

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Kineret 100 mg solution for injection in a pre-filled syringe.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe contains 100 mg of anakinra* per 0.67 ml (150 mg/ml).

* Human interleukin-1 receptor antagonist (r-metHuIL-1ra) produced in *Escherichia coli* cells by recombinant DNA technology.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection) in a pre-filled syringe.

Clear, colourless-to-white solution for injection that may contain some product-related translucent-to-white amorphous particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Kineret is indicated for the treatment of the signs and symptoms of rheumatoid arthritis in combination with methotrexate, in patients with an inadequate response to methotrexate alone.

4.2 Posology and method of administration

The recommended dose of Kineret is 100 mg administered once a day by subcutaneous injection. The dose should be administered at approximately the same time each day.

For patient convenience, Kineret is supplied ready for use in a pre-filled syringe. The instructions for use and handling are given in section 6.6.

Alternating the injection site is recommended to avoid discomfort at the site of injection.

Kineret treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis.

Elderly patients (≥ 65 years)

No dose adjustment is required. Posology and administration are the same as for adults 18 to 64 years of age.

Children and adolescents (< 18 years)

There are insufficient data to recommend the use of Kineret in children and adolescents under 18 years of age.

Hepatic impairment

No dose adjustment is required.

Renal impairment

No dosage adjustment is needed for patients with mild renal impairment (CL_{cr} 50 to 80 ml/minute). In the absence of adequate data, Kineret should be used with caution in patients with moderate renal impairment (CL_{cr} 30 to 50 ml/minute). Kineret should not be used in patients with severe renal impairment ($CL_{cr} < 30$ ml/minute) (see section 4.3).

4.3 Contraindications

Hypersensitivity to the active substance, any of the excipients or to *E. coli* derived proteins.

Kineret should not be used in patients with severe renal impairment ($CL_{cr} < 30$ ml/minute) (see section 4.2).

4.4 Special warnings and precautions for use

Allergic reactions

Allergic reactions associated with administration of Kineret during clinical trials were rare. The majority of these reactions were maculopapular or urticarial rashes. If a severe allergic reaction occurs, administration of Kineret should be discontinued and appropriate treatment initiated.

The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

Serious infections

Kineret has been associated with an increased incidence of serious infections (1.8%) vs. placebo (0.7%). For a small number of patients with asthma, the incidence of serious infection was higher in Kineret-treated patients (4.5%) vs. placebo-treated patients (0%). The safety and efficacy of Kineret in patients with chronic infections have not been evaluated.

Physicians should exercise caution when administering Kineret to patients with a history of recurring infections or with underlying conditions which may predispose them to infections.

Neutropenia

Administration of Kineret was associated with neutropenia ($ANC < 1.5 \times 10^9/l$) in 2.4% of patients compared with 0.4% of placebo patients. None of these patients had serious infections associated with the neutropenia.

Kineret treatment should not be initiated in patients with neutropenia ($ANC < 1.5 \times 10^9/l$). It is recommended that neutrophil counts be assessed prior to initiating Kineret treatment, and while receiving Kineret, monthly during the first 6 months of treatment and quarterly hereafter. In patients who become neutropenic ($ANC < 1.5 \times 10^9/l$) the ANC should be monitored closely and Kineret treatment should be discontinued.

Immunosuppression

The impact of treatment with Kineret on pre-existing malignancy has not been studied. Therefore the use of Kineret in patients with pre-existing malignancy is not recommended.

Vaccinations

In a placebo-controlled clinical trial (n = 126), no difference was detected in anti-tetanus antibody response between the Kineret and placebo treatment groups when a tetanus/diphtheria toxoid vaccine was administered concurrently with Kineret. No data are available on the effects of vaccination with other inactivated antigens in patients receiving Kineret.

No data are available on either the effects of live vaccination or on the secondary transmission of infection by live vaccines in patients receiving Kineret. Therefore, live vaccines should not be given concurrently with Kineret.

Elderly patients (≥ 65 years)

A total of 635 patients ≥ 65 years of age, including 131 patients ≥ 75 years of age, were studied in clinical trials. No overall differences in safety or effectiveness were observed between these patients and younger patients. Because there is a higher incidence of infections in the elderly population in general, caution should be used in treating the elderly.

