

For the Patient: BRAVTRVIN

Other names: BRAVTRVIN

TR Trastuzumab

VIN Vinorelbine

ABOUT THIS MEDICATION:

What are these drugs used for?

- BRAVTRVIN is an intravenous drug treatment, given in the hope of destroying or stopping the growth of breast cancer cells that have spread in your body. This treatment may improve your overall survival and help reduce your cancer symptoms.

How do these drugs work?

- Vinorelbine works by interfering with dividing cells and preventing an increase in the number of cells.
- Trastuzumab helps your immune system to interfere with how cancer cells grow and divide.

INTENDED BENEFITS:

- This therapy is given to destroy and/or limit the growth of cancer cells in your body. This treatment may improve your current symptoms, and delay the onset of new symptoms.
- It may take several treatments before your doctor can judge whether or not this treatment is helping.

TREATMENT PLAN:

How are these drugs given?

- Trastuzumab will be given intravenously (via the vein) on day 1 of treatment. This is then followed by an observation time, to ensure that the trastuzumab does not cause any infusion related side effects. If your body does not experience any infusion related side effects, the observation time may be shortened, as determined by your chemotherapy nurse. Your first treatment will take longer, as the nurse will review information on the chemotherapy drugs
- Vinorelbine will be given intravenously (via the vein) on days 1 and 8 of treatment over 6-10 minutes.
- This three week or 21-day period of time is called a “cycle”. The cycles are repeated as long as you are benefiting from chemotherapy, and not having too many side effects, as determined by your oncologist.
- If your treatment has been delayed for over 3 weeks due to blood counts, or your oncologist feels you have received enough chemotherapy with Vinorelbine, they may wish to switch to the protocol BRAVTR, and treat you with Trastuzumab by itself, usually every 3 weeks. No premedication is needed for Trastuzumab alone.

The calendar below shows how the medications are given each 3 week cycle.

C Y C L E 1	DATE	TREATMENT PLAN
		▶ Week 1 → Trastuzumab IV, Vinorelbine IV
		▶ Week 2 → Vinorelbine IV only
		▶ Week 3 → no treatment

C Y C L E 2	DATE	TREATMENT PLAN
		▶ Week 1 → Trastuzumab IV, Vinorelbine IV
		▶ Week 2 → Vinorelbine IV only
		▶ Week 3 → no treatment

What will happen when I get my drugs?

- A blood test is done each cycle, on or about the day before each treatment day. The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.
- You will be given a prescription for anti-nausea drugs to take 30 minutes before the treatment.

- Bring your anti-nausea pills with you to take before each treatment. You may also need to take your anti-nausea drugs at home after therapy. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.
- It is important that you increase your fluid intake throughout the treatment period. Drink reasonable amounts of fluids for the first day or two after chemotherapy (6-8 cups a day).
- If you are still having menstrual periods, BRAVTRVIN may cause your ovaries to stop working, resulting in menopausal symptoms (such as hot flashes) and infertility. Your periods may stop. **This may be permanent**, especially if you are 40 years of age or older. Even if you have stopped having periods after treatment, if you were fertile prior to chemotherapy, you may be able to conceive a pregnancy. Use birth control (but **not** birth control pills) if you could become pregnant, even if you have stopped menstruating because of chemotherapy. Do not breast feed during treatment. Talk to your doctor if you have questions about fertility and birth control after treatment.

MEDICATION INTERACTIONS:

- Other drugs such as warfarin (COUMADIN®) may ***interact*** with trastuzumab. Other drugs such as carbamazepine, phenytoin, and ketoconazole may ***interact*** with vinorelbine. Tell your doctor if you are taking the above or any other drugs, as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start taking any new drugs.

Serious Risks of Treatment:

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly relevant to your treatment plan:

During treatment:

- **Infection:** The number of white blood cells that help fight infections will be temporarily lowered by the Vinorelbine, usually starting after about day 7 of each cycle. Your blood count will usually be checked every week during this protocol, and your doses changed or delayed, if necessary. If your white blood cell count becomes very low between treatments, you could get a serious infection. **If you have a fever over 38°C or 100°F, call your cancer doctor immediately (24 hours a day) or go immediately to your nearest Hospital Emergency and tell the doctor you are on chemotherapy.**
- **Increased risk of bleeding:** The number of platelets (special blood cells that help your blood to clot normally after injury) may be temporarily lowered by the treatment. They will be checked weekly. When the platelet count is low you may be more likely to bruise or bleed. Notify your cancer doctor promptly if you develop large or numerous bruises, or unusual bleeding (eg. nosebleed that won't stop, blood in stool, urine, or sputum). Try to avoid using ASA or ibuprofen, if other pain medications could be used. Talk to your doctor if you feel you need to use one of these medications while on chemotherapy. For patients receiving Warfarin, a modification of the dose may be required based on blood test results.
- **Tissue or vein injury:** Vinorelbine can cause tissue injury if it leaks out of the vein while being given. Report any sensation of burning or pain to your nurse immediately. Chemotherapy may cause some inflammation and/or scarring in the veins, which may make it difficult to start an IV. Your nurse will help your doctor assess whether a special intravenous device (PICC line or portacath) needs to be considered for your therapy. Pain or tenderness may occur where the needle was placed in your vein. If so, Apply warm compresses or soak in warm water for 15-20 minutes several times a day.
- “Ileus” (temporary halt in bowel function) : Vinorelbine may cause constipation, which can rarely be so serious as to stop bowel activity altogether for a few days. This could cause constipation, abdominal discomfort, and even vomiting. If you are unable to move your bowels and keep fluids down, you may need to be treated in hospital briefly, until this effect wears off. Contact your cancer doctor if you develop these problems.

