

Solution For Injection In A Pre-Filled Syringe
Satralizumab

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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.

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.

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.

Before you use Enspryng

When you must not use it

Do not use Enspryng:

- if you are allergic to satralizumab or any of the other ingredients of this medicine (listed in ingredient).
- If the below applies to you or you are not sure, do not use Enspryng and talk to your doctor, pharmacist or nurse.
- The package is torn or shows signs of tampering.
- The expiry date (EXP) printed on the pack has passed.

Before you start to use it

Talk to your doctor immediately if you experience any allergic reaction

Talk to your doctor, pharmacist or healthcare professional before using Enspryng if any of the following applies to you (or if you are not sure whether any of the following applies to you):

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.

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 machine

Taking other medicines

Tell your healthcare provider about all the medicines you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

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 to use

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

How to inject it

- 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

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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.

When to use it

- 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 long to use it

Continue using Enspryng for as long as your doctor tell you. 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.

If you forget to use it

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 use too much (overdose)

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 as you may need urgent medical attention. Always

take the outer carton with you when you go to see the doctor.

While you are using Enspryng

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was ineffective and change your treatment unnecessarily.

Tell your doctor if you feel your symptoms have worsened after taking Enspryng.

Things you must not do

Do not stop using Enspryng or change the dose without first checking with your doctor.

Do not give Enspryng to anyone else even if they have the same condition.

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.

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

Things to be careful of

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.

Side effects

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

All medicines can have side effects, but 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

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liver problems)

- high level of bilirubin (possible sign of liver problems)
- low level of platelets (which may lead to bleeding or bruising easily)

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumer→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal Enspryng

Storage

- 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.

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 container as instructed by your doctor, nurse or pharmacist.

Never put the used syringe in your normal household garbage.

Product Description

What Enspryng looks like

Enspryng is supplied as a single-dose Satralizumab 120 mg/mL prefilled syringe. This solution for injection is colourless to slightly yellowish (PFS) with needle safety device.

Ingredients

Active ingredient – satralizumab

Inactive ingredients

L-histidine, L-aspartic acid, L-arginine hydrochloride, poloxamer 188, water for injection

MAL number

MAL22046009ACRZ

Manufacturer

Made for Hoffman-La Roche Ltd.,

Basel, Switzerland

by Chugai Pharma Manufacturing Co., Ltd, Japan

Product Registration Holder

Roche (M) Sdn. Bhd. Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor, Malaysia.

Date of Revision

02 August 2024

MYPILEnspryng20240802CDS5.1 (ENG)

Serial Number

NPRA (R3/01)22122022/0231

Directions for self-injection

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.

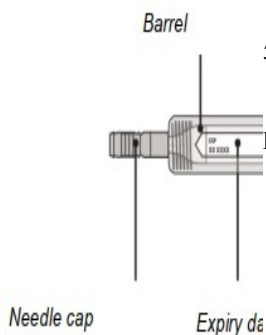
Important Information

- 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.

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

Before use:



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

Do not:

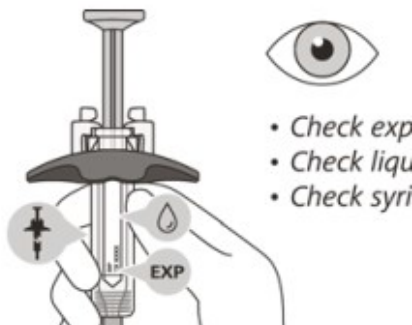
- turn the carton upside down to remove the syringe.
- touch the activation guards because this may damage the syringe.
- hold the plunger or needle cap.

Fig



Check the syringe (See Figure F)

6. Check the expiration 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 colorless to slightly yellow. Do not inject the medicine if the liquid is cloudy, discolored, 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.



If the expiration (EXP) date has passed, the syringe is damaged or the liquid is cloudy, discolored or has particles in it, do not use. Then go to Step 21 “Disposing of Enspryng” and contact your healthcare provider.

Let your syringe warm up

9. After 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. It is important to let the syringe gently warm up as injecting cold medicine may feel uncomfortable and make it harder to push.

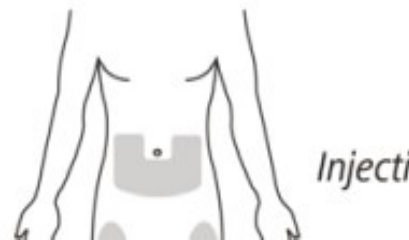
Do not:

- speed up the warming process in any way, such as using a microwave or placing the syringe in warm water.
- remove the needle cover while the syringe is reaching room temperature.

10. Wash your hands with soap and water.

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 G).



Figure

- Do not inject into the 2-inch (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 place to inject which is at least 1 inch (2.5 cm) away from the place where you last injected.**

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.
- touch the injection site again before you give the injection.

Inject Enspryng

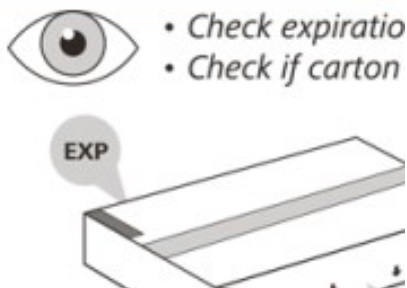
13. Hold the barrel of the syringe between your thumb and index finger. With your other hand, pull the needle cap straight off. You may see a drop of liquid at the end of the needle. This is normal and will not affect your dose.

After use:

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 expiration (EXP) date on the back of the carton (See Figure C). Do not use if the carton has expired.
3. Check the front of the carton to make sure it is sealed (Figure C). Do not use if the seal has been broken

If the expiration date has passed or the seal is broken, do not use. Then go to Step 21 “Disposing of Enspryng” and contact your healthcare provider.



4. Open the sealed carton (See Figure D).

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- 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.
- put the needle cap back on after it has been removed as this may damage the needle.
- touch the needle or let it touch any surfaces after removing the needle cap.

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.

16. Use a quick, dart-like motion to insert the needle at an angle between 45° to 90° (See Figure H).

Do not:

- insert the needle through clothing.
- change the angle of the injection.
- insert the needle again.

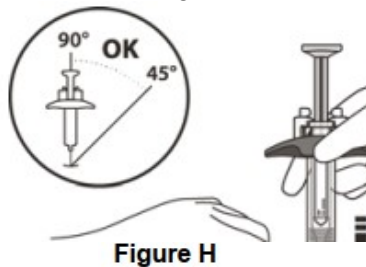


Figure H

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 I).



Figure I

19. Gently release the plunger and allow the needle to come out of the skin at the same angle it was inserted.

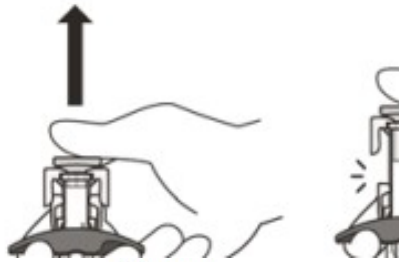


Figure J

- The needle will now be covered by the needle-shield. 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 but **do not** rub it. If needed, you may also cover the area you injected with a small bandage. If the medicine gets 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 sharps disposal container immediately after use. Do not throw away (dispose of) the syringe in your household trash.

- Ask your doctor or pharmacist where you can get a sharps disposal container or what other types of puncture-resistant containers you can use to safely dispose of your used syringes and needle caps, if you do not yet have such a container.
- Dispose of the full sharps disposal container as instructed by your doctor or pharmacist.
- Do not dispose of the full sharps disposal container in household waste.
- Do not recycle the full sharps disposal container