Over the entire study, the rate of febrile neutropenia was 13% of pegfilgrastim-treated patients compared with 20% of filgrastim-treated patients (difference 7%, 95% CI of -19%, 5%). In a second study (n=310), which used a weight-adjusted dose (100 mcg/kg), the mean duration of grade 4 neutropenia for the pegfilgrastim group was 1.7 days, compared with 1.8 days in the filgrastim group (difference 0.03 days, 95% CI -0.36, 0.30). The overall rate of febrile neutropenia was 9% of patients treated with pegfilgrastim and 18% of patients treated with filgrastim (difference 9%, 95% CI of -16.8%, 1.1%).

5.2 Pharmacokinetic properties

After a single subcutaneous dose of pegfilgrastim, the peak serum concentration of pegfilgrastim occurs at 16 to 120 hours after dosing and serum concentrations of pegfilgrastim are maintained during the period of neutropenia after myelosuppressive chemotherapy. The elimination of pegfilgrastim is non-linear with respect to dose; serum clearance of pegfilgrastim decreases with increasing dose. Pegfilgrastim appears to be mainly eliminated by neutrophil mediated clearance, which becomes saturated at higher doses. Consistent with a self-regulating clearance mechanism, the serum concentration of pegfilgrastim declines rapidly at the onset of neutrophil recovery (see Figure 1).

Figure 1. Profile of Median Pegfilgrastim Serum Concentration and Absolute Neutrophil Count (ANC) in Chemotherapy Treated Patients After a Single 6 mg Injection

Due to the neutrophil-mediated clearance mechanism, the pharmacokinetics of pegfilgrastim is not expected to be affected by renal or hepatic impairment.

Limited data indicate that the pharmacokinetics of pegfilgrastim in elderly subjects (≥ 65 years) is similar to that in adults.

5.3 Preclinical safety data

Preclinical data from conventional studies of repeated dose toxicity revealed the expected pharmacological effects including increases in leucocyte count, myeloid hyperplasia in bone marrow, extramedullary haematopoiesis and splenic enlargement.
There were no adverse effects observed in offspring from pregnant rats given pegfilgrastim subcutaneously, but in rabbits pegfilgrastim has been shown to cause embryo/foetal toxicity (embryo loss) at low subcutaneous doses. In rat studies, it was shown that pegfilgrastim may cross the placenta. The relevance of these findings for humans is not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium acetate*,
Sorbitol (E420),
polysorbate 20,
water for injections.

*Sodium acetate is formed by titrating glacial acetic acid with sodium hydroxide.

6.2 Incompatibilities

Neulasta is incompatible with sodium chloride solutions.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at 2°C – 8°C (in a refrigerator).
Neulasta may be exposed to room temperature (not above 30°C) for a maximum single period of up to 72 hours. Neulasta left at room temperature for more than 72 hours should be discarded.

Do not freeze. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect the stability of Neulasta.

Keep the container in the outer carton, in order to protect from light.

6.5 Nature and contents of container

Single use Type I glass pre-filled syringe with a stainless steel needle.

Each carton contains 1 pre-filled syringe.

6.6 Instructions for use, handling and disposal

Neulasta is a sterile but unpreserved solution.

Before administration, Neulasta solution should be inspected for visible particles. Only a solution that is clear and colourless should be injected.

Excessive shaking may aggregate pegfilgrastim, rendering it biologically inactive.

Allow the pre-filled syringe to reach room temperature before injecting.

Any unused product or waste material should be disposed of in accordance with local requirements.
7. MARKETING AUTHORISATION HOLDER

Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10. DATE OF REVISION OF THE TEXT
ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION
A  MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORIZATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Amgen Inc.
One Amgen Center Drive
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CA 91320
USA

Name and address of the manufacturer responsible for batch release

Amgen Europe BV
Minervum 7061
NL-4817 ZK Breda
The Netherlands

B  CONDITIONS OF THE MARKETING AUTHORISATION

• CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristics, 4.2).

• OTHER CONDITIONS

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
1. NAME OF THE MEDICINAL PRODUCT

Neulasta 6 mg
Solution for injection
Pegfilgrastim

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled syringe contains 6 mg pegfilgrastim (10 mg/ml).

