

Package leaflet: Information for the patient

Enspryng 120 mg solution for injection in pre-filled syringe satralizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.

In addition to this leaflet, your doctor will also give you a patient alert card, which contains important safety information that you need to be aware of before and during treatment with Enspryng. Keep this alert card with you at all times.

What is in this leaflet

1. What Enspryng is and what it is used for
2. What you need to know before you use Enspryng
3. How to use Enspryng
4. Possible side effects
5. How to store Enspryng
6. Contents of the pack and other information

Instructions for use

1. What Enspryng is and what it is used for

What Enspryng is

Enspryng contains the active substance satralizumab. It is a type of protein called a monoclonal antibody. Monoclonal antibodies are designed to recognise and attach to a specific substance in the body.

What Enspryng is used for

Enspryng is a medicine for treating neuromyelitis optica spectrum disorders (NMOSD) in adults and young people from 12 years of age.

What is NMOSD

NMOSD is a disease of the central nervous system that mainly affects the optic nerves and spinal cord. It is caused by the immune system (the body's defences) working incorrectly and attacking nerves in the body.

- The damage to the optic nerves causes swelling, leading to pain and loss of sight.
- The damage to the spinal cord causes weakness or loss of movement in the legs or arms, loss of feeling, and problems with bladder and bowel function.

In an attack of NMOSD, there is swelling in the nervous system. This also happens when the disease comes back (relapse). The swelling causes new symptoms or a return of previous symptoms.

How Enspryng works

Enspryng blocks the action of a protein called interleukin-6 (IL-6), which is involved in the processes that lead to damage and swelling in the nervous system. By blocking its effects, Enspryng reduces the risk of a relapse or attack of NMOSD.

2. What you need to know before you use Enspryng

Do not use Enspryng

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

If the above applies to you or you are not sure, do not use Enspryng and talk to your doctor, pharmacist or nurse.

Warnings and precautions

Talk to your doctor immediately if you experience any allergic reaction (see section 4. Possible side effects).

Talk to your doctor, pharmacist or nurse before using Enspryng if any of the below apply to you (or if you are not sure).

Infections

You cannot use Enspryng while you have an infection. **Tell your doctor or nurse straight away if you think you have any signs of infection** before, during, or after Enspryng treatment such as:

- fever or chills
- cough that does not go away
- sore throat
- cold sore or genital sores (herpes simplex)
- shingles (herpes zoster)
- skin redness, swelling, tenderness or pain
- feeling or being sick, diarrhoea or belly pain.

You will also find this information in the patient alert card you have been given by your doctor. It is important that you keep this alert card with you at all times and show it to any doctor, nurse or caregiver.

Your doctor will wait until the infection is controlled before giving you Enspryng or allowing you to continue to inject Enspryng.

Vaccinations

Tell your doctor if you have recently been given any vaccine or might be given a vaccine in the near future.

- Your doctor will check if you need any vaccines before you start Enspryng.
- Do not have live or live attenuated vaccines (for example BCG for tuberculosis or vaccines against yellow fever) while you are being treated with Enspryng.

Liver enzymes

Enspryng can have effects on your liver and increase the amount of some liver enzymes in your blood. Your doctor will do blood tests before you are given Enspryng, and during your treatment, to check how well your liver is working. **Tell your doctor or nurse straight away** if you have any of these signs of liver damage during or after Enspryng treatment:

- yellowing of the skin and the whites of the eyes (jaundice)
- dark-coloured urine
- feeling and being sick
- abdominal pain

White blood cell count

Your doctor will perform blood tests before you are given Enspryng, and during your treatment, to check your white blood cell count.

Children and young people

Do not give this medicine to children under 12 years of age. This is because it has not yet been studied in this age group.

Other medicines and Enspryng

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking medicines such as warfarin, carbamazepine, phenytoin and theophylline as doses might need to be adjusted.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor may advise you to stop breast-feeding if you are to be given Enspryng. It is not known whether Enspryng passes into breast milk.

Driving and using machines

Enspryng is not likely to affect you being able to drive, cycle or use any tools or machines.