Concurrent Kineret and TNF antagonist treatment

Concurrent administration of Kineret and etanercept has been associated with an increased risk of serious infections and neutropenia compared to etanercept alone. This treatment combination has not demonstrated increased clinical benefit.

The concurrent administration of Kineret and etanercept or other TNF antagonists is not recommended (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Interactions between Kineret and other medicinal products have not been investigated in formal studies. In clinical trials, interactions between Kineret and other medicinal products (including nonsteroidal anti-inflammatory drugs, corticosteroids, and DMARDs) have not been observed.

Concurrent Kineret and TNF antagonist treatment

In a clinical trial with patients receiving background methotrexate, patients treated with Kineret and etanercept were observed to have a higher rate of serious infections (7%) and neutropenia than patients treated with etanercept alone and higher than observed in previous trials where Kineret was used alone. Concurrent Kineret and etanercept treatment has not demonstrated increased clinical benefit.

The concurrent use of Kineret with etanercept or any other TNF antagonist is not recommended (see section 4.4).

For information on vaccinations see section 4.4.

4.6 Pregnancy and lactation

There are no adequate data from the use of Kineret in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).

The use of Kineret in pregnant women is not recommended.

Women of child-bearing potential must use effective contraception during treatment.

It is not known whether anakinra is excreted in human milk. The use of Kineret in women who are breast-feeding is not recommended.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

In all placebo-controlled studies, the most frequently reported adverse event with Kineret was injection site reaction (ISRs), which was mild to moderate in the majority of patients. The most common reason for withdrawal from study in Kineret-treated patients is injection site reaction. The subject incidence of serious adverse events at the recommended dose of Kineret (100 mg/day) is comparable with placebo (7.1% compared with 6.5% in the placebo group). The incidence of serious infection was higher in Kineret-treated patients compared with patients receiving placebo (1.8% vs. 0.7%). Neutrophil decreases occurred more frequently in patients receiving Kineret compared with placebo.

MedDRA Organ System	Frequency	Undesirable Effect
Blood and lymphatic system disorders	Common ($\geq 1/100$ to $< 1/10$)	Neutropenia
Nervous system disorders	Very common ($\geq 1/10$)	Headache
Skin and subcutaneous tissue disorders	Very common ($\geq 1/10$)	Injection site reaction
Infections and infestations	Common ($\geq 1/100$ to $< 1/10$)	Serious infections requiring hospitalisation

Injection site reactions

The most common and consistently reported treatment-related adverse events associated with Kineret were ISRs. The majority (95%) of ISRs were reported as mild to moderate. These were typically characterised by 1 or more of the following: erythaema, ecchymosis, inflammation, and pain. At a dose of 100 mg/day, 71% of patients developed an ISR compared to 28% of the placebo treated patients, which was typically reported within the first 4 weeks of therapy. The median duration of the above mentioned typical symptoms was 14 to 28 days. The development of ISRs in patients who had not previously experienced ISRs was uncommon after the first month of therapy.

Serious infections

The incidence of serious infections in the studies conducted at the recommended dose (100 mg/day) was 1.8% in Kineret treated patients and 0.7% in placebo-treated patients. In observations up to 3 years, the serious infection rate remained stable over time. The infections observed consisted primarily of bacterial events such as cellulitis, pneumonia, and bone and joint infections. Most patients continued on study drug after the infection resolved. There were no on-study deaths due to serious infectious episodes.

In clinical studies and post-marketing experience, rare cases of opportunistic infections have been observed and included fungal, mycobacterial, bacterial, and viral pathogens. Infections have been noted in all organ systems and have been reported in patients receiving Kineret alone or in combination with immunosuppressive agents.

Neutropenia

In placebo-controlled studies with Kineret, treatment was associated with small reductions in the mean values for total white blood count and absolute neutrophil count (ANC). Neutropenia (ANC < 1.5 x 10⁹/l) was reported in 2.4% patients receiving Kineret compared with 0.4% of placebo patients.

Malignancies

Rheumatoid arthritis (RA) patients may be at a higher risk (on average 2-3 fold) for the development of lymphoma. In clinical trials, whilst patients treated with Kineret had a higher incidence of lymphoma than the expected rate in the general population, this rate is consistent with rates reported in general for RA patients.

In clinical trials, the crude incidence rate of malignancy was the same in the Kineret-treated patients and the placebo-treated patients and did not differ from that in the general population. Furthermore, the overall incidence of malignancies was not increased during 3 years of patient exposure to Kineret.

