

For the Patient: **BRAJACTTG**

Other names: Neoadjuvant or Adjuvant Therapy for Breast Cancer Using Dose Dense Therapy: DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab

BR = **BR**east
AJ = **AdJ**uvant
A = **DOXO**rubicin (**ADRIAMYCIN**®)
C = **Cyclophosphamide**
T = **T**rastuzumab
T = **PACL**itaxel (**TAXOL** ®)
G = Filgrastim (**G**-CSF)

Uses:

- BRAJACTTG is a drug treatment given after breast cancer **diagnosis** in the hope of destroying breast cancer cells that may have spread to other parts of your body. **It can be given before (called neoadjuvant) or after (called adjuvant) breast cancer surgery.** This treatment may reduce the chance of your breast cancer coming back and may improve your overall survival or chance of a cure.

Treatment Plan:

- Your treatment plan consists of 8 chemotherapy cycles (about 5 months), followed by 13 cycles of trastuzumab (about 9 months). Total time on drug treatment would be up to about 14 months. A cycle length is 2 weeks for the first 4 cycles, then 3 weeks for the remainder. All the drugs are given intravenously at every visit. For each cycle, you will need to have a blood test and see your oncologist before the treatment. The dose and timing of your chemotherapy may be changed based on your blood counts and/or other side effects.
- Doxorubicin and Cyclophosphamide (AC) are given for the first 4 cycles. Each treatment takes about one hour. You will be given a prescription for anti-nausea drugs to take 30 minutes before the treatment and again about 6-8 hours after, and will usually be on anti-nausea drugs the following 2 days also.
- A medication called Filgrastim (G-CSF) will be prescribed after each of the first 4 chemotherapy cycles for a period of 7-8 days starting on day 3 of treatment. It is a medication that you will inject under your skin, and it will help your bone marrow make new white blood cells (WBC) in time for your next treatment in 2 weeks. WBC helps protect your body by fighting bacteria (germs) that cause infection. You will receive some teaching so that you can perform the G-CSF injection yourself.
- The next 4 cycles with Paclitaxel and Trastuzumab take about 6 hours in the chemotherapy room each time. On the first treatment with these two drugs, the drugs will be given on separate days, so that it is possible to tell whether there is any allergy to either of the drugs the first time they are given. After this the drugs will be given on the same day. You will be

given some intravenous medications before the Paclitaxel to prevent or lessen the chance of allergy.

- If needed, radiation therapy will start after your 8th chemotherapy cycle is finished and will continue during your Trastuzumab therapy. Hormone treatments may also be started during Trastuzumab therapy, if your oncologist has recommended these for you.

Instructions:

- Bring your anti-nausea drugs with you to take before each AC treatment. You will 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.
- Drink lots of fluids for the first day or two after chemotherapy, especially while on AC (8 or more cups a day).
- Check with your doctor or pharmacist before you start taking any new drugs. Other drugs such as Phenytoin (DILANTIN®), Warfarin (COUMADIN®), Digoxin (LANOXIN®), and Thiazide diuretics (“water pills”) may interact with BRAJACTTG.
- You may drink small amounts of alcohol, as it will not affect the safety or usefulness of your treatment.
- Tell other doctors or dentists that you are being treated with BRAJACTTG before you receive any treatment from them.
- If you are still having menstrual periods, BRAJACTTG 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.

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 lowered by the chemotherapy drugs, usually starting after about day 7 of each of the first 8 cycles. Your blood count is expected to return to normal by day 1 of the next cycle, and will be normal after the 4 months of chemotherapy drugs. If your white blood cell count becomes very low 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. While you are on**

G-CSF, it will speed up the rate of recovery of your WBC, but may not prevent low WBC levels altogether, nor infection.

- **Increased risk of bleeding:** The number of platelets (special blood cells that help your blood to clot normally after injury) may be lowered by the treatment. They are expected to return to normal by day 1 of next cycle. 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 (e.g. 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 (increased INR due to possible interaction with Trastuzumab).
- **Tissue or vein injury:** Doxorubicin and Paclitaxel can cause tissue injury if they leak 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 cool compresses or soak in cool water for 15-20 minutes several times a day.