3. How to use Enspryng

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 much Enspryng to use

Each injection contains 120 mg of satralizumab. The first injection will be given under the supervision of your doctor or nurse.

- The first three injections are given once every 2 weeks. These are called 'loading doses'.
- After this, the injection is given every 4 weeks. This is called the 'maintenance dose'. Continue with the injections once every 4 weeks for as long as your doctor tells you to.

How to use Enspryng

- Enspryng is given by injection under the skin (sub-cutaneously).
- Inject the entire content of the syringe each time.

At the start, your doctor or nurse may inject Enspryng. However, your doctor may decide that you or an adult caregiver can inject Enspryng.

- You or your caregiver will get training on how to inject Enspryng.
- Talk to your doctor or nurse if you or your caregiver have any questions about giving injections.

Read carefully and follow the “Instructions for use” at the end of this leaflet on how to inject Enspryng.

If you use more Enspryng than you should

Because Enspryng is in a pre-filled syringe, it is unlikely that you will receive too much. However, if you are worried, talk to your doctor, pharmacist or nurse.

If you accidentally inject more doses than you should, call your doctor. Always take the outer carton with you when you go to see the doctor.

If you forget to use Enspryng

For the treatment to be fully effective, it is very important to keep having the injections.

If your doctor or nurse is giving your injections and you miss an appointment, make another one straight away.

If you are injecting Enspryng yourself and you miss an injection, inject it as soon as possible. Do not wait until the next planned dose. After you have had the injection for the missed dose, your next injection should be either:

- for loading doses – 2 weeks later
- for maintenance doses – 4 weeks later

Check with your doctor, pharmacist or nurse if you are not sure.

If you stop using Enspryng

Do not suddenly stop using Enspryng without asking your doctor first. 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.

Allergic reactions

Tell your doctor straight away or go to the emergency department of your nearest hospital, if you have any signs of allergic reactions during or after the injection. They include:

- tight chest or wheezing
- feeling short of breath
- fever or chills
- severe dizziness or light-headedness
- swelling of the lips, tongue, face
- skin itching, hives or rash.

Do not take the next dose until you have spoken with your doctor and your doctor has told you to take the next dose.

Injection-related reactions (very common: may affect more than 1 in 10 people)

In most cases these are mild reactions, but some can be serious.

Tell your doctor or nurse straight away if you have any of these signs during or after the injection, particularly in the first 24 hours after the injection:

- redness, itching, pain or swelling where the injection is given
- rash, red or itchy skin or hives
- feeling flushed
- headache
- throat irritation, swelling or pain
- feeling short of breath
- low blood pressure (dizziness and light-headedness)
- fever or chills
- feeling tired
- feeling or being sick, or diarrhoea
- fast heart rate, fluttering or pounding heart (palpitations).

Tell your doctor or nurse straight away if you have any of the signs above.

Other side effects:

Very common (may affect more than 1 in 10 people)

- headache
- joint pain
- high levels of blood lipids (fats)
- low level of white blood cells in tests

Common (may affect up to 1 in 10 people)

- feeling stiff
- migraine
- slow heart beat (bradycardia)
- increase in blood pressure
- being unable to sleep
- swelling in your lower legs, feet or hands
- rash or itching
- allergies or hay fever
- stomach inflammation (gastritis), including stomach pain and nausea
- weight increase
- blood tests showing:
 - low fibrinogen levels (a protein involved in blood clotting)
 - high level of liver enzymes (transaminases, possible sign of liver problems)
 - high level of bilirubin (possible sign of liver problems)
 - low level of platelets (which may lead to bleeding or bruising easily)

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 via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enspryng

- 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 pre-filled syringe 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. Do not use the syringe if it has been frozen. Always keep the syringe dry.
- Keep the pre-filled syringes in the outer carton in order to protect from light and moisture.
- If unopened and kept in the outer carton, Enspryng may be left out of the refrigerator below 30°C for a single period up to 8 days. Do not return Enspryng to the refrigerator.
- Do not use and discard the pre-filled syringe if it has been left out of the refrigerator for longer than 8 days.

