

FUZEON[®]

powder for injection

Pronounced "few-zee-on"

Contains the active ingredient enfuvirtide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FUZEON. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using FUZEON against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What FUZEON is used for

FUZEON is used for the treatment of HIV (Human Immunodeficiency Virus), the virus which causes AIDS.

FUZEON belongs to a group of medicines called anti-HIV drugs.

FUZEON is the first in a new class of drugs called HIV fusion inhibitors.

It works by blocking the entry of HIV into cells that the virus attacks (called CD4 or T cells) in your blood.

FUZEON is used in combination with other anti-HIV medicines to treat people with HIV.

FUZEON has been shown to reduce the amount of HIV in the blood

("viral load") and increase the number of CD4 cells. Reducing the amount of HIV in the blood reduces the risk of death or infections which are due to your low immunity (called opportunistic infections).

You should always report any changes in your condition to your doctor to ensure that any opportunistic infections are treated promptly.

Your doctor may have prescribed FUZEON for another purpose.

Ask your doctor if you have any questions about why FUZEON has been prescribed for you.

FUZEON does not cure HIV infection or AIDS.

FUZEON does not reduce the risk of passing HIV to other people through unprotected sexual contact, sharing needles, or contaminated blood.

This medicine is available only with a doctor's prescription.

Before you use FUZEON

When you must not use it

Do not use FUZEON if:

you have allergies to enfuvirtide or any ingredients listed at the end of this leaflet

the package is torn or shows signs of tampering

- **the expiry date (EXP) printed on the pack has passed..**

If you use this medicine after the expiry date has passed it may not work as well.

If you are not sure if you should be using FUZEON, talk to your doctor.

Use in children

Do not give FUZEON to children less than 6 years of age.

Safety and effectiveness in children younger than 6 years have not been established. There is limited information available about the use of FUZEON in children older than 6 years of age.

Before you start to use it

Your doctor must know all about the following before you start to take FUZEON.

- 1. if you are pregnant or plan to become pregnant**

It is not known whether FUZEON is harmful to an unborn baby when taken by a pregnant woman. If there is a need to use FUZEON when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

- 2. if you are breast-feeding or plan to breast-feed**

It is not known whether FUZEON passes into breast milk.

To reduce the risk of passing the virus to the baby, breast-feeding by HIV infected women is not recommended.

3. if you are allergic to any other medicines, foods, dyes or preservatives

4. if you have any other health problems including:

- kidney disease
- poor liver function
- a heart condition
- problems with your immune system (e.g. Guillain-Barré syndrome, Grave's disease)

If you have not told your doctor about any of the above, tell them before you use FUZEON.

Taking other medicines

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

FUZEON has been shown not to interact with other anti-HIV medicines or rifampicin (an antibiotic).

How to use FUZEON

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How much to inject

Use FUZEON only when prescribed by your doctor.

For adults, the recommended dose of FUZEON is 90 mg two times a day.

For children aged 6 to 16 years, the recommended dose of FUZEON is 2.0 mg/kg up to a maximum dosage of 90 mg two times a day.

How to inject it

FUZEON is administered by subcutaneous injection (under the skin) into the upper arm, thigh or abdomen.

FUZEON should not be given intravenously (directly into your

veins) or intramuscularly (directly into your muscle).

Directions for self-administration

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

Please follow these instructions carefully.

Contact your doctor or pharmacist if you have any further questions about administering FUZEON.

Safety Tips

- Wash your hands well to reduce the risk of bacterial infections. Then 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 the alcohol swabs.
- Make sure none of the items in your kit have been opened. Do not use opened materials.
- Never use a syringe with a bent or damaged needle.
- Never mix FUZEON with tap water.
- Never inject FUZEON with other injectable medicines.
- Do not use FUZEON if you see any particles in the powder or in the solution after the water has been added. Also do not use the "water for injection" if you see any particles in the vial or if the water is cloudy.
- Discard used syringes into your puncture proof (sharps) container. Consult your doctor if you have any questions about the safe disposal of these items.

When to have a carer's help

Certain injection sites, such as the upper arms, can be difficult to use at first. Have a friend or family member with you if you need help.

To reduce the risk of needlestick injury, you should have a caregiver

attend an injection training session with your healthcare provider.

Your syringes

The syringes supplied with this medicine have a needle protection device that is attached to the needle. This safety device covers the needle after use and reduces the risk of needle-stick injuries.

