Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ZIIHERA®**

Zanidatamab for injection

This patient medication information is written for the person who will be taking **ZIIHERA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ZIIHERA**, talk to a healthcare professional.

Serious warnings and precautions box

ZIIHERA can cause harm to your unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with ZIIHERA.

- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ZIIHERA.
- Females who are able to become pregnant should use effective birth control (contraception) during treatment with ZIIHERA and for 4 months after the last dose.

What ZIIHERA is used for:

For the following indication(s) ZIIHERA has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- ZIIHERA is used to treat adults with a type of cancer known as 'biliary tract cancer' (BTC) when:
  - it has high levels of a protein known as 'HER2-positive' BTC, and
  - it has spread to nearby tissues (locally advanced), or to other parts of the body (metastasized) or
  - the cancer has returned or worsened after previous chemotherapy treatment or you were not able to continue your prior treatment.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How ZIIHERA works:

ZIIHERA is a type of medicine that contains the active substance zanidatamab, which is a 'bispecific' antibody that attaches itself to specific proteins or antigens on cancer cells. It recognizes and attaches

to a protein called “human epidermal growth factor receptor 2” (HER2). HER2 is found in large amounts on the surface of some cancer cells where it stimulates their growth. When ZIIHERA attaches to the HER2 receptor on cancer cells, it may slow or stop the cancer cells from growing or may kill them.

The ingredients in ZIIHERA are:

Medicinal ingredient(s): zanidatamab

Non-medicinal ingredients: Polysorbate 20, sodium succinate anhydrous (Disodium succinate), succinic acid, sucrose, water for injection

ZIIHERA comes in the following dosage form(s):

One vial of powder contains 300 mg of zanidatamab.
After reconstitution one single-dose vial contains 50 mg/mL of zanidatamab.

Do not use ZIIHERA if:

- you are allergic to zanidatamab or to any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZIIHERA. Talk about any health conditions or problems you may have, including if you:

- are feeling short of breath, cough, feeling tired, swelling of ankles or legs, irregular heartbeat, sudden weight gain, feeling dizzy, or loss of consciousness. These may be symptoms of a condition where your heart cannot pump blood well enough (decreased left ventricular ejection fraction). Your doctor will check your heart function before starting treatment with ZIIHERA.
- are pregnant or breast-feeding, if you think you may be pregnant, or if you and your partner are planning to have a baby.
    - Tell your doctor immediately if you get pregnant during treatment with ZIIHERA or during the 4 months after stopping treatment.
    - Ask your doctor if you can breast-feed during treatment with ZIIHERA and for 4 months following treatment, as it may be harmful to the child.

Other warnings you should know about:

- **Infusion reactions**
  Infusion reactions can happen. Your doctor or nurse will monitor you for side effects during and after your infusion as needed. If you get any serious reaction, your doctor may stop treatment with ZIIHERA.
- **Contraception**
  ZIIHERA may harm the unborn baby. You should use effective contraception during treatment with this medicine and for 4 months after stopping treatment. Talk to your doctor about the best contraception for you.
- **Driving and using machines**
  You may feel tired after receiving ZIIHERA. If this happens, do not drive or use any tools or machines.
- **Children and adolescents**
  ZIIHERA is not recommended in children or adolescents, as it has not been tested in this age group.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take ZIIHERA:

ZIIHERA will be given to you by a healthcare professional in a hospital or clinic.

Usual dose:

- ZIIHERA is given by a drip into a vein (intravenous infusion) once every two weeks.
- The amount of medicine you are given is dependent upon your weight and will be decided by your doctor.
- The length of time the infusion will last may be different for the first dose and later doses depending on how well you tolerate receiving the infusions.
- The number of infusions you will be given depends on how you respond to treatment and how well you tolerate the treatment.
- Before each infusion your healthcare professional may give you some medicines to help prevent infusion reactions.

Do not stop treatment with this medicine without talking to your doctor first. It is important that you are given all the infusions that have been recommended by your treatment team.

Overdose:

If you think you, or a person you are caring for, have taken too much ZIIHERA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget or miss your appointment to receive ZIIHERA, make another appointment with your healthcare professional as soon as possible.

Possible side effects from using ZIIHERA:

These are not all the possible side effects you may have when taking ZIIHERA. If you experience any side effects not listed here, tell your healthcare professional.

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

- diarrhea
- stomach pain
- feeling sick nausea
- being sick vomiting
- feeling tired
- decreased appetite
- rash
- low levels of red blood cells count – shown in blood tests (anemia)
- abnormal liver function – shown in blood tests

If you get any of the above side effects after treatment with ZIIHERA, you should talk to your doctor straight away and tell them that you have previously been treated with ZIIHERA.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
Very common			
Reactions related to the infusion of the medicine. Symptoms that can either be mild or more severe: feeling sick (nausea), fever, chills, feeling tired, headache, loss of appetite, joint and muscle pains, and hot flashes		X	X
Common			
Heart problems: feeling short of breath, cough, feeling tired, swelling of ankles or legs, irregular heartbeat, sudden weight gain, feeling dizzy, or loss of consciousness		X	X
Uncommon			
Lung problems (pneumonitis): Chest symptoms such as a dry cough or breathlessness or other new or worsening breathing problems as these may be symptoms of a lung problem		X	X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

ZIIHERA will be stored by the healthcare professionals at the hospital or clinic where you receive your treatment. The storage details are as follows:

- Do not use ZIIHERA after the expiry date which is stated on the carton and vial label after "EXP". The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- Store vials in the original carton.
- The diluted solution should be used immediately after preparation.

If you want more information about ZIIHERA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.jazzpharma.com; or by calling 1-800-520-5568.

This leaflet was prepared by Jazz Pharmaceuticals Ireland Limited.

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