Do not use this medicine if it is cloudy, discoloured or contains particles. Enspryng is a colourless to slightly yellow liquid.

The medicine must be injected right after removing the cap and no later than 5 minutes to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of removing the cap, you must dispose of it in a puncture-resistant container and use a new pre-filled syringe.

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 Enspryng contains

- The active substance is satralizumab. Each pre-filled syringe contains 120 mg of satralizumab in 1 mL.
- The other ingredients are histidine, aspartic acid, arginine, poloxamer 188, water for injections.

What Enspryng looks like and contents of the pack

- It is a colourless to slightly yellow liquid.
- Enspryng is a solution for injection.
- Each pack of Enspryng contains 1 pre-filled syringe. Each multipack of Enspryng contains 3 (3 packs of 1) pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Welwyn Garden City
AL7 1TW, United Kingdom

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Instructions for use

Read these instructions for use:

- **Before you start using your pre-filled syringe**
- **Each time you get a prescription refill, because it may contain new information.**
- This information does not take the place of talking to your doctor or nurse about your medical condition or treatment.
- Your doctor or nurse will decide if you or a caregiver can give you injections of Enspryng at home. They will also show you or a caregiver the correct and safe way to use the syringe before you use it for the first time.
- Talk to your doctor or nurse if you have any questions.

Important Information

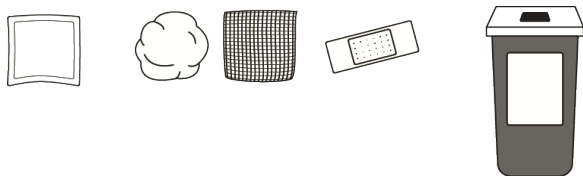
- Each syringe is pre-filled with a medicine called Enspryng.
- Each carton of Enspryng contains only 1 pre-filled syringe.
- Each pre-filled syringe can be used only once.
- Do not share your syringes with other people.
- Do not take the needle cap off until you are ready to inject Enspryng.
- Do not use the syringe if it has been dropped or damaged.
- Do not try to take the syringe apart at any time.
- Do not leave the syringe unattended.
- Do not re-use the same syringe.

Supplies needed to give your injection

Each Enspryng carton contains:

- 1 pre-filled syringe for one-time use only.

You also need the following but they are not included in the carton:



- 1 alcohol pad
- 1 sterile cotton ball or gauze
- 1 small bandage
- 1 puncture-resistant sharps container for safe disposal of the needle cap and used syringe. See step 21 “Disposing of Enspryng” at the end of these instructions for use.

Enspryng pre-filled syringe
(See Figure A and Figure B)
Before use:

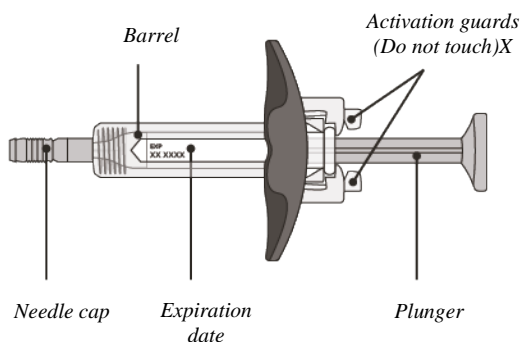


Figure A

After use:

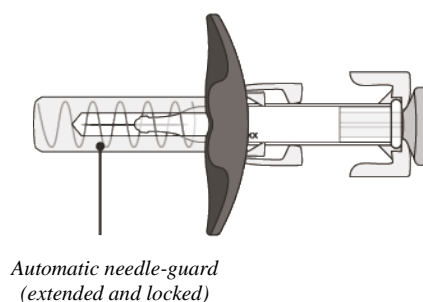


Figure B

The syringe has an automatic needle-guard that covers the needle when the injection is complete.

Prepare to use Enspryng

1. Take the carton containing the syringe out of the refrigerator and place it on a clean, flat work surface (like a table).
2. Check the expiry date on the back of the carton (see Figure C). **Do not** use if the carton has expired.
3. Check that the front of the carton is sealed (see Figure C). **Do not** use if the seal is broken.