3. LIST OF EXCIPIENTS

Excipients: sodium acetate, sorbitol (E420), polysorbate 20, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 single use pre-filled syringe
0.6 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Avoid vigorous shaking.
Before use, read package leaflet carefully.

8. EXPIRY DATE

EXP.:
9. **SPECIAL STORAGE CONDITIONS**

Store at 2°C – 8°C (in a refrigerator).
Do not freeze.
Keep the container in the outer carton, in order to protect from light.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

12. **MARKETING AUTHORISATION NUMBER(S)**

EU/0/00/000/000

13. **MANUFACTURER’S BATCH NUMBER**

LOT:

14. **GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

15. **INSTRUCTIONS ON USE**
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</th>
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</thead>
<tbody>
<tr>
<td>BLISTER PACK WITH PRE-FILLED SYRINGE</td>
</tr>
<tr>
<td>1. NAME OF THE MEDICINAL PRODUCT</td>
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<tr>
<td>Neulasta 6 mg injection Pegfilgrastim</td>
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<tr>
<td>2. NAME OF THE MARKETING AUTHORISATION HOLDER</td>
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<tr>
<td>Amgen Europe B.V.</td>
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<tr>
<td>3. EXPIRY DATE</td>
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<tr>
<td>EXP.:</td>
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<tr>
<td>4. BATCH NUMBER</td>
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<tr>
<td>LOT:</td>
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</tbody>
</table>
**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**PRE-FILLED SYRINGE LABEL**

<table>
<thead>
<tr>
<th><strong>1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION</strong></th>
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</thead>
</table>
| Neulasta 6 mg  
| Pegfilgrastim                                    |

<table>
<thead>
<tr>
<th><strong>2. METHOD OF ADMINISTRATION</strong></th>
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<tr>
<th><strong>3. EXPIRY DATE</strong></th>
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<th><strong>4. BATCH NUMBER</strong></th>
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<tr>
<th><strong>5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT</strong></th>
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<tr>
<td>0.6 ml</td>
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</table>

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<tr>
<th><strong>6. OTHER</strong></th>
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<tbody>
<tr>
<td>Amgen Europe B.V.</td>
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</tbody>
</table>
B. PACKAGE LEAFLET
1. WHAT NEULASTA IS AND WHAT IT IS USED FOR

Neulasta is a solution for injection in a pre-filled syringe. Each pack contains 1 pre-filled syringe. Neulasta is a clear, colourless solution.

Neulasta contains the active substance pegfilgrastim. Pegfilgrastim is a protein produced by biotechnology in bacteria called *E. coli*. It belongs to a group of proteins called cytokines, and is very similar to a natural protein (granulocyte-colony stimulating factor) produced by your own body.

Neulasta is used to reduce the duration of neutropenia (low white blood cell count) and the occurrence of febrile neutropenia (low white blood cell count with a fever) which can be caused by the use of cytotoxic chemotherapy (medicines that destroy rapidly growing cells). White blood cells are important as they help your body fight infection. These cells are very sensitive to the effects of chemotherapy which can cause the number of these cells in your body to decrease. If white blood cells fall to a low level there may not be enough left in the body to fight bacteria and you may have an increased risk of infection.

Your doctor has given you Neulasta to encourage your bone marrow (part of the bone which makes blood cells) to produce more white blood cells that help your body fight infection.
2. **BEFORE YOU USE NEULASTA**

Neulasta is for use in adults aged 18 and over.

**Do not use Neulasta**

- if you are hypersensitive (allergic) to pegfilgrastim, filgrastim, *E. coli* derived proteins, or any of the other ingredients of Neulasta.

**Please tell your doctor**

- if you experience a cough, fever and difficulty breathing;
- if you have sickle cell anaemia; or
- if you get left upper abdominal pain or pain at the tip of your shoulder.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. Neulasta has not been tested in pregnant women. It is important to tell your doctor if you:

- are pregnant;
- think you may be pregnant; or
- plan to become pregnant.

You must stop breast feeding if you use Neulasta.

**Driving and Using Machines**

The effect of Neulasta on the ability to drive or use machinery is not known.

**Using other medicines**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. **HOW TO USE NEULASTA**

Always take Neulasta exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. The usual dose is one 6 mg subcutaneous injection (injection under your skin) using a pre-filled syringe and it should be given approximately 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

**Injecting Neulasta yourself**

Your doctor may decide that it would be more convenient for you to inject Neulasta yourself. Your doctor or nurse will show you how to inject yourself. Do not try to inject yourself if you have not been trained.

