

Package leaflet: Information for the patient

Fuzeon 90 mg/ml powder and solvent for solution for injection Enfuvirtide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fuzeon is and what it is used for
2. What you need to know before you use Fuzeon
3. How to use Fuzeon
4. Possible side effects
5. How to store Fuzeon
6. Contents of the pack and other information
7. **Step-by-step guide to injecting Fuzeon**

1. What Fuzeon is and what it is used for

What Fuzeon is

Fuzeon contains the active substance enfuvirtide and belongs to a group of medicines called 'antiretrovirals'.

What Fuzeon is used for

Fuzeon is used for the treatment of Human Immune deficiency Virus (HIV) - in combination with other antiretroviral medicines in patients infected with HIV.

- Your doctor has prescribed Fuzeon to help control your HIV infection.
- Fuzeon is not a cure for HIV infection.

How Fuzeon works

HIV attacks cells in your blood called CD4 or T-cells. The virus needs to make contact with, and get inside these cells in order for the virus to multiply. Fuzeon helps by preventing this.

2. What you need to know before you use Fuzeon

Do not use Fuzeon if

- you are allergic to enfuvirtide or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before using Fuzeon.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Fuzeon if:

- you have ever had any lung problems
- you have ever had any kidney problems
- you have chronic hepatitis B or C or another liver disease - you are more likely to get serious liver problems while using this medicine

Signs of previous infections

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to a recovery of the body's immune system. This improvement enables the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

Signs of autoimmune disorders

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Patients with liver disease

Patients with chronic hepatitis B or C and treated with anti-HIV therapy are at an increased risk for serious liver problems. Speak with your doctor if you have a history of liver disease.

Bone disease (osteonecrosis)

Some patients taking combination anti-HIV medicines may develop a bone disease called osteonecrosis. This is where the bone tissue dies because the blood supply has been lost (death of bone tissue caused by loss of blood supply to the bone).

- Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these signs please inform your doctor.
- Risk factors for developing this disease include: how long you have been taking anti-HIV medicines, whether you take corticosteroids, how much alcohol you drink, how well your immune system works and being overweight.

Passing HIV to others

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your physician the precautions needed to avoid infecting other people.

Other medicines and Fuzeon

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. Fuzeon has been shown not to interact with your other anti-HIV medicines or rifampicin (an antibiotic).

Fuzeon with food and drink

You can use Fuzeon with or without food. However, you still need to follow the instructions given in the package leaflets for the other medicines you are taking.

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not use Fuzeon unless specifically told to by your doctor.
- Do not breast-feed if you have HIV because HIV may be passed on to the baby.

Driving and using machines

Fuzeon has not been tested for its effect on your ability to drive a car or use tools or machines. If you feel dizzy while using Fuzeon do not drive or use any tools or machines.

Fuzeon contains sodium

Fuzeon contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially 'sodium-free'.

3. How to use Fuzeon

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to prepare and inject Fuzeon

Fuzeon must be given as an injection just below the skin – called a 'subcutaneous' injection. Section 7 tells you how to prepare Fuzeon and how to give yourself an injection.

How much to use

- The recommended dose is 90 mg twice a day for adults and adolescents (16 years and older).
- This is given as a 1 ml injection just below the skin.
- It is best to use Fuzeon at the same time each day.
- Try and space the doses evenly apart at times which are good for you – for example, first thing in the morning and then in the early evening.

See further instructions on how to use Fuzeon at the end of this leaflet (see Section 7). There you will find instructions on how to prepare Fuzeon and how to give yourself an injection.

If you use more Fuzeon than you should

If you use more Fuzeon than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to use Fuzeon

- If you forget to use a dose, use it as soon as you remember it. However if it is less than 6 hours before you are going to take your next regular dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Fuzeon

- Keep using your medicine until your doctor tells you to stop. If you stop and there is a gap in your treatment this may speed up the chances of the HIV in your blood becoming resistant to Fuzeon. This is less likely if you use it regularly and without gaps in treatment.
- The HIV virus in your blood may eventually become resistant to Fuzeon. If this happens, your blood levels of virus may begin to rise. This is when your doctor may decide to no longer keep treating you with Fuzeon. Your doctor should discuss this with you at that time.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Fuzeon and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- Allergic reaction (hypersensitivity) – signs may include: rash, a high temperature or chills, feeling or being sick, sweating or shaking.

This side effect is rare (affects less than 1 in 1,000 people). These signs do not definitely mean you are allergic to this medicine.

Tell your doctor if you get side effects where the injection is given

The most common side effects (affect more than 1 in 10 people), are problems at the place on your body where you have the injection. You will probably have one or more of the following mild to moderate reactions:

- redness
- swelling
- feeling itchy
- bruises
- hardened skin or bumps
- pain, feeling sore or tender

These reactions can appear in the first week of treatment and usually only last for up to 7 days. They generally do not get worse after this time. If you have any of these reactions do not stop using Fuzeon, but talk to your doctor about any concerns you have.