Immunogenicity

In clinical trials, up to 3% of adult patients tested seropositive at least once during the study for antibodies capable of neutralising the biologic effects of anakinra. The occurrence of antibodies was typically transient and not associated with clinical adverse reactions or diminished efficacy. In addition, in a clinical trial 6% of paediatric patients tested seropositive at least once during the study for antibodies capable of neutralising the biologic effects of anakinra.

4.9 Overdose

No dose-limiting toxicities were observed during clinical trials in rheumatoid arthritis patients.

In studies of sepsis, 1,015 patients received Kineret at doses up to 2 mg/kg/hour over a 72 hour treatment period. The adverse event profile from these studies show no overall difference from that seen in the rheumatoid arthritis studies.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Immunosuppressants, ATC code: L04AC03

Anakinra neutralises the biologic activity of interleukin-1 α (IL-1 α) and interleukin-1 β (IL-1 β) by competitively inhibiting their binding to interleukin-1 type I receptor (IL-1RI). Interleukin-1 (IL-1) is a pivotal pro-inflammatory cytokine mediating many cellular responses including those important in synovial inflammation.

IL-1 is found in the plasma and synovial fluid of patients with rheumatoid arthritis, and a correlation has been reported between IL-1 concentrations in the plasma and the activity of the disease. Anakinra inhibits responses elicited by IL-1 *in vitro*, including the induction of nitric oxide and prostaglandin E₂ and/or collagenase production by synovial cells, fibroblasts, and chondrocytes.

Clinical data

The safety and efficacy of anakinra in combination with methotrexate have been demonstrated in patients with varying degrees of disease severity.

A clinical response to anakinra generally appeared within 2 weeks of initiation of treatment and was sustained with continued administration of anakinra. Maximal clinical response was generally seen within 12 weeks after starting treatment.

Combined anakinra and methotrexate treatment demonstrates a statistically and clinically significant reduction in the severity of the signs and symptoms of rheumatoid arthritis in patients who have had an inadequate response to methotrexate alone (38% vs. 22% responders as measured by ACR₂₀ criteria). Significant improvements are seen in the pain, tender joint count, physical function (HAQ score), acute phase reactants and in the patient's and physician's global assessment.

X-ray examinations have been undertaken in one clinical study with anakinra. These have shown no deleterious effect on joint cartilage.

Immunogenicity

See section 4.8.

5.2 Pharmacokinetic properties

The absolute bioavailability of anakinra after a 70 mg SC bolus injection in healthy subjects (n = 11) is 95%. The absorption process is the rate-limiting factor for the disappearance of anakinra from the plasma after SC injection. In subjects with RA, maximum plasma concentrations of anakinra occurred at 3 to 7 hours after SC administration of anakinra at clinically relevant doses (1 to 2 mg/kg; n = 18); the terminal half-life ranged from 4 to 6 hours. In RA patients, no unexpected accumulation of anakinra was observed after daily SC doses for up to 24 weeks.

The influence of demographic covariates on the pharmacokinetics of anakinra was studied using population pharmacokinetic analysis encompassing 341 patients receiving daily SC injection of anakinra at doses of 30, 75, and 150 mg for up to 24 weeks. The estimated anakinra clearance increased with increasing creatinine clearance and body weight. Population pharmacokinetic analysis demonstrated that the mean plasma clearance value after SC bolus administration was approximately 14% higher in men than in women and approximately 10% higher in subjects < 65 years than in subjects ≥ 65 years. However, after adjusting for creatinine clearance and body weight, sex and age were not significant factors for mean plasma clearance.

5.3 Preclinical safety data

Anakinra had no observed effect on the fertility, early development, embryo-foetal development, or peri- and postnatal development in the rat at doses up to 100 times the human dose. No effects on embryo-foetal development in the rabbit were observed at doses 100 times the human dose.

In a standard battery of tests designed to identify hazards with respect to DNA, anakinra did not induce bacterial or mammalian cell gene mutations. Neither did anakinra increase the incidence of chromosomal abnormalities or micronuclei in bone marrow cells in mice. Long-term studies have not been performed to evaluate the carcinogenic potential of anakinra. Data from mice over expressing IL-1ra and IL-1ra mutant knock-out mice, did not indicate an increased risk of tumour development.