Although these syringes offer this safety feature it is important that you dispose of used syringes properly and according to the instructions given to you by your healthcare provider.

Getting started

1. Gather the following supplies:

- One vial of FUZEON powder
- One vial of water for injections
- One 3 mL syringe (larger syringe)
- One 1 mL syringe (smaller syringe)
- 3 alcohol swabs
- Puncture proof (sharps) container

2. Open syringe packages and remove vial caps

- Discard packages and vial caps into the trash.
- Place syringes and vials onto a clean surface.

3. Select injection site

- Injection sites include the upper arms, thighs and abdomen.
- Choose a site that is in a different area from the site used for your previous injection and where there are no current injection site reactions.
- With the tips of your fingers, feel for any hard lumps that may be present from past injections. Do not inject in the areas where these lumps are present. Also, avoid areas that could be irritated by your belt or the waistline of your clothing.

4. Wash hands thoroughly

- After washing hands, do not touch anything except the

injection supplies and the injection site.

5. Clean the tops of vials

- Wipe each vial top with a fresh alcohol swab. Let the tops air-dry.
- Be sure not to touch the rubber tops after cleaning them. If you touch them, be sure to clean them again.

Mixing FUZEON

Draw up sterile water for injections

Step 1:

Pick up the 3 mL large syringe. Using your index finger, push back the needle protection device towards the syringe.

To ensure that the needle is secure, hold the clear plastic cap and tighten the needle with a gentle clockwise twist. Do not use too much force as the needle may loosen.

Step 2:

To remove the clear plastic cap, push towards the syringe and then pull the cap off.

Draw back 1.1 mL of air.

Step 3:

Insert the syringe needle into the rubber top of the water for injections vial and press the plunger, injecting the air.

Step 4:

- Turn the vial upside down. Make sure the tip of the needle is always below the surface of the sterile water to help keep any air bubbles from entering the syringe.
- Slowly pull back the plunger until the water reaches the 1.1 mL mark. The solvent vial contains 2 mL of water for injections. You only need to withdraw 1.1 mL of it to prepare your medication properly.

Step 5:

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

- If excess air enters the syringe, gently press the plunger to force any air back into the vial and withdraw the sterile water again, making sure you have 1.1 mL of sterile water for injections in the syringe.

Step 6:

- **Remove the needle from the vial, making sure you never touch the needle with your fingers or any other object.**
- Discard the sterile water vial into the trash. The sterile water for injections vial is intended for single use only. The remaining water for injections in the vial should be discarded.

Inject sterile water into the FUZEON powder

Step 1:

- Gently tap the vial to loosen the powder.
- Hold the water-filled syringe by the barrel and push the needle through the rubber top of the vial at a slight angle.

Step 2:

Press the syringe plunger slowly. Allow the water to 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 occurs, it may take longer for the solution to completely dissolve.

Step 3:

- After all of the sterile water has been added to the FUZEON vial, remove the syringe from the vial
- Hold the barrel of the syringe with one hand and gently press the needle protection device 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.

- Discard the syringe into the puncture proof (sharps) container.

Mix the water with the FUZEON powder

Step 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 excessive foaming.

Step 2:

- After the powder begins to dissolve, set the vial aside to allow it to completely dissolve. The FUZEON solution may take up to 45 minutes to dissolve. The vial can be gently rolled between your hands after adding the water until it is fully dissolved and this may reduce the time it takes for the powder to dissolve.
- If you accidentally touch the rubber stopper, be sure to clean it again with a new alcohol swab.
- Make sure the solution has dissolved completely, allowing any bubbles that may have formed to settle. If bubbles still exist, gently tap the side of the vial to help settle them.
- As with all injectable medicines, it is important to inspect the solution for particles. If you notice any particles in the solution, discard the vial or return it to the pharmacy.
- **Once a dose is mixed with sterile water for injections, it must be used immediately or stored in a refrigerator and used within 24 hours.**
- FUZEON solution that has been refrigerated should be brought back to room temperature before being used.
- If you are preparing both of your daily doses at one time, be sure to use new syringes, sterile water for injections, and FUZEON for each dose.

Giving the injection

Choose an injection site

The most suitable places for injection are the upper arm, thighs and the abdomen, except for the belly button area. Rotate injection sites to avoid the risk of soreness at any one site.