Reactions may be worse when injections are repeated in the same place on the body. They may also be worse when the injection is given deeper than intended (for example, into a muscle). Rarely, you may get an infection at a place where an individual injection was given. To reduce the risk of infection, it is important that you follow the instructions provided in Section 7.

Fuzeon can cause a build-up of a type of protein, called amyloid, under the skin at the injection site. This may feel like lumps under the skin. Please contact your doctor if this occurs.

Other possible side effects

Very common (*affects more than 1 in 10 people*)

- diarrhoea
- feeling sick
- weight loss
- pain and feeling numb in hands, feet or legs.

Common (*affects less than 1 in 10 people*)

- pneumonia
- ear infection
- swollen glands (lymph nodes)
- inflamed eye (conjunctivitis)
- flu or 'flu-like' symptoms
- inflamed sinuses
- nasal congestion
- anorexia
- heart burn
- inflamed pancreas
- decreased appetite
- diabetes,
- nightmares
- feeling dizzy

- shaking (tremor)
- feeling anxious or irritated
- not being able to concentrate
- decreased sensation
- acne
- redness of the skin
- eczema
- dry skin
- warts
- muscle pain
- kidney stones
- feeling weak
- blood in the urine
- changes shown in blood tests (increased blood fat)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Fuzeon

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label of either the Fuzeon or the Water for Injections Vials after EXP. The expiry date refers to the last day of that month.

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

Once the solution has been prepared for your injection it should be used immediately. If it is not used straight away it must be stored in a refrigerator (2°C – 8°C) and used within 24 hours.

Do not use this medicine if you notice any particles in the powder or the solution once the water for injection has been added. Also do not use the Water for Injections if you see any particles in the vial or if the water is cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fuzeon contains

- The active substance is enfuvirtide. Each vial contains 108 mg enfuvirtide. After reconstitution with the solvent provided 1 ml of reconstituted solution contains 90 mg enfuvirtide.
- The other ingredients are:

Powder

Sodium Carbonate, anhydrous

Mannitol

Sodium Hydroxide
Hydrochloric Acid

Solvent
Water for Injections

What Fuzeon looks like and contents of the pack

Fuzeon powder and solvent for solution for injection comes in a carton containing:

60 vials of Fuzeon
60 vials of Water for Injections that is used to reconstitute the Fuzeon powder
60 3 ml syringes
60 1 ml syringes
180 alcohol swabs.

This pack provides you with everything you need to prepare and take your Fuzeon for 30 days of injections.

Marketing Authorisation Holder

Roche Products Limited
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Welwyn Garden City
AL7 1TW
United Kingdom

The Manufacturer responsible for batch release is

Roche Pharma AG
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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

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Tel: +44 (0) 1707 366000

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7. STEP-BY-STEP GUIDE TO INJECTING FUZEON

Always use this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

What to do if you are left-handed

The pictures in this leaflet show people who are right-handed. If you are left-handed, do what comes naturally to you. You will probably find it most comfortable to:

- hold the syringe in your left hand and
- hold the vial between the thumb and forefinger of your right hand.

When to have someone to help you

It may be difficult at first to inject in some places, such as the upper arms. If you need help, ask your partner, a friend, or a family member. You may like to ask someone to come with you to an injection training session with your doctor or nurse.

Your syringes

The syringes supplied with this medicine have a coloured needle protector. This is attached to the needle and covers it after use to lower the risk of the needle accidentally pricking another person. Although these syringes have this safety feature, it is still important that you dispose of used syringes properly. Follow the instructions given to you by your doctor, pharmacist or nurse.

Safety Tips

- Wash your hands well. This will reduce the risk of bacterial infections.
- Once you have washed your hands, do not touch anything except the medicine and supplies.
- When handling the syringe, do not touch the needle.
- Do not touch the tops of the vials once they have been cleaned with alcohol swabs.
- Do not use opened materials. Make sure none of the items in your kit have been opened before use.
- Never use or share used needles.
- Never use a syringe with a bent or damaged needle.
- Never mix your medicine with tap water.
- Never inject your medicine with other injectable medicines.
- Only inject Fuzeon under the skin ('subcutaneous').
- Do not inject Fuzeon into your veins ('intravenously') or into your muscles ('intramuscularly').

- Dispose of all used materials into your special waste container with a lid. Do this even if the vials contain unused amounts of medicine or Water for Injections as these are for single use only. Talk to your doctor, pharmacist or nurse if you have any questions about safe disposal of these items.

The following is a basic, step-by-step guide to injecting your medicine.