A formal toxicologic and toxicokinetic interaction study in rats revealed no evidence that Kineret alters the toxicologic or pharmacokinetic profile of methotrexate.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate
Sodium chloride
Disodium edetate
Polysorbate 80
Sodium hydroxide
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Store in the original container in order to protect from light.

For the purpose of ambulatory use, Kineret may be removed from the refrigerator for 12 hours at temperature not above 25°C, without exceeding the expiry date. At the end of this period, the product must not be put back in the refrigerator and must be disposed of.

6.5 Nature and contents of container

0.67 ml of solution for injection in a pre-filled syringe (Type I glass) with a plunger stopper (bromobutyl rubber) in pack sizes of 1, 7 or 28.

Not all pack sizes may be marketed.

The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex). See section 4.4.

6.6 Special precautions for disposal and other handling

Kineret is a sterile unpreserved solution. For single use only.

Do not shake. Allow the pre-filled syringe to reach room temperature before injecting.

Before administration, visually inspect the solution for particulate matter and discolouration. Only clear, colourless-to-white solutions that may contain some product-related translucent-to-white amorphous particles should be injected.

The presence of these particles does not affect the quality of the product.

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

7. MARKETING AUTHORISATION HOLDER

Biovitrum AB (publ)
SE-112 76 Stockholm
Sweden

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/02/203/001 – 1-pack
EU/1/02/203/002 – 7-pack
EU/1/02/203/003 – 28-pack

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8 March 2002
Date of latest renewal: 20 March 2007

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu/>.

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Kineret 100 mg solution for injection in a pre-filled syringe Anakinra

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Kineret is and what it is used for
2. Before you use Kineret
3. How to use Kineret
4. Possible side effects
5. How to store Kineret
6. Further information

1. WHAT KINERET IS AND WHAT IT IS USED FOR

Kineret (an immunosuppressive agent) is a type of cytokine that is used to treat rheumatoid arthritis. Cytokines are proteins made by your body that co-ordinate communication between cells and help control cell activity. In rheumatoid arthritis, your body produces too much of a cytokine called interleukin-1. This results in harmful effects such as swelling and tissue damage.

Normally, your body produces a protein that blocks the harmful effects of interleukin-1. In rheumatoid arthritis your body does not produce enough of this blocking protein. The active substance of Kineret is anakinra produced by DNA technology using the micro-organism *E. coli* and works in the same way as your natural blocking protein.

Kineret is used to treat the signs and symptoms of rheumatoid arthritis in combination with another medicine called methotrexate. Kineret is for patients whose response to methotrexate on its own is not good enough to control the rheumatoid arthritis.

2. BEFORE YOU USE KINERET

Kineret is for use in adults only (age 18 years and over).

Do not use Kineret:

- if you are allergic (hypersensitive) to Kineret (anakinra) or to any of the other ingredients in Kineret;
- if you are allergic to other products that are produced by DNA technology using the micro-organism *E. coli*;
- if you have severe renal impairment (kidney damage).

Contact your doctor immediately:

- if you get a rash all over your body, shortness of breath, wheezing, fast pulse or sweating after your Kineret injection. These may be signs that you are allergic to Kineret.

Take special care with Kineret

Discuss with your doctor:

- if you have a history of recurring infections, or if you suffer from asthma. Kineret may worsen these conditions;
- if you have cancer. Your doctor will have to decide if you can still be given Kineret;
- if you require vaccinations. You must not be given live vaccines while being treated with Kineret;
- if you know you are allergic to latex. The needle cover on the pre-filled syringe contains a derivative of latex.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Kineret 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 get pregnant.

It is not known whether anakinra is excreted in human milk. You must stop breast-feeding if you use Kineret.

Important information about some of the ingredients of Kineret

This medicinal product contains less than 1 mmol sodium (23 mg) per 100 mg dose, i.e. essentially 'sodium-free'.

3. HOW TO USE KINERET

Always use Kineret exactly as your doctor has told you. Kineret must be injected under your skin (subcutaneous) once daily. You should try to have the injection at the same time each day.

Injecting Kineret yourself

Your doctor may decide that it would be more convenient for you to inject Kineret 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 instructions on how to inject yourself with Kineret, please read the section at the end of this leaflet.

If you use more Kineret than you should

You should have no serious problems if you accidentally take more Kineret than you need. However, you should contact your doctor, nurse or pharmacist if this does happen. If you feel unwell in any way you should contact your doctor or nurse immediately.

If you forget to use Kineret

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Kineret may cause side effects, although not everybody gets them.

Very common side effects (seen in more than 1 in 10 people who take Kineret) are:

- Redness, swelling, bruising or itching at the injection site. This is generally mild to moderate and is more common at the start of your treatment.
- Headaches.

Common side effects (seen in more than 1, but less than 10 in 100 people taking Kineret) are:

- Neutropenia (low white blood cell count) determined after a blood test. This might increase the risk of you getting an infection. Symptoms of infection might include a fever or a sore throat.
- Serious infections such as pneumonia (a chest infection) or infections of the skin. Symptoms might include a fever, a cough or redness and tenderness of the skin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. HOW TO STORE KINERET

Keep out of the reach and sight of children.

Do not use Kineret after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Store in original carton in order to protect from light.

Do not use Kineret if you think it has been frozen. Once a syringe has been removed from the refrigerator and has reached room temperature (up to 25°C) it must either be used within 12 hours or disposed of.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Kineret contains

The active substance is anakinra. Each pre-filled syringe contains 100 mg of anakinra.

The other ingredients are:

- sodium citrate, sodium chloride, disodium edetate, polysorbate 80 and sodium hydroxide and water for injections.

What Kineret looks like and contents of the pack

Kineret is a clear, colourless-to-white solution for injection and is supplied ready for use in a pre-filled syringe. It may contain some translucent-to-white particles of protein. The presence of these particles does not affect the quality of the product.

Pack sizes of 1, 7 or 28 pre-filled syringes.
Not all pack sizes may be marketed.

Manufacturer:

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

Marketing Authorisation Holder:

Biovitrum AB (publ)
SE-112 76 Stockholm
Sweden

This leaflet was last approved in

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu/>

Information on how to give yourself an injection of Kineret

This section contains information on how to give yourself an injection of Kineret. It is important that you do not try to give yourself the injection unless you have received training from your doctor, nurse or pharmacist. If you have questions about how to inject, please ask your doctor, nurse or pharmacist for assistance.

How do you or the person injecting you, use the Kineret pre-filled syringe?

You will need to give yourself an injection at the same time every day. Kineret is injected just under the skin. This is called a subcutaneous injection.

Equipment:

To give yourself a subcutaneous injection you will need:

- a new pre-filled syringe of Kineret; and
- alcohol wipes or similar.

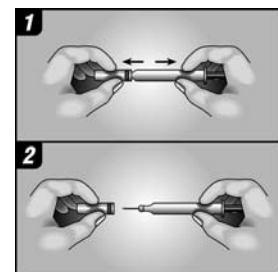
What should you do before you give yourself a subcutaneous injection of Kineret?

1. Take your Kineret 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 Kineret. It must be a clear, colourless-to-white solution. There may be some translucent-to-white particles of protein in the solution. The presence of these particles does not affect the quality of the product. The solution should not be used if it is discoloured or cloudy, or if any particles other than translucent-to-white particles are present.
5. For a more comfortable injection, leave at room temperature for approximately 30 minutes or hold the pre-filled syringe gently in your hand for a few minutes. **Do not** warm Kineret in any other way (for example, do not warm it in a microwave or in hot water).
6. **Do not** remove the cover from the syringe until you are ready to inject.
7. **Wash your hands thoroughly.**
8. Find a comfortable, well-lit, clean surface and put all the equipment you need within reach.

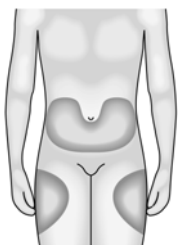
How do you prepare your Kineret injection?

Before you inject Kineret 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. You may notice a small air bubble in the pre-filled syringe. You do not have to remove the air bubble before injecting. Injecting the solution with the air bubble is harmless.
3. You can now use the pre-filled syringe.



Where should you give your injection?



The most suitable places to inject yourself are:

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

Change the place that you inject each time so you don't become sore in one area. If someone else is injecting for you, they can also use the back of your arms.

How do you give your injection?

1. Disinfect your skin by using the alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it.
2. Put the needle fully into the skin as shown by your nurse or doctor.

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.

Remember

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

Disposing of used syringes

- Do not put the cover back on used needles.
- Keep used syringes out of reach and sight of children
- Never put the pre-filled syringes that you have used into your normal household rubbish bin.
- The used pre-filled syringe should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.