

MEDICATION GUIDE
ZIIHERA® (zye HAYR rah)
(zanidatamab-hrii)
for injection, for intravenous use

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

ZIIHERA can cause serious side effects, including:

- **Diarrhea.** Diarrhea during treatment with ZIIHERA can be severe, life threatening, and can lead to death. Diarrhea may cause loss of fluids and body salts (electrolytes). To help prevent or reduce diarrhea during treatment with ZIIHERA, your healthcare provider:
 - will tell you to drink more fluids.
 - start you on an antidiarrheal medicine such as loperamide or other treatment, as needed.
 - may temporarily stop, reduce your dose or permanently stop treatment with ZIIHERA, or other medicines you take.

If you get new or worsening diarrhea, tell your healthcare provider right away and take antidiarrheal medicine as prescribed. Follow all of your healthcare providers instructions to help with your diarrhea.

- **Harm to your unborn baby.** Taking ZIIHERA during pregnancy or within 4 months before pregnancy can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ZIIHERA.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with ZIIHERA.
- Use effective birth control (contraception) during treatment with ZIIHERA and for 4 months after the last dose.

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

What is ZIIHERA?

ZIIHERA is a prescription medicine used to treat adults with:

- gastroesophageal cancer (GEA) including gastric cancer, esophageal cancer, and gastroesophageal junction (GEJ) cancer. ZIIHERA is used in combination with fluoropyrimidine-and platinum- containing chemotherapy with or without tislelizumab-jsgr as the first treatment when your GEA:
 - cannot be removed by surgery or has spread to other parts of your body (metastatic) **and**
 - your tumor tests positive for human epidermal growth factor receptor 2 (HER2 IHC3+ or IHC 2+/ISH+).
- biliary tract cancer (BTC) that includes cancer of the bile duct (cholangiocarcinoma) and cancer of the gallbladder. ZIIHERA is used alone when your BTC:
 - cannot be removed by surgery or has spread to other parts of your body (metastatic), **and**
 - was previously treated, **and**
 - your tumor tests positive for human epidermal growth factor receptor 2 (HER2 IHC3+).

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

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

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

- have or have had any heart problems.
- are breastfeeding or plan to breastfeed. It is not known if ZIIHERA passes into your breastmilk. Talk to your healthcare provider about the best way to feed your baby if you receive treatment with ZIIHERA.

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

How should I receive ZIIHERA?

- ZIIHERA is given through a vein by an intravenous (IV) infusion over 120 minutes for your first infusions. If you tolerate the first infusion well, your second infusion will be given to you over 90 minutes. Each additional infusion may be given to you over 60 minutes.
- ZIIHERA is given every 2 or 3 weeks.
- Your healthcare provider:
 - will give you medicines 30 to 60 minutes before each treatment to help prevent infusion-related reactions or make them less severe
 - will give you diarrhea medicines during your first cycle of treatment, if you are being treated for GEA
 - may slow down your infusion, temporarily stop, or permanently stop your treatment with ZIIHERA if you have certain side effects
 - may do certain tests to check you for side effects
 - will decide how many treatments you need
- If you miss a dose, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of ZIIHERA?

ZIIHERA can cause serious side effects, including:

- See “**What is the most important information I should know about ZIIHERA?**”
- **Heart problems** that may affect how well your heart pumps blood. Your healthcare provider will check your heart function before and during treatment with ZIIHERA. Tell your healthcare provider right away if you get any of the following signs and symptoms of a heart problem:
 - new or worsening shortness of breath
 - feeling more tired than usual
 - swelling of your ankles or feet
 - loss of consciousness
 - irregular heartbeat
 - sudden weight gain
 - dizziness or feeling light-headed
- **Infusion-related reactions.** Your healthcare provider will check for side effects during your infusions. Tell your healthcare provider right away if you get any of the following symptoms during or after your infusions of ZIIHERA:
 - shortness of breath or trouble breathing
 - fever
 - chills
 - rash
 - flushing
 - nausea or vomiting
 - dizziness or feeling lightheaded
 - chest discomfort

Other common side effects when ZIIHERA is given in combination with chemotherapy and tislelizumab-jsgr include:

- diarrhea
- nausea
- decreased appetite
- vomiting
- low levels of blood potassium
- feeling tired
- numbness, pain, tingling, or burning in your hands or feet
- rash
- infusion-related reactions

Other common side effects when ZIIHERA is given in combination with chemotherapy include:

- diarrhea
- nausea
- vomiting
- numbness, pain, tingling, or burning in your hands or feet
- decreased appetite
- feeling tired
- low levels of blood potassium
- infusion-related reactions
- rash

Other common side effects of ZIIHERA when used alone include:

- diarrhea
- infusion-related reactions
- stomach pain
- feeling tired

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of ZIIHERA.

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 ZIIHERA.

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 ZIIHERA that is written for health professionals.

What are the ingredients in ZIIHERA?

Active ingredient: zanidatamab-hrii

Inactive ingredients: polysorbate 20, sodium succinate, succinic acid, and sucrose

Distributed by: Jazz Pharmaceuticals, Inc., Palo Alto, CA 94306

Manufactured by:

Jazz Pharmaceuticals Ireland Limited

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D04 E5W7

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For more information, go to www.ZIIHERA.com or call 1-800-520-5568.

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

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