

For the Patient: SAAJAP

Other Names: Adjuvant Treatment of Osteosarcoma with Doxorubicin and Cisplatin

SA = SArcoma AJ = AdJuvant

A = Doxorubicin (ADRIAMYCIN®)

P = CisPlatin

ABOUT THIS MEDICATION

What are these drugs used for?

SAAJAP is an intravenous (through the vein) drug treatment for Osteosarcoma. It is used for patients with localized osteosarcoma to prevent metastases. The goal of this treatment is to prevent spread of the cancer (metastases) in patients with localized osteosarcoma.

This treatment is offered to people who have good kidney function and a good performance status. Performance status is a measure of how well a person is able to perform their usual daily activities.

How do these drugs work?

Doxorubicin is an anticancer drug that works by *interfering* with the synthesis of DNA and RNA that are needed for cancer cells to divide.

Cisplatin is an anticancer drug that works by *preventing* the synthesis of DNA, RNA and proteins that are needed for cancer cells to divide.

INTENDED BENEFITS

This treatment is being given to destroy and/or limit the growth of cancer cells that may have spread from the bone tumor to other parts of your body. This treatment may improve your current symptoms, and delay or prevent new symptoms from starting. It is not given to replace surgery which is the best way to cure osteosarcoma; it can however, eliminate the appearance of metastases – spread of the tumor – for many patients.

SAAJAP TREATMENT SUMMARY

How are these drugs given?

- You will generally be admitted to a hospital unit to receive this treatment.
- You should bring all your medications that you take at home with you to the hospital.
- Your treatment plan consists of up to 6 chemotherapy "cycles". Each cycle lasts 3 weeks (21 days).

BC Cancer Agency Protocol Summary (Patient Version) SAAJAP

- For each cycle, you will be given the two chemotherapy medications intravenously (through the vein) on Day 1.
 - Doxorubicin is given first, and is given as an injection.
 - You will then be given extra fluids intravenously for several hours before cisplatin. This is to help flush out your kidneys and prevent any kidney problems.
 - Cisplatin is given intravenously over two hours (120 minutes).
 - Intravenous fluids will be continued for 12 hours after the cisplatin has been given.

What will happen when I get my drugs?

- A blood test is also done before Day 1 of each cycle.
- The dose and timing of your chemotherapy may be changed based on your blood test results and/or other side effects.
- Your intravenous will be started to give you fluids after you have been checked in.
- Your nurse will be reviewing with you the possible side effects of your chemotherapy plan and how to manage them. It is a good idea to have someone with you at your first chemotherapy.
- You will be given anti-nausea medications by mouth and by vein to prevent nausea due to the chemo drugs.
- You will be in hospital overnight so you can be observed after the treatment.
- On discharge from the hospital unit, you will be given prescriptions for anti-nausea medications. Fill these prescriptions at your regular pharmacy. Your nurse will tell you when to take the anti-nausea medication. It is easier to prevent nausea than to treat it once it happens, so follow the directions closely.

SAAJAP TREATMENT PROTOCOL

Start Date:	
Cycle 1:	

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Blood Test	No	No	No	No	No	No
Doxorubicin,	Chemo	Chemo	chemo	chemo	chemo	chemo
Cisplatin						
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
No	No	No	No	No	No	No
chemo	chemo	chemo	chemo	chemo	chemo	chemo
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
No	No	No	No	No	No	No
chemo	chemo	chemo	chemo	chemo	chemo	chemo

This 21-day cycle will be repeated 5 more times. Generally 3 cycles are given before surgery and 3 after surgery.

BC Cancer Agency Protocol Summary (Patient Version) SAAJAP

CHEMOTHERAPY SIDE EFFECTS AND MANAGEMENT

Are there any risks?

• Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of.

SERIOUS SIDE EFFECTS	How Common Is It?	MANAGEMENT
Your white blood cells will decrease after your treatment. They usually return to normal within 3 weeks. 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.	Very Common	 To help prevent infection: Wash your hands often and always after using the bathroom. Take care of your skin and mouth by gently washing regularly. Avoid crowds and people who are sick. Call your doctor <i>immediately</i> at the first sign of an <i>infection</i> such as fever (over 100°F or 38°C by an oral thermometer), chills, cough or burning when you pass urine.
Your platelets may decrease after your treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual.	Common	 To help prevent bleeding problems: Try not to bruise, cut or burn yourself. Clean your nose by blowing gently, do not pick your nose. Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. Avoid taking ASA (eg: ASPIRIN®) or Ibuprofen (eg: ADVIL®), unless prescribed by your doctor.
Doxorubicin and cisplatin burn if they leak under the skin.	Rare	Tell your nurse or doctor <i>immediately</i> if you feel burning, stinging, or any other change while the drugs are being given.

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SERIOUS SIDE EFFECTS	How Common Is It?	MANAGEMENT
Allergic reactions to cisplatin may rarely occur. Signs of an allergic reaction are dizziness, confusion and wheezing. This reaction may occur immediately or several hours after receiving cisplatin. This reaction can occur after the first dose of cisplatin or after many doses of cisplatin.	Rare	Tell your nurse if this happens while you are receiving cisplatin or contact your oncologist immediately or get immediate emergency help if this happens after you leave the clinic.