For further instructions on how to inject yourself with Neulasta, please read section 6 at the end of this leaflet.
If you use more Neulasta than you should

If you use more Neulasta than you should contact your doctor, nurse or pharmacist.

If you forget to inject Neulasta

If you have forgotten a dose of Neulasta, you should contact your doctor to discuss when you should inject the next dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Neulasta can have side effects.

A very common side effect (more than 10%) is bone pain. Your doctor will tell you what you can take to ease the bone pain.

Common side effects (more than 1%, less than 10%) include; pain at the site of the injection, headaches, and general aches and pains in the joints, muscles, chest, limbs, neck or back. An uncommon side effect (more than 0.1%, less than 1%) is nausea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING NEULASTA

Keep out of the reach and sight of children.

Store at 2°C – 8°C (in a refrigerator). You may take Neulasta out of the refrigerator and keep it at room temperature (not above 30°C) for no longer than 3 days. Once a syringe has been removed from the refrigerator and has reached room temperature (not above 30°C) it must either be used within 3 days or disposed of.

Do not freeze. Neulasta may be used if it is accidentally frozen for a single period of less than 24 hours.

Keep the container in the outer carton in order to protect from light.

The expiry date for Neulasta is printed on the box and on the syringe label. Do not use Neulasta after this date, the last day of the month shown.

Do not use Neulasta if you notice it is cloudy or there are particles in it.

Do not shake Neulasta vigorously as this may affect its activity.

6. INFORMATION FOR INJECTING YOURSELF

This section contains information on how to give yourself an injection of Neulasta. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. It is also important that you dispose of the syringe in a puncture-proof container. If you are not sure about giving yourself the injection or you have any questions, please ask your doctor or nurse for help.

How do I inject Neulasta myself?

You will need to give yourself the injection into the tissue just under the skin. This is known as a subcutaneous injection.
Equipment that you need

To give yourself a subcutaneous injection you will need:

- a pre-filled syringe of Neulasta;
- alcohol wipes; and
- a puncture-proof container so you can dispose of used syringes safely.

What should I do before I give myself a subcutaneous injection of Neulasta?

1. Take your Neulasta pre-filled syringe out of the refrigerator.
2. Do not shake the pre-filled syringe.
3. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
4. Check the appearance of Neulasta. It must be a clear and colourless liquid. If there are particles in it, you must not use it.
5. For a more comfortable injection, let the pre-filled syringe stand for 30 minutes to reach room temperature or hold the pre-filled syringe gently in your hand for a few minutes. Do not warm Neulasta in any other way (for example, do not warm it in a microwave or in hot water).
6. Wash your hands thoroughly.
7. Find a comfortable, well-lit place and put everything you need where you can reach it (the Neulasta pre-filled syringe, alcohol wipes and the puncture-proof container).

How do I prepare my Neulasta injection?

Before you inject Neulasta you must do the following:

1. Hold the syringe barrel and gently take the cover from the needle without twisting. Pull straight as shown in pictures 1 and 2. Do not touch the needle or push the plunger.
2. Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are, gently press the plunger until all the air (but none of the liquid) has been removed.
3. You can now use the pre-filled syringe.

Where should I give my injection?

The most suitable places to inject yourself are:

- the top of your thighs; and
- the abdomen, except for the area around the navel.

If someone else is injecting you, they can also use the back of your arms.
How do I give my injection?

1. Disinfect your skin by using an alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it.

2. Put the needle fully into the skin at an angle of about 45°.

3. 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 re-insert it in another place.

4. Inject the liquid slowly and evenly, always keeping your skin pinched.

5. After injecting the liquid, remove the needle and let go of your skin.

6. Only use each syringe for one injection. Do not use any Neulasta that is left in the syringe.

Disposed of used syringes

- Do not put the cover back on used needles.
- Put used syringes into the puncture-proof container and keep it out of the reach and sight of children.
- Dispose of the full puncture-proof container as instructed by your doctor, nurse or pharmacist.
- Never put the syringes that you have used into your normal household rubbish bin.

Remember

If you have any problems, please do not be afraid to ask your doctor or nurse for help and advice.

Further information

If you want more information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved on