

For the Patient: BRAVPTRAD

Other Names: Palliative Therapy for Metastatic Breast Cancer using PERTuzumab, Trastuzumab, and DOCEtaxel as First-Line Treatment for Advanced Breast Cancer

BR = **B**Reast
AV = **AdV**anced
P = **P**ertuzumab
TRA = **TR**Astuzumab
D = **D**ocetaxel

ABOUT THIS MEDICATION

What are these drugs used for?

- Pertuzumab, trastuzumab, and docetaxel are drugs 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?

- Pertuzumab (per tooz' ue mab) and trastuzumab (tras too' zoo mab) are monoclonal antibodies, a type of protein designed to target and interfere with the growth of cancer cells.
- Docetaxel (doe-se-TAX-el) works by interfering with dividing cells and preventing an increase in the number of cancer cells.

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.

TREATMENT SUMMARY

How are these drugs given?

- Each medication will be given directly into the vein, intravenously (IV).
- The treatment will be given in 'cycles'. Each cycle length is 3 or 4 weeks in length.
- There will be two parts to this treatment.
 - In the first part, you will receive 6 to 8 cycles of pertuzumab, trastuzumab, and docetaxel. Treatment will be given every 3 weeks.
 - In the second part of your treatment, you will receive pertuzumab and trastuzumab once every 3 or 4 weeks for as long as it is helping, as determined by your oncologist.

The calendar below outlines your treatment plan.

Cycle 1:

C Y C L E	DATE	TREATMENT PLAN
		▶ Week 1 → Day 1: Pertuzumab Day 2: Trastuzumab and docetaxel
		Week 2 → No treatment
	1	Week 3 → No treatment

Cycles 2 to 8:

C Y C L E	DATE	TREATMENT PLAN
		▶ Week 1 → Day 1: Pertuzumab, trastuzumab, and docetaxel
		Week 2 → No treatment
	2	Week 3 → No treatment

Cycles 9 and onward:

C Y C L E	DATE	TREATMENT PLAN
		▶ Week 1 → Day 1: Pertuzumab and Trastuzumab
		Week 2 → no treatment
	9	Week 3 → no treatment

This treatment will repeat either every 3 weeks, or every 4 weeks, as determined by your oncologist. It will continue as long as it is helping, as determined by your oncologist.

What will happen when I get my drugs?

- You will see your clinician and will need to have a blood test before each treatment.
- The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.
- Your very first treatment will take longer than other treatments because a nurse will be reviewing the possible side effects of your treatment plan and will discuss with you how to manage them. *It is a good idea to bring someone with you to your first chemotherapy appointment.*
- For the cycles of your treatment that contain docetaxel:
 - You will be given a prescription for dexamethasone (eg, DECADRON®, DEXASONE®, HEXADROL®). Dexamethasone helps prevent nausea, fluid retention and allergic reactions.
 - It is important to take the dexamethasone exactly as directed or you may not be able to have your treatment. On treatment days, it is especially important to take the morning dose before your treatment.
 - Always take dexamethasone with food.
 - Start taking the dexamethasone the day before your treatment and continue taking it twice a day for 3 days. You must take at least 3 doses before your treatment.

INSTRUCTIONS FOR THE PATIENT:

- Tell your doctor if you have ever had an unusual or **allergic reaction** to the following drugs before starting this treatment: pertuzumab, trastuzumab, docetaxel, paclitaxel or any other medication.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of treatment.
- Pertuzumab, trastuzumab, and docetaxel may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with pertuzumab, trastuzumab, and docetaxel, and for at least seven months following end of treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.
- **Tell** doctors, dentists and other health professionals that you are being treated with pertuzumab, trastuzumab, and docetaxel before you receive any treatment from them.

Medication Interactions:

- Other drugs may **interact** with this treatment. Tell your doctor if you are taking 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 or stop taking any drugs including all prescription and non-prescription medicines, vitamins, and herbal supplements.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Allergic reactions to docetaxel may sometimes occur, and may rarely occur to pertuzumab or trastuzumab.</p> <p>Signs of an allergic reaction may include flushing, rash, itching, dizziness, swelling, chills, fever, shivering, nausea, vomiting, headache, problems breathing, weakness during the infusion, or joint or muscle pain.</p> <p>This can occur immediately or several hours after receiving pertuzumab and usually only with the first or second dose.</p> <p>Reactions are less common with later treatments of trastuzumab even if you have a reaction with the first treatment</p>	<p>Tell your nurse if this happens while you are receiving treatment or contact your oncologist immediately if this happens after you leave the clinic.</p> <ul style="list-style-type: none"> • Your medication may be temporarily stopped and then given more slowly when restarted. • You may be given other drugs to treat the reaction. • Take your dexamethasone tablets as directed by doctor, pharmacist, or nurse.
<p>Docetaxel burns if it leaks under the skin.</p>	<p>Tell your nurse or doctor immediately if you feel burning, stinging, or any other change while the drug is being given.</p>
<p>Pain or tenderness may occur where the needle was placed.</p>	<p>Apply cool compresses or soak in cool water for 15-20 minutes, several times a day.</p>
<p>Fever chills, and flu-like illness may rarely occur shortly after treatment with trastuzumab and pertuzumab. Fever may also occur shortly after treatment with docetaxel. Fever should last no longer than 24 hours.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. • Fever (over 38°C or 100°F by an oral thermometer) which occurs more than a few days after treatment may be a sign of an infection. Report this to your healthcare team immediately.