Step A: Getting Started

1. Get the following things together:
 - One vial of Fuzeon (glass container with white powder inside)
 - One vial of Water for Injections (glass container with clear and colourless liquid inside)
 - One 3 ml syringe (larger syringe) with a 25 mm needle
 - One 1 ml syringe (smaller syringe) with a 13 mm needle
 - Three alcohol swabs
 - Special waste container with a lid for the safe disposal of the waste materials.
2. Open syringe packs and take off vial caps.
 - Dispose of packaging and vial caps into your special waste container with a lid.
 - Place syringes and vials onto a clean surface.
3. Wash hands thoroughly.
 - After washing your hands, do not touch anything except the injection supplies and where the injection will be given.
4. Clean the tops of the vials.
 - Wipe each vial top with a fresh alcohol pad. Let the tops dry in the air.
 - Make sure you do not touch the rubber tops after cleaning them. If you touch them, make sure you clean them again.

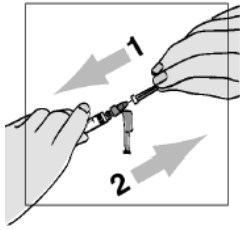
Step B: Mixing Fuzeon

Draw Up Water for Injections

1. Pick up the **3 ml large syringe**. Using your index finger, move the coloured needle protector away from the needle.

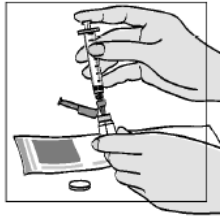


2. To make sure that the needle is firmly on the syringe:
 - hold the plastic cap under the needle protector
 - tighten the needle and cap with a gentle clockwise twist. Do not use too much force as the needle may loosen.
3. To remove the clear plastic cap:
 - push towards the syringe and then pull the cap off.



4. Draw back 1.1 ml of air.

5. Push the syringe needle into the rubber top of the vial of Water for Injections and press the plunger. This injects the air.



6. Gently turn the vial upside down. **Make sure the tip of the needle is always below the surface of the Water for Injections to help keep any air bubbles from entering the syringe.**

7. Slowly pull back the plunger until the water reaches the 1.1 ml mark. **Please be aware that the vial contains more liquid than you need (2 ml); you only have to pull out 1.1 ml to prepare your injection properly.**



8. Tap the syringe gently to make any air bubbles rise to the top.

- If too much air gets into the syringe, gently press the plunger to force any air back into the vial.
- Then pull out the water again.
- Make sure you have 1.1 ml of Water for Injections in the syringe.
- This step may be repeated until the correct amount of Water for Injections is in the syringe.

9. Take out the needle from the vial. **Make sure you never touch the needle with your fingers or anything else.**

10. Dispose of the vial and the Water for Injections into your special waste container with a lid - this vial is for single use only.

Injecting Water For Injections Into Fuzeon Powder

1. Gently tap the vial of Fuzeon to loosen the powder.

2. Hold the main part of the water-filled syringe and push the needle through the rubber top of the vial at a slight angle.

3. Press the syringe plunger in slowly.

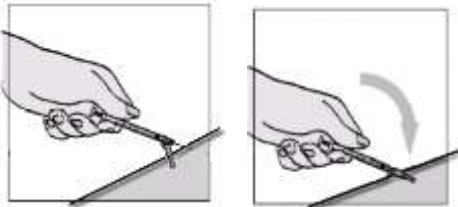
- Let the water flow slowly down the inside of the vial.
- Be careful not to forcefully shoot water into the powder, since this can cause foaming.
- If foaming happens, it may take longer for the powder to dissolve completely.



4. After all of the Water for Injections has been added to the vial of Fuzeon, take out the syringe from the vial.

5. Hold the main part of the syringe with one hand and gently press the coloured needle protector down on a flat surface until it covers the needle.

- You will hear a click. Do not use your free hand to press the device over the needle.



6. Throw away the syringe into the special waste container with a lid.

Mixing the Water for Injections with the Fuzeon Powder

1. Gently tap the vial with your fingertip until the powder begins to dissolve. **Never shake the vial or turn it upside down to mix—this will cause too much foaming.**

2. When the powder begins to dissolve you can put the vial aside to allow it to completely dissolve.

- The powder may take up to 45 minutes to dissolve into solution.
- The vial can also be gently rolled between your hands after adding the Water for Injections until it is fully dissolved.
- This may reduce the time it takes for the powder to dissolve.

3. After the powder has dissolved completely

- Let any bubbles that may have formed settle.
- If the bubbles are still there, gently tap the side of the vial to help settle them.

4 It is important to check the liquid for bits (particles).

- If you see any bits in the liquid, do not use it.
- Dispose of the vial into the special waste container with a lid or return it to the pharmacy.