During or after treatment:

- **Heart Failure:** Rarely, Trastuzumab can have a serious effect on the heart, causing failure of the heart's pumping action, which results in shortness of breath, fatigue and leg swelling. This can sometimes develop years after treatment. Your doctor may or may not recommend a heart function test before you start treatment, or at intervals while you remain on treatment. The

treatment may be stopped or interrupted if there are concerns about your heart function while on therapy.

- **Neuropathy:** Vinorelbine can cause you to develop damage to the peripheral nerve endings (the nerves to the hands and feet, and rarely, the face). This can result in feelings of numbness and tingling, or sometimes painful burning sensations. You will need to be careful when handling things that are sharp, hot, or very cold. The majorities of the time, these feelings develop after a number of treatments, are not severe, and will resolve fully over a period of months once treatment stops. Infrequently (<5%), these feelings might occur early, might be severe, or might not entirely resolve.

Common chemotherapy side effects and management:

SIDE EFFECT	MANAGEMENT
<p>Nausea and vomiting can occur and, if so, you will need to take anti-nausea drugs at the time of the injections. You will not usually need anti-nausea drugs for Vinorelbine or trastuzumab.</p>	<p>If you have nausea, you will be given a prescription for anti-nausea drugs to take before your chemo treatment and afterwards at home if needed.</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. • Refer to the following pamphlets: <i>For the Patient: Managing Nausea; Chemotherapy & You; Food choices to help control nausea*</i>.
<p>Pain or tenderness may occur where the needle was placed within 1-2 days after treatment. This may extend all the way up the arm. Sometimes pain may occur where the cancer is located.</p>	<ul style="list-style-type: none"> • Apply warm compresses or soak in warm water for 15-20 minutes several times a day. • For minor pain, take acetaminophen (eg, TYLENOL®). Take ibuprofen (e.g., ADVIL®) for mild to moderate pain. • See your doctor if the pain continues to bother you.
<p>Fatigue is common, especially as the number of chemotherapy treatments increases. It may get worse or last longer.</p> <p>Mouth sores may occur a few days after chemotherapy treatment and may last days or weeks. Mouth sores can occur on the tongue, gums, and the sides of the mouth or in the throat.</p>	<ul style="list-style-type: none"> • Your energy level will improve with time after treatment is completed. • You may obtain a suggestion pamphlet for handling fatigue from nursing staff in your facility • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Try baking soda mouth rinses (using 1/4 tsp baking soda in 1 cup warm water) and rinse several times a day. Try ideas in <i>Easy to chew, easy to swallow food ideas*</i>. • Tell your doctor about a sore mouth, as your chemotherapy doses may need to be decreased if mouth sores are severe. Call your doctor if you are having difficulty eating or drinking due to pain.

SIDE EFFECT	MANAGEMENT
<p>Hair thinning or loss sometimes occurs with Vinorelbine. Your hair will grow back once you stop treatment with Vinorelbine. Color and texture may change.</p>	<ul style="list-style-type: none"> • Use a gentle shampoo and soft brush. • Care should be taken with use of hair spray, bleaches, dyes and perms.
<p>Constipation or diarrhea may occur between treatments.</p>	<p>To help constipation:</p> <ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids (8 cups a day). <p>Discuss with your cancer doctor or nurse whether you need to consider a laxative</p> <p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of liquids. • Eat and drink often in small amounts. <p>Avoid high fiber foods as outlined in <i>Food ideas to help with diarrhea during chemotherapy</i>.</p>

*available through your nurse or nutritionist

** available through your nurse

Common trastuzumab side effects and management:

SIDE EFFECT	MANAGEMENT
<p>A flu-like illness may occur shortly after your treatment with Trastuzumab. You may have fever, chills, headache, muscle aches, joint aches, cough, sore throat, and stuffy or runny nose. Flu-like symptoms usually disappear on their own.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 3-4 hours if needed. • Fever and chills which occur more than 48 hours after treatment may be signs of an infection. They should be reported to the doctor immediately. See details below.

SIDE EFFECT	MANAGEMENT
<p>Chills or fever are common while trastuzumab is being infused during the first treatment. Less common are nausea, vomiting, pain, shivering, headache, dizziness, problems breathing, rash and weakness during the infusion. Reactions are uncommon with later treatments even if you have a reaction with the first treatment.</p>	<p>Tell your nurse or doctor <i>immediately</i> if you have a reaction during the treatment.</p> <ul style="list-style-type: none"> • Your trastuzumab may be given more slowly. • You may be given other drugs to treat the reaction.
<p>Diarrhea may infrequently occur.</p>	<p>See above under chemotherapy side effects.</p>

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact _____ at telephone number _____.