During or after treatment:

- **Heart Failure:** Rarely, Doxorubicin or 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 heart function will be tested after AC and before you start Trastuzumab, as well as every 3 months while you complete the Trastuzumab therapy. The treatment may be stopped or interrupted if there are concerns about your heart function during the year.
- **Leukemia:** After chemotherapy, there is an increase in the risk of leukemia, a cancer of the white blood cells. The risk is about 1% or less after this type of chemotherapy.
- **Neuropathy:** Paclitaxel 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 majority 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 with AC and you will need to take anti-nausea drugs at the time of the injections and on days 2 and 3 while at home. You will not usually need anti-nausea drugs for paclitaxel or trastuzumab.</p>	<p>You will be given a prescription for anti-nausea drugs to take before your IV treatment and afterwards at home.</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>Allergic reactions often occur during or after the administration of Paclitaxel. Signs of an allergic reaction are flushing, rash, itching, dizziness, swelling or breathing problems, or sudden chest or back pain.</p>	<ul style="list-style-type: none"> • Dexamethasone is used to help prevent allergic reactions. You will be given dexamethasone either as a single injection at the time of your treatment. • Your nurse will check your heart rate (pulse) and blood pressure if needed. • Tell your nurse or doctor <i>immediately</i> if you have any sign of an allergic reaction
<p>Hair loss. Your hair will fall out 2-4 weeks after AC treatment begins. Your scalp may feel tender. You may lose hair on your face and body. Your hair will grow back once your chemotherapy treatments are over and sometimes between treatments. The colour and texture of the new hair growth may be different.</p>	<ul style="list-style-type: none"> • Avoid hair spray, bleaches, dyes and perms. • 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-rimmed hat and glasses. • Ask your nurse about information on wigs and head coverings.
<p>Fatigue is common especially in the first week after your treatment. As the number of chemotherapy cycles increases, fatigue may get worse or last longer.</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.

SIDE EFFECT	MANAGEMENT
<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"> • 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.
<p>Diarrhea may occur between treatments.</p>	<p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of liquids. • Eat and drink often in small amounts. • You can purchase IMODIUM® over the counter if diarrhea is persistent. Don't take this if you have abdominal pain, blood in your stool, or fever. In that case, consult your doctor promptly for tests. <p>Avoid high fiber foods as outlined in <i>Food ideas to help with diarrhea during chemotherapy</i>.</p>
<p>Burning on urination. AC can cause an irritation of the bladder that result in burning on urination and/or frequency of urination. Urine color may be red after AC for a short while.</p>	<ul style="list-style-type: none"> • Drink more fluids to keep the urine dilute and empty your bladder often.
<p>Pain affecting joints or muscles may occur for a few days after paclitaxel. After you stop chemotherapy altogether, you may also feel increased joint aching or stiffness for a few months.</p>	<ul style="list-style-type: none"> • Take ibuprofen (e.g., ADVIL®) or acetaminophen (e.g. TYLENOL®) for mild to moderate pain. Contact your cancer doctor if your pain is severe. • Your family doctor can help you to manage symptoms of joint pain after chemotherapy.

*Please ask your chemotherapy nurse, pharmacist or dietician for a copy.

Common trastuzumab side effects and management:

SIDE EFFECT	MANAGEMENT
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.	<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.
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>Tell your nurse or doctor immediately 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.
Diarrhea may infrequently occur.	See above under chemotherapy side effects.

Common filgrastim side effects and management:

SIDE EFFECT	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	<ul style="list-style-type: none"> • Apply warm compresses or soak in warm water for 15-20 minutes several times a day.
Bone pain may occur when the white blood cells start to come back in your bone marrow. It often occurs in the lower back or hips. The pain is usually mild and often lasts for only a day. Rarely, the pain may be more severe.	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) for mild to moderate pain. • If you have more severe pain, contact your doctor about whether to continue the G-CSF®, and about what to use for pain relief. It may be appropriate to have your doctor check your WBC level in this case, as sometimes recovery is faster than expected.

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 _____