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Your white blood cells will decrease after your treatment. They usually return to normal after your last treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.</p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your healthcare team immediately at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, cough, or burning when you pass urine.
<p>Nausea and vomiting may occur after your treatment. If you are vomiting and it is not controlled, you can quickly become dehydrated.</p>	<p>Take your dexamethasone tablets as directed by your healthcare team. You may be given a prescription for anti-nausea drug(s) to take before your treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> • Drink plenty of liquids. • Eat and drink often in small amounts. • Try the ideas in Practical Tips to Help Manage Nausea* <p>Tell your healthcare team if nausea or vomiting continues or is not controlled with your anti-nausea drug(s).</p>
<p>Diarrhea may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.</p>	<p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in Food Ideas to Help Manage Diarrhea.* <p>Tell your healthcare team if you have diarrhea for more than 24 hours.</p>
<p>Sore mouth may sometimes occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.</p>	<ul style="list-style-type: none"> • 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. • Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day. • Try the ideas in Food Ideas to Try with a Sore Mouth.*

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Fluid retention may occur. Signs of extra fluid build-up are swelling of feet, hands or belly, breathing problems, cough, or rapid weight gain.</p>	<ul style="list-style-type: none"> • Take your dexamethasone tablets as directed by your healthcare team. • Elevate your feet when sitting. • Avoid tight clothing. • Tell your healthcare team at your next visit.
<p>Muscle or joint pain may occur a few days after your treatment.</p>	<p>You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.</p>
<p>Tiredness and lack of energy may occur.</p>	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in <i>Fatigue/Tiredness-patient handout*</i>
<p>Nail changes such as change in colour may occur. Rarely, nails will loosen or fall off, or the nail beds will be painful.</p>	<ul style="list-style-type: none"> • You may be given frozen gloves to wear on your hands during your treatment to help prevent nail changes. • If nails are painful, you may take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day.
<p>Hand-foot skin reaction may rarely occur during docetaxel treatment. The palms of your hands and soles of your feet may tingle, become red, numb, painful, or swollen. Skin may also become dry or itchy. You may not be able to do your normal daily activities if blisters, severe pain, or ulcers occur.</p>	<ul style="list-style-type: none"> • Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity. • Avoid tight-fitting jewellery. • Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. • Apply a sunscreen with an SPF (sun protection factor) of at least 30. • Apply lanolin-containing creams (e.g., BAG BALM®, UDDERLY SMOOTH®) to hands and feet, liberally and often. • Tell your healthcare team at your next visit if you have any signs of hand-foot skin reaction as your dose may need to be changed.

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Hair loss is common with docetaxel, is rare with pertuzumab, and does not occur with trastuzumab. It may begin within a few days or weeks of treatment. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. Hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change.</p>	<p>Refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout.*</i> You may also want to:</p> <ul style="list-style-type: none"> • Apply mineral oil to your scalp to reduce itching. • If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-brimmed hat and glasses.
<p>Skin rash and itching may sometimes occur</p>	<p>If itching is very irritating, call your healthcare team. Otherwise, be sure to mention it at your next visit.</p>
<p>Numbness or tingling of the fingers or toes may commonly occur. This will slowly return to normal once your treatments are over. This may take several months.</p>	<ul style="list-style-type: none"> • Be careful when handling items that are sharp, hot, or cold. • Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady. • Tell your healthcare team at your next visit if you have trouble with buttons, writing, picking up small objects, walking, or have fallen.
<p>You may have trouble sleeping.</p>	<ul style="list-style-type: none"> • Tell your healthcare team if you continue to have trouble sleeping. • This will return to normal when you stop treatment
<p>Headache may sometimes occur.</p>	<p>Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.</p>

Side effects of the dexamethasone premedication and management:

SIDE EFFECTS	MANAGEMENT
Heartburn may occur.	<ul style="list-style-type: none">• Take your dexamethasone after eating.• Take an antacid one hour before or two hours after dexamethasone if you have heartburn. Antacids can reduce the amount of dexamethasone absorbed when taken at the same time.• When possible avoid ASA (eg, ASPIRIN®) or ibuprofen (eg, ADVIL®), as this can increase heartburn or stomach irritation also.• Notify your oncologist if you have had ulcers, hiatus hernia, or reflux problems.
Blood sugar may be elevated, especially in diabetics.	<ul style="list-style-type: none">• Check your blood sugar regularly if you are diabetic. Seek medical advice if your readings are poorly controlled.• If you have an unexpected degree of thirst and have to urinate very frequently, you should contact your treatment clinic to get your blood sugar tested.
You may have difficulty in falling asleep on the days you take dexamethasone. You may feel restless or anxious, or find that your moods are more variable .	<ul style="list-style-type: none">• Mild exercise before bed (such as a walk around the block) may help. Avoid caffeine and other stimulants. If the problem seems very difficult, discuss this with your oncologist.

SIDE EFFECTS	MANAGEMENT
<p>Swelling of hands, feet or lower legs occur if your body retains extra fluid. This is usually temporary. This may arise after you have stopped docetaxel, and resolve gradually over weeks or a couple of months.</p> <p>If only one limb swells, you should inform your cancer treatment team right away, in case this is a signal of a blood clot in that limb.</p>	<ul style="list-style-type: none"> • Elevate your feet when sitting. • Avoid tight clothing. • Avoid food with high salt or sodium.

***Please ask a member of your healthcare team for a copy.**

THE FOLLOWING INFORMATION IS VERY IMPORTANT

CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heartbeat, face swelling or breathing problems.
- Signs of an **infection** such as fever (over 38°C or 100°F by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath, or difficulty in breathing, swelling of ankles, or fainting.

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: _____