

MEDICATION GUIDE

ENSPRYNG® (en-spryng)

(satralizumab-mwge)

injection, for subcutaneous use

What is the most important information I should know about ENSPRYNG?

ENSPRYNG may cause serious side effects including:

1. **Infections.** ENSPRYNG can increase your risk of serious infections some of which can be life-threatening. Talk to your healthcare provider if you are being treated for an infection or call them right away if you think you have signs of an infection, with or without a fever, such as:

- chills, feeling tired, muscle aches, cough that will not go away or a sore throat
- skin redness, swelling, tenderness, pain or sores on your body
- diarrhea, belly pain, or feeling sick
- burning when you urinate or urinating more often than usual

Your healthcare provider will check if you have an infection and treat it if needed before you start or continue to take ENSPRYNG.

- Your healthcare provider should test you for hepatitis and tuberculosis (TB) before you start taking ENSPRYNG.
- All required vaccinations should be completed before starting ENSPRYNG. People using ENSPRYNG should not be given 'live' or 'live-attenuated' vaccines. 'Live' or 'live-attenuated' vaccines should be given at least 4 weeks before you start ENSPRYNG. Your healthcare provider may recommend that you get a 'non-live' (inactivated) vaccine, such as some of the seasonal flu vaccines. If you plan to get a 'non-live' (inactivated) vaccine, it should be given, whenever possible, at least 2 weeks before you start ENSPRYNG.

2. **Increased liver enzymes.**

Your healthcare provider should order blood tests to check your liver enzymes before and while you are taking ENSPRYNG. Your healthcare provider will tell you how often you will need to have these blood tests. Make sure you get all of your follow-up blood tests as ordered by your healthcare provider. Your healthcare provider will tell you if you need to wait to start ENSPRYNG if your liver enzymes are increased.

3. **Low neutrophil count.**

ENSPRYNG can cause a decrease in your neutrophil counts in your blood. Neutrophils are white blood cells that help the body fight off bacterial infections. Your healthcare provider should order blood tests to check your neutrophil count while you are taking ENSPRYNG.

See "What are the possible side effects with ENSPRYNG?"

What is ENSPRYNG?

ENSPRYNG is a prescription medicine used to treat neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4 (AQP4) antibody positive.

It is not known if ENSPRYNG is safe and effective in children.

Do not take ENSPRYNG if you:

- are allergic to satralizumab-mwge or any of the ingredients in ENSPRYNG. See "What are the ingredients in ENSPRYNG?" at the end of this Medication Guide for a complete list of ingredients in ENSPRYNG.
- have an active hepatitis B infection.
- have active or untreated inactive (latent) TB.

Before you take ENSPRYNG, tell your healthcare provider about all of your medical conditions, including if you:

- have or think you have an infection. See "What is the most important information I should know about ENSPRYNG?"
- have liver problems.
- have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have had or have been in contact with someone with tuberculosis.
- have had a recent vaccination or are scheduled to receive any vaccination.
- are pregnant, think that you might be pregnant, or plan to become pregnant. It is not known if ENSPRYNG will harm your unborn baby.
 - **Pregnancy Registry:** There is a registry for pregnant women who take ENSPRYNG. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ENSPRYNG, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-833-277-9338 to enroll.
- are breastfeeding or plan to breastfeed. It is not known if ENSPRYNG passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ENSPRYNG.

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

How should I take ENSPRYNG?

- ENSPRYNG is provided as a solution in a single-dose, prefilled syringe of 120 mg/mL of satralizumab-mwge.
- See the **Instructions for Use** inside the carton for complete instructions for the right way to prepare and inject ENSPRYNG.
- ENSPRYNG is given by an injection under the skin (subcutaneously). If your healthcare provider decides that you or your caregiver can give your injections of ENSPRYNG, you or your caregiver should receive training on the right way to prepare and inject ENSPRYNG.
- Always inject all of the medicine in the syringe.
- The first 3 injections (loading period) of ENSPRYNG are taken 1 time every 2 weeks.
- After this, injection of ENSPRYNG is taken every 4 weeks (maintenance period). Keep taking ENSPRYNG 1 time every 4 weeks for as long as your healthcare provider tells you to.
- If you miss a dose of ENSPRYNG, talk to your health care provider about restarting dosing.

What are the possible side effects of ENSPRYNG?

ENSPRYNG may cause serious side effects, including:

- See “What is the most important information I should know about ENSPRYNG?”
- **Serious allergic reactions.** Serious allergic reactions that may be life-threatening have happened with other medicines like ENSPRYNG. Tell your healthcare provider before taking your next dose if you had hives, rash, or flushing after your injection. Seek medical attention right away if you have any symptoms of a serious allergic reaction, such as:
 - shortness of breath or trouble breathing
 - swelling of your lips, face, or tongue
 - dizziness or feeling faint
 - moderate or severe stomach (abdominal) pain or vomiting
 - chest pain
- The most common side effects of ENSPRYNG include:
 - sore throat, runny nose (nasopharyngitis)
 - headache
 - rash
 - upper respiratory tract infection
 - fatigue
 - nausea
 - extremity pain
 - inflammation of the stomach lining (gastritis)
 - joint pain

These are not all the possible side effects of ENSPRYNG.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Genentech at 1-888-835-2555.

How should I store ENSPRYNG?

- Store ENSPRYNG in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton.
- Protect from light.
- **Do not** freeze or use the syringe if it has been frozen.
- **Do not** shake.
- ENSPRYNG, if unopened, can be removed from and returned to the refrigerator, if needed. The total combined time out of the refrigerator should not be more than 8 days at a temperature that does not go above 86°F (30°C).

General information about the safe and effective use of ENSPRYNG.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ENSPRYNG for a condition for which it was not prescribed. Do not give ENSPRYNG to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ENSPRYNG that is written for health professionals.

What are the ingredients in ENSPRYNG?

Active ingredient: satralizumab-mwge

Inactive ingredients: L-arginine, L-histidine, poloxamer 188, L-aspartic acid, and Water for Injection.

Manufactured by: **Genentech, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990

ENSPRYNG® is a registered trademark of Chugai Pharmaceutical Co., Ltd., Tokyo, Japan

U.S. License No.: 1048

For more information, go to www.ENSPRYNG.com or call 1-844-NSPRYNG.