If the expiry date has passed or the seal is broken, go to step 21 “Disposing of Enspryng” and contact your doctor or nurse.

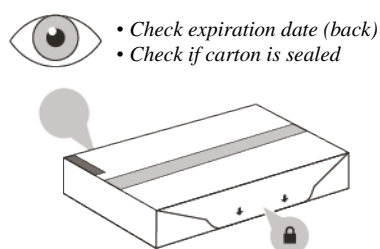


Figure C

4. Open the sealed carton (see **Figure D**).

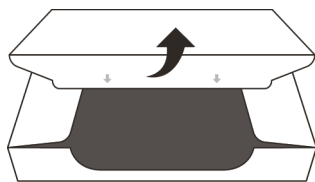


Figure D

5. Carefully lift the syringe out of the carton by holding the barrel (see **Figure E**).

- Do not turn the carton upside down to remove the syringe.
- Do not touch the activation guards. This may damage the syringe.
- Do not hold the plunger or needle cap.

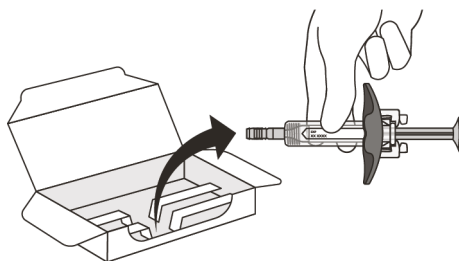


Figure E

Check the syringe

(See **Figure F**)

6. Check the expiry date on the syringe. **Do not** use the syringe if it has expired.
7. Check the syringe for any damage. **Do not** use if it is cracked or broken.
8. Check that the liquid through the viewing window is clear and colourless to slightly yellow. **Do not** inject the medicine if the liquid is cloudy, discoloured, or has particles in it.
 - There may be some small air bubbles in the syringe. This is normal and you should not try to remove them.

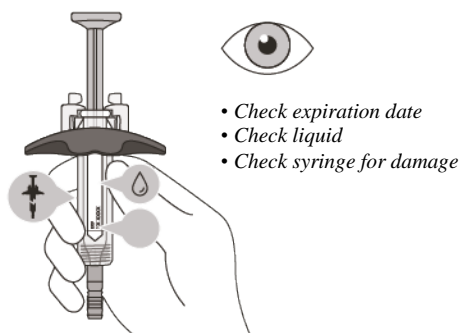


Figure F

If the expiry date has passed, the syringe is damaged or the liquid is cloudy, discoloured or has particles in it, do not use. Then go to step 21 “Disposing of Enspryng” and contact your doctor or nurse.

Let your syringe get to room temperature

9. Once you have checked the syringe, place it on a clean, flat work surface (like a table) for **30 minutes**. This will allow it to reach room temperature (see **Figure G**).

It is important to let the syringe gently reach room temperature because injecting cold medicine may feel uncomfortable and make it harder to push the plunger.

- Do not speed up the warming process by heating the syringe in any way.
- Do not remove the needle cover while the syringe is reaching room temperature.



Wash your hands

10. Wash your hands with soap and water (see **Figure H**).



Figure H

Choose the injection site

11. Choose your injection site in either:

- the lower part of your stomach (abdomen) or,
- the front and middle of your thighs (**see Figure I**).

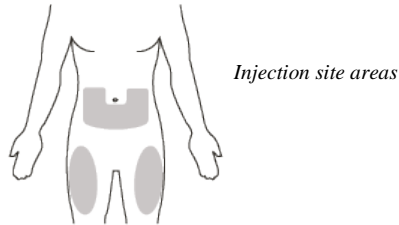


Figure I

- Do not inject into the 5 cm area around your belly button.
- Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or broken.

Choose a different injection site for **each new injection**. Choose a different site for each new injection at least **2.5 cm** away from the place used last time.

Clean the injection site

12. Wipe the injection site with an alcohol pad and let it air dry.

- Do not fan or blow on the area which you have cleaned.
- Do not touch the injection site again before you give the injection.