• **Clean the injection site:**

cleanse the area for injection with an alcohol swab. Start at the centre, apply pressure, and cleanse in a circular motion, working outward. Allow to air-dry completely.

Draw up the FUZEON solution into the 1mL syringe

Step 1:

- Wipe the top of the FUZEON vial again with a new alcohol swab.
- Now, pick up the 1 mL small syringe. Using your index finger, push back the needle protection device towards the syringe.

Step 2:

- To remove the clear plastic cap push towards the syringe and then pull the cap off.
- Draw back 1 mL of air. Be careful not to pull the plunger too fast past the 1 mL marker and/or out of the barrel.
- Insert the syringe needle into the rubber top of the FUZEON vial and press the plunger, injecting the air. 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.**

Slowly pull back the plunger until the solution reaches the 1.0 mL mark. Be careful not to pull the plunger too fast past the 1 mL marker and/or out of the barrel.

Step 3:

- Tap the syringe gently to make any air bubbles rise to the top.
- If excess air enters the syringe, gently press the plunger to inject the air back into the vial and withdraw the solution again, making sure you have 1.0 mL of

solution in the syringe (or the corresponding volume that your doctor prescribed, if different.)

This step may be repeated until the correct amount of solution is in the syringe.

- Remove the syringe from the vial.

Inject the FUZEON solution

FUZEON solution should be injected subcutaneously (under the skin) into the upper arm, thigh or abdomen.

Step 1:

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

Step 2:

- Pierce the skin at a 45-degree angle.

Tip: Your healthcare provider may suggest different injection techniques that will work best for you.

Step 3:

When the needle is in, release the skin, and using the same hand, hold on to the syringe barrel to help steady it and prevent shifting.

Step 4:

- Using the thumb, depress the plunger to inject the solution.
- After the dose is fully delivered, remove the needle from the skin.
- Hold the barrel of the syringe with one hand and gently press the needle protection device 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.

- Discard the syringe into the puncture proof (sharps) container.
- Cover the injection site with a bandage if any blood or medicine is present.

Discarding used supplies

Discard all used syringes directly into the puncture proof (sharps) container. Keep the cover of this

container tight and keep the container out of the reach of children. Check with your doctor or pharmacist about proper disposal of the container.

In addition, you should safely discard all used alcohol swabs and vials, even if the vials contain unused amounts of medicine or sterile water. The vials of FUZEON and water for injections are intended for single use only. Used supplies other than syringes (alcohol swabs and vials) may be discarded into the trash as long as no blood is visible. If blood is visible, discard the items into the puncture proof (sharps) container.

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

When to inject it

Use FUZEON two times a day.

It is best to use FUZEON at the same time each day. First thing in the morning and again in the evening are good times.

It is not important to take FUZEON with food but you still need to follow the instructions given for your other anti-HIV medicines.

How long to take FUZEON

FUZEON helps control your HIV infection but does not cure it. You must use FUZEON every day exactly as your doctor has prescribed. Do not change your dose or stop taking FUZEON without first talking to your doctor.

If you forget to use FUZEON

Take a dose as soon as you remember and return to your normal routine.

Do not take a double dose to make up for one you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you miss or skip doses of FUZEON, HIV may develop resistance to FUZEON and become harder to treat.

In case of an overdose

If you think that you or anyone else may have taken too much FUZEON, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

While you are using FUZEON

Things you must do

Use FUZEON exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are using FUZEON.

Continue to use safe sexual practices while using FUZEON. FUZEON has not been shown to decrease the chance of giving HIV to your partner.

If you become pregnant while using FUZEON, tell your doctor.

Tell your doctor if, for any reason, you have not used FUZEON exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop using FUZEON or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Do not give FUZEON to anyone else even if their symptoms seem similar to yours.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how FUZEON affects you.

FUZEON generally does not cause problems with your ability to drive a car or operate machinery. However, as with many medicines, FUZEON may cause dizziness in some people. Make sure you know how you react to FUZEON before you drive a car or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FUZEON.

