

MEDICATION GUIDE
EMRELIS™ (EM-rell-is)
(telisotuzumab vedotin-tllv)
for injection, for intravenous use

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

EMRELIS can cause serious side effects, including:

- **Nerve problems in your hands or feet (peripheral neuropathy).** Nerve problems are common during treatment with EMRELIS and can also be severe. Tell your healthcare provider if you develop any new or worsening signs or symptoms of nerve problems, including:
 - numbness
 - tingling
 - burning sensation
 - pain or discomfort
 - muscle weakness
 - difficulty walking
- **Lung problems.** EMRELIS can cause lung problems that may be severe, life-threatening or that may lead to death. Tell your healthcare provider right away if you develop new or worsening lung symptoms, including:
 - cough
 - trouble breathing or shortness of breath
 - fever
 - wheezing
- **Eye problems.** Your healthcare provider may send you to an eye care professional to check your eyes if you develop eye problems. Tell your healthcare provider right away if you develop any new or worsening eye problems or vision changes, including:
 - blurred vision
 - dry eyes
 - sensitivity to light
 - eye pain or swelling
 - eye redness
- **Infusion-related reactions.** EMRELIS can cause infusion reactions that can be severe or life-threatening. Tell your healthcare provider right away if you develop any signs and symptoms of infusion reactions, including:
 - itching or rash
 - shortness of breath or wheezing
 - flushing
 - chest discomfort
 - fever
 - back pain
 - chills
 - headache
 - nausea or vomiting
 - feel like passing out

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with EMRELIS and may provide treatment for your side effects. Your healthcare provider may also need to change your dose, temporarily stop, or completely stop treatment with EMRELIS if you have severe side effects.

See **“What are the possible side effects of EMRELIS?”** for more information about side effects.

What is EMRELIS?

EMRELIS is a prescription medicine used to treat adults with non-squamous non-small cell lung cancer (NSCLC):

- that has spread to areas near the lungs (locally advanced) or to other parts of the body (metastatic), **and**
- whose tumors have high c-Met protein overexpression, **and**
- who have received a prior treatment.

Your healthcare provider will perform a test to make sure EMRELIS is right for you.

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

Before receiving EMRELIS, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of nerve problems
- have lung or breathing problems other than your lung cancer
- have eye problems
- have liver problems
- are pregnant or plan to become pregnant. EMRELIS can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with EMRELIS.
- You should use effective birth control (contraception) during treatment and for 2 months after your last dose of EMRELIS.
- Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with EMRELIS.

Males with female partners who are able to become pregnant:

- You should use an effective birth control during treatment and for 4 months after your last dose of EMRELIS.
- are breastfeeding or plan to breastfeed. It is not known if EMRELIS passes into your breast milk. Do not breastfeed during treatment with EMRELIS and for 1 month after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking certain medicines with EMRELIS may increase your risk of side effects.

How will I receive EMRELIS?

- Your healthcare provider will give you EMRELIS into your vein through an intravenous (IV) line over 30 minutes.
- EMRELIS is given 1 time every 2 weeks.
- Your healthcare provider will decide how many infusions of EMRELIS you will receive.

What are the possible side effects of EMRELIS?

EMRELIS can cause serious side effects, including:

- See “What is the most important information I should know about EMRELIS?”

The most common side effects of EMRELIS include:

- feeling tired
- decreased appetite
- swelling in the feet, ankles, legs or hands

The most common severe abnormal laboratory test results with EMRELIS include:

- decreased white blood cell counts
- increased blood sugar levels
- increased blood liver enzyme levels
- decreased blood phosphorus levels
- decreased blood sodium levels
- decreased red blood cell counts
- decreased blood calcium levels

EMRELIS may cause fertility problems in females and males, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of EMRELIS.

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

General information about the safe and effective use of EMRELIS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about EMRELIS that is written for healthcare professionals.

What are the ingredients in EMRELIS?

Active ingredient: telisotuzumab vedotin-tllv

Inactive ingredients: histidine, polysorbate 80, sucrose. Hydrochloric acid added to adjust the pH.

Manufactured by: AbbVie Inc., North Chicago, IL 60064, USA

U.S. License Number: 1889

Marketed by: AbbVie Inc., North Chicago, IL 60064 U.S.A.

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For more information, go to www.EMRELIS.com or call 1-844-859-5760.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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