Figure J

Inject Enspryng

13. Hold the barrel of the syringe between your thumb and index finger. With your other hand, pull the needle cap straight off. You may see a drop of liquid at the end of the needle. This is normal and will not affect your dose (**see Figure K**).

- **Use the syringe within 5 minutes of removing the cap or the needle may clog.**
- Do not take the needle cap off until you are ready to inject Enspryng.
- Do not put the needle cap back on once it has been removed as this may damage the needle.

- Do not touch the needle or let it touch any surfaces after removing the needle cap.

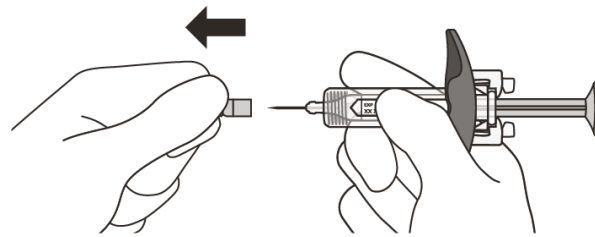


Figure K

14. Throw away the needle cap in a puncture-resistant sharps container immediately. See step 21 “Disposing of Enspryng”.
15. Hold the barrel of the syringe using your thumb and index finger. With your other hand, pinch the area of skin you have cleaned (see **Figure L**).
16. Use a quick, dart-like motion to insert the needle at an angle between 45° to 90° (see **Figure L**).
 - Do not change the angle of the injection while performing the injection.
 - Do not insert the needle again.

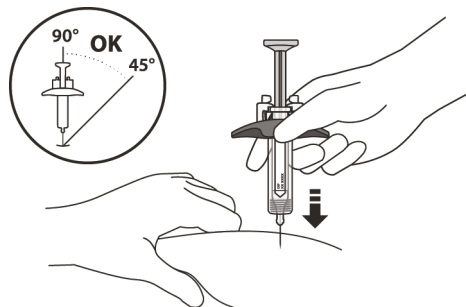


Figure L

17. After the needle is inserted, let go of the pinched skin.

18. Slowly inject all of the medicine by gently pushing the plunger all the way down until it touches the activation guards (**see Figure M**).

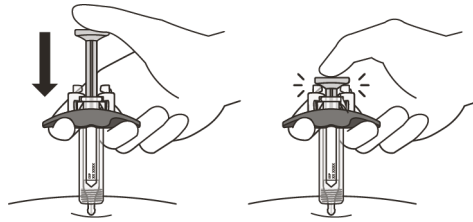


Figure M

19. Gently release the plunger and allow the needle to come out of the skin at the same angle it was inserted (**see Figure N**).

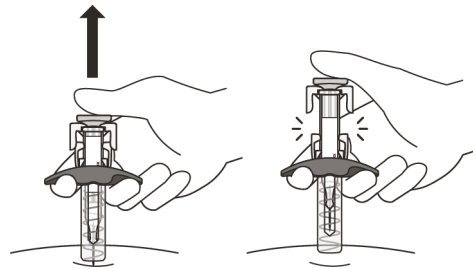


Figure N

- **The needle will now be covered by the automatic needle-guard.** If the needle is not covered, carefully place the syringe into a puncture-resistant sharps container to avoid injury. See step 21 “Disposing of Enspryng”.

Taking care of the injection site

20. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site until any bleeding stops but **do not** rub it. If needed, you may also cover the area you injected with a small bandage. If the medicine comes into contact with your skin, wash the area with water.

Disposing of Enspryng

21. Do not try to re-cap your syringe. Put your used syringe in a sharps disposal container immediately after use (**see Figure O**). **Do not** throw the syringe in your household waste and do not recycle it.



Figure O

- Ask your doctor or nurse or pharmacist for information about where you can get a "sharps" container or what other types of puncture-resistant containers you can use to safely dispose of your used syringes and needle caps.
- Dispose of the used sharps disposal container as instructed by your healthcare provider or pharmacist .
- Do not dispose of your used sharps disposal container in your household waste.
- Do not recycle your used sharps disposal container.