OTHER SIDE EFFECTS	How Common Is It?	MANAGEMENT
Nausea and vomiting may occur after your treatment. It usually improves after 48 hours but may linger for 5 – 7 days after treatment for some patients (i.e. delayed nausea and vomiting).	Very Common	You will be given a prescription for anti-nausea drug(s) to take before your chemotherapy treatment and/or at home. It is easier to prevent nausea than to treat it once it has happened, so follow directions closely. • Drink plenty of liquids. • Eat and drink often in small amounts. • Try the ideas in "Food Choices to Control Nausea". Your doctor may manage delayed nausea and vomiting differently. Be sure to let your doctor know if you experience this.

Hair loss is common and may begin within a few days or weeks of treatment. Your hair may thin or you may become totally bald. Your scalp may feel tender. You may lose hair on your face and body. Your hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change.	Very Common	 Use a gentle shampoo and soft brush. Care should be taken with use of hair spray, bleaches, dyes, and perms. Protect your scalp with a hat, scarf or wig in cold weather. Cover your head or apply sunblock on sunny days. 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.
Sore mouth may 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.	Common	 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 ½ teaspoon baking soda or salt in 1 cup warm water and rinse several times a day. Try soft, bland foods like puddings, milkshakes and cream soups. Avoid spicy, crunchy or acidic food, and very hot or cold foods. Call your doctor if you are having difficulty eating or drinking due to pain. Try the ideas in "Food Ideas for a Sore Mouth during Chemotherapy"
Diarrhea may occur.	Common	 To help diarrhea: Drink plenty of liquids. Eat and drink often in small amounts. Avoid high fibre foods as outlined in "Food Ideas to Help with Diarrhea".

Loss of appetite and weight loss are common and may persist after your treatments are over.	Common	Try ideas in "High Energy High Protein Ideas" and in "Healthy Eating Using High Energy, High Protein Foods".
Pain or tenderness may occur where the needle was placed in your vein.	Uncommon	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Your skin may darken in some areas such as your nails, soles or palms.	Uncommon	This will slowly return to normal once you stop treatment.

INSTRUCTIONS FOR THE PATIENT

What other drugs can interact with SAAJAP?

- Other drugs such as some antibiotics given by vein (e.g., tobramycin, vancomycin), furosemide (LASIX®), phenytoin (DILANTIN®), pyridoxine, digoxin (LANOXIN®), warfarin (COUMADIN®) and cyclosporine (NEORAL® or SANDIMMUNE®) may interact with SAAJAP. Tell your doctor if you are taking these or other drugs as you may need extra blood tests, your dose may need to be changed or your treatment may need to be held for a few days.
- Check with your doctor or pharmacist before you start taking any new prescription or non-prescription drugs.

Other important things to know:

- Heart failure: rarely, doxorubicin 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. Your treatment may be stopped or interrupted if there are concerns about your heart function.
- Tell your doctor if you have ever had an unusual or allergic reaction to daunorubicin, epirubicin, idamycin, mitomycin or mitoxantrone before treatment begins.
- Your urine may be pink or reddish for 1-2 days after your treatment. This is expected as doxorubicin is red and is passed in your urine.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.
- Sometimes, the nerve which allows you to hear can be affected by cisplatin. As a result, you may experience "tinnitus" (ringing in the ears) or a change in your hearing. Report any of these problems to your doctor and/or nurse.
- Cisplatin can cause changes in kidney function, but this is not frequent with the
 doses used in this type of treatment. It is important that you are well-hydrated before
 and after treatment. Following your treatment, your doctor may ask you to drink
 plenty ofliquids (8-12 cups a day) to prevent kidney problems. Report any signs of
 kidney problems such as lower back or side pain, swelling of feet or lower legs to
 your doctor as soon as possible.
- This treatment will interfere with menstrual cycle and less commonly may cause <u>sterility</u> in men and <u>menopause</u> in women. If you plan to have children, discuss this with your doctor before starting treatment.
- This treatment may damage sperm and may cause harm to the baby if used during pregnancy. It is best to use <u>birth control</u> while you are undergoing treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Tell all doctors or dentists you see that you are being treated with doxorubicin and cisplatin before you receive treatment of any form.

SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer); chills; cough; pain or burning when you pass urine.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heartbeat, face swelling or breathing problems.
- Signs of **heart problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty breathing, swelling of ankles or fainting.
- 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 a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain or shortness of breath.
- Seizures or loss of consciousness.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Muscle weakness.
- Signs of anemia such as unusual tiredness or weakness.
- Signs of **gout** such as joint pain.
- Changes in eyesight.
- Signs of **kidney problems** such as lower back or side pain, swelling of feet.
- Uncontrolled **nausea**, **vomiting**, or **diarrhea**.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE TO BOTHER YOU:

- Easy bruising or bleeding.
- Redness, swelling, pain or sores where the needle was placed.
- Redness, swelling, pain or sores on your lips, tongue, mouth or throat.
- Ringing in your ears or hearing problems.
- Sings of anemia such as unusual tiredness or weakness.
- Skin rash or itching.
- Numbness or tingling in feet or hands or painful leg cramps.

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