Then start again with a new vial of Fuzeon powder.

5. If you accidentally touch the rubber stopper, make sure to clean it again with a new alcohol swab

6. Once a dose is mixed with Water for Injections, it must be used straight away. If not, store in a refrigerator and use within 24 hours.

- Let the liquid get back to room temperature before using.

7. If you are preparing both of your daily doses at one time, make sure to use new syringes, Water for Injections, and Fuzeon for each dose.

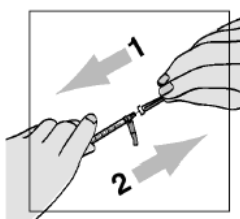
Step C: Preparing for the injection

Drawing up Fuzeon into the 1 ml syringe

1. Wipe the top of the Fuzeon vial again with a new alcohol swab.
2. Pick up the **1 ml small syringe**. Using your index finger, move back the coloured needle protector away from the needle.



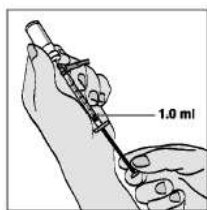
3. To make sure that the needle is firmly on the syringe:
 - hold the plastic cap under the needle protector
 - tighten the needle and cap by slightly turning and pushing it towards the syringe.
4. To remove the clear plastic cap:
 - push towards the syringe and then pull the cap off.



5. Draw back 1 ml of air.
 - Be careful not to pull the plunger too fast - it may go past the 1 ml marker or out of the syringe.
6. Push the syringe needle into the rubber top of the Fuzeon vial and press the plunger. This injects the air.
7. Gently turn the vial upside down.

Make sure the tip of the needle is always below the surface of the solution to help keep air bubbles from entering the syringe.

8. Slowly pull back the plunger until the solution reaches the 1.0 ml mark.
 - Be careful not to pull the plunger too fast - it may go past the 1 ml marker or out of the syringe.



9. Tap the syringe gently to make any air bubbles rise to the top.
 - If too much air enters the syringe, gently press the plunger to force the air back into the vial.

- Then pull out the liquid again.
- Make sure you have 1.0 ml of liquid in the syringe (or whatever amount your doctor prescribed, if it is different).
- This step may be repeated until the correct amount of solution is in the syringe.

10. Take out the syringe from the vial.

Step D: Injecting Fuzeon

Tip: Your doctor or nurse may suggest different injection techniques that will work best for you.

Where to Inject



- Fuzeon is given as a 1 ml injection just below the skin – called a ‘subcutaneous’ injection.
- You can inject into your upper arm, upper thigh or stomach area (abdomen).
- Choose a different area from where you last injected yourself.
- Do not inject to a place where there is still a reaction from an earlier dose. Check for any places where you may have a reaction by pressing the skin to see if there are any hard bumps.
- Do not inject into areas that could become irritated by your belt or the waistline of your clothes.
- Do not inject into moles, scar tissue, bruises or your belly button (navel).

Cleansing the injection site

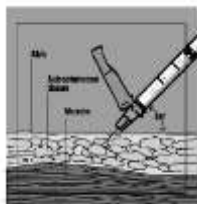
Clean the area for injection well with an alcohol swab. Do this in a circular motion, starting in the middle and working outward. Allow it to dry in the air completely.

Putting in the needle and injecting

1. Pinch as much of a skin fold as possible - without making yourself uncomfortable.



2. Push the needle into the skin at a 45-degree angle.



3. When the needle is in:

- release the skin
- use this free hand to hold on to the main part of the syringe – this will help steady it and stop it from moving.

4. Using the thumb of your other hand, press the plunger to inject the liquid.

- After the dose is fully delivered, remove the needle from the skin.

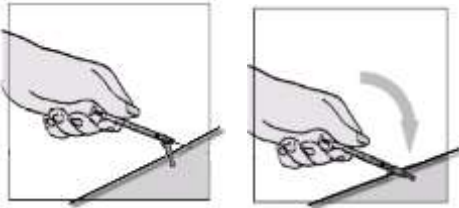
After pulling out the needle

1. Hold the main part of the syringe with one hand

- then gently press the coloured needle protector down on a **flat surface** until it covers the needle.

- you will hear a click.

Do not use your free hand to press the protector over the needle.



2. Dispose of the syringe into a special waste container with a lid.

3. If there is any blood where you have given the injection, cover the skin with a sticking plaster.

Step E: Disposing of used supplies

- Dispose of all used items straight into the special waste container with a lid. Do this even if the vials contain unused amounts of medicine or Water for Injections as these are for single use only.

- Keep the cover of this container tight and keep it out of the reach of children.

- Check with your doctor, pharmacist or nurse about proper disposal of the container.

. If you have any questions or concerns about the safe disposal of these materials, please talk to your doctor, pharmacist or nurse.