FUZEON helps most people with HIV infection but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Frequently it is difficult to tell whether side effects are the result of taking FUZEON, effects of the HIV disease or side effects of other medicines you may be taking. For this reason it is very important to inform your doctor of any change in your condition. Your doctor may advise you to stop using FUZEON.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea or constipation,
- nausea (feeling sick) or vomiting,

- fever, chills,
- cough (dry), sore throat, trouble swallowing,
- general feeling of achiness and cramps, back pain, pain in your limbs,
- anxiety, irritability,
- less sensation in your fingers/feet,
- tiredness, weakness,
- loss of appetite, weight loss,
- swollen runny eyes, eyes with discharge with itchiness and crusty eyelids,
- swelling in the neck, armpit or groin,
- dizziness or spinning sensation.

These are the more common side effects of FUZEON.

Injection site reactions:

Reactions at the site of injection are a common side effect of using FUZEON.

You may experience one or more of the following where you inject your medicine:

- itchiness,
- swelling,
- redness,
- pain or tenderness,
- hardened skin, lumps/bumps or bruising.

These reactions are normally mild or moderate and can appear within the first week of treatment. They generally do not get worse with continued use of FUZEON and last less than 7 days.

Reactions may be worse when injections are repeated in the same place on the body, or when the injection is given deeper than intended (e.g. into the muscle).

If you experience reactions at an injection site, it is important not to stop using FUZEON until you have talked to your doctor.

Infection:

Tell your doctor immediately if you experience or notice any symptoms of infection.

- skin infection (not at injection site): symptoms include hot, tender, red skin, fever, chills,
- sinusitis: feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a headache, fever, stuffy nose and loss of the sense of smell,
- sepsis (blood poisoning): high fever, chills, headache, confusion, rapid breathing,
- pneumonia: symptoms include fever, chills, cough, rapid breathing, shortness of breath.

Hypersensitivity:

Stop using FUZEON and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you experience any of the following symptoms of a hypersensitivity (allergic) reaction:

- nausea (feeling sick) and vomiting,
- fever, chills, shivering,
- low blood pressure (lightheaded, dizzy)
- fainting,
- rash, itching or hives on the skin,
- swelling of the face, lips, tongue or other parts of the body,
- shortness of breath, wheezing or trouble breathing.

These are very serious side effects. if you have them, you may have had a serious allergic reaction to FUZEON. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in your liver function) can only be found when

your doctor does tests from time to time to check your progress.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using FUZEON

Storage

Keep FUZEON and the Water for Injections vials in a cool dry place where the temperature stays below 30°C.

Do not store them, or any other medicine, in a bathroom or near a sink.

Once the solution has been prepared for your injection it should be used immediately.

If it is not used immediately it must be stored at 2-8°C in a refrigerator and used within 24 hours.

Do not leave your medicine in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep FUZEON where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

The syringe is intended for single use only and must be thrown away after the injection.

Dispose of the syringe with the needle (protected in the needle guard) in a puncture proof (sharps) container as instructed by your doctor, nurse or pharmacist.

Never put the used syringe in your normal household garbage.

Dispose of full puncture proof (sharps) container as instructed by your doctor, nurse or pharmacist.

Keep puncture proof (sharps) container out of reach of children.

If your doctor tells you to stop using FUZEON, or the vial has passed its expiry date, ask your pharmacist what to do with it.

Product Description

Availability

FUZEON vials are available in the following packs:

Patient Convenience Pack

- 60 vials of FUZEON powder
- 60 vials of water for Injections
- 60 x 3 mL (larger) syringes + needles
- 60 x 1 mL (smaller) syringes + needles
- 180 alcohol swabs

What FUZEON looks like

FUZEON is a white to off-white powder and comes in a glass vial.

Ingredients

Active ingredient - enfuvirtide

- each vial contains 108 mg enfuvirtide. Reconstituted FUZEON solution contains 90 mg/mL enfuvirtide.

Inactive ingredients - FUZEON vials also contain:

- sodium carbonate (anhydrous)
- mannitol
- sodium hydroxide
- hydrochloric acid

Manufacturer

FUZEON is distributed in Australia by:

Roche Products Pty Ltd
ABN 70 000 132 865

4 - 10 Inman Road
Dee Why NSW 2099
AUSTRALIA

Medical enquiries: 1800 233 950

FUZEON is distributed in New Zealand by:

Roche Products (New Zealand)
Limited
PO Box 109113
Newmarket, Auckland 1149
NEW ZEALAND

Medical enquiries: 0800 656 464

Please check with your pharmacist for the latest Consumer Medicine Information.

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- AUST R 96669

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