For the Patient: PROTOCOL SMAJIFN
Other Names: Adjuvant Therapy of High Risk Malignant Melanoma with High Dose Interferon (HDIFN) alph-2b

SM = Melanoma
AJ = Adjuvant
IFN = Interferon

ABOUT THIS MEDICATION
What is this drug used for?
- Interferon (in-ter-FEER-on) is a drug that is used to treat many types of cancers including melanoma. This treatment is given after you have had surgery to remove all visible cancer.
- Interferon is offered to people who have adequate liver and kidney function.

How does this drug work?
Interferon is a man-made version of a substance your body produces naturally to fight infections and tumours. We do not know exactly how Interferon helps overcome cancer. We believe that it works in several ways. It may act directly against cancer cells, slowing their growth or shutting off their ability to make new cancer cells. It may also help the immune system work more effectively against cells that are not normal.

INTENDED BENEFITS
Treatment with Interferon may reduce the chance of the melanoma coming back.

TREATMENT SUMMARY
How are these drugs given?
Your treatment plan consists of two phases: Four weeks of Induction phase and 48 weeks of Maintenance phase (Total 52 weeks).

Induction phase
- You will have high dose Interferon daily for 5 days of a week for 4 weeks.
- Interferon will be given into a vein (I.V.) over 20 minutes by a nurse in the chemotherapy room.
- Then you will be given extra fluids into a vein over 30-60 minutes.

Maintenance phase
- You will have lower dose Interferon three times a week (Monday, Wednesday and Friday) for 48 weeks.
- Interferon will be given under the skin (S.C.) by yourself or a caregiver. A nurse will teach you how to inject interferon under the skin.
- Depending on how you are tolerating, a rest period of 2-3 weeks may be considered after 4 weeks of treatment of high dose (Induction phase).
The following calendar outlines your overall treatment plan.

**Induction Phase (Weeks 1-4):**

- You will see your cancer doctor once a week for an assessment.

<table>
<thead>
<tr>
<th>MON</th>
<th>TUE</th>
<th>WED</th>
<th>THR</th>
<th>FRI</th>
<th>SAT</th>
<th>SUN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>No Treatment</td>
<td>No Treatment</td>
</tr>
<tr>
<td>Day 8</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>No Treatment</td>
<td>No Treatment</td>
</tr>
<tr>
<td>Day 15</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>No Treatment</td>
<td>No Treatment</td>
</tr>
<tr>
<td>Day 22</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>Interferon I.V.</td>
<td>No Treatment</td>
<td>No Treatment</td>
</tr>
</tbody>
</table>

**Maintenance Phase (Weeks 5-52):**

- You will see your cancer doctor every 4 weeks for an assessment.
- This 7-day cycle will repeat for a total of 48 cycles.

<table>
<thead>
<tr>
<th>MON</th>
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<th>WED</th>
<th>THR</th>
<th>FRI</th>
<th>SAT</th>
<th>SUN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Interferon S.C.</td>
<td>No Treatment</td>
<td>Interferon S.C.</td>
<td>No Treatment</td>
<td>Interferon S.C.</td>
<td>No Treatment</td>
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</tbody>
</table>

**What will happen when I get my drugs?**

- Your very first treatment will take longer than other treatments because a nurse will be reviewing the possible side effects of your chemotherapy plan and how to manage them. It is a good idea to bring someone with you to your first chemotherapy appointment.
- A blood test (lab work) is done every week during the induction phase and every 4 weeks during the maintenance phase.
- The dose and timing of your treatment may be changed based on your blood
counts, liver function and/or other side effects.

- You will be asked to take Acetaminophen (eg, TYLENOL®) 650 mg 30 minutes before you receive interferon and then every 4-6 hours regularly during induction phase (Weeks 1-4) to help flu-like side effect.
- Your doctor may tell you to drink plenty of liquids e.g., 8-12 cups (2000-3000 mL or 70-100 oz) a day. This helps prevent low blood pressure.
- Interferon may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with interferon. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Tell doctors or dentists that you are being treated with interferon before you receive any treatment from them.

INSTRUCTIONS FOR THE PATIENT

How should I store this drug?

- Store interferon injections in the refrigerator, out of the reach of children. Do not shake interferon vigorously, as it may be damaged. Do not freeze.

How should I use this drug?

- It is important to use interferon exactly as directed. Always use the same brand of interferon. Make sure you understand the directions.
- Use a different site for each injection.
- Inject at bedtime to lessen side effects.
- Take the interferon out of the refrigerator and allow it to warm to room temperature for 30 minutes before injection. Do not use heat to warm the injection.
- Do not shake the vial. Bubbling and foaming make it difficult to draw up a full dose.
- If you are using the multidose pen, be sure you understand how to turn the exact number of clicks on the pen, in order to prime the pen to the dose which your doctor has prescribed.
- Inspect each vial or multidose pen of Interferon Alfa before using. It should be clear, colourless and there should be no particles in the liquid.
- If you are using the multi-dose pen, once a pen is opened and first used, it should not be used longer than 4 weeks. Up to 48 hours of storage at 15-25°C is permitted during the 4 weeks. If the pen is accidentally left at room temperature longer than 48 hours during the 4 weeks, it must be discarded.
- Return remaining interferon to the refrigerator immediately after your injection.
- Use each needle only once to avoid infection. Place used needles in a rigid plastic container with a lid. Discard container as instructed by your treatment centre. Keep out of reach of children.

What other drugs can interact with Interferon?

- Other drugs such as captopril (CAPOTEN®), enalapril (VASOTEC®), phenobarbital, erythropoietin (EPREX®), melphalan (ALKERAN®), prednisone...
(DELTASONE®), theophylline (UNIPHYL®), warfarin (COUMADIN®), zidovudine (RETROVIR®, AZT), and some vaccines may interact with interferon. Tell your doctor if you are taking these 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.

- The herbal remedy Sho-saiko-to (Chinese name: Xiao Chai Hu Tang) interacts with interferon to cause serious side effects. Do not use this product at any time while using interferon.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of interferon.
SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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 as they are directly related to the common actions of the drug in your treatment plan.

<table>
<thead>
<tr>
<th>SERIOUS SIDE EFFECTS</th>
<th>How common is it?</th>
<th>MANAGEMENT</th>
</tr>
</thead>
</table>
| Your white blood cells may decrease. 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.  
• Avoid crowds and people who are sick.  
• Interferon may cause fever (over 100°F or 38°C by an oral thermometer) even though you do not have an infection (see page 4, a flu-like illness). If you have fever plus another sign of infection, call your doctor immediately. These other signs include chills, cough, or burning when you pass urine. |
| Your platelets may decrease. Platelets help your blood to clot normally after an injury (e.g., cut). **When the platelet count is low, you may be more likely to bruise or bleed.** | 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.  
• Avoid constipation.  
• Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene.  
• Some medications such as ASA (e.g., ASPRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.  
• Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart).  
• For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable. |
### SERIOUS SIDE EFFECTS

<table>
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<tr>
<th><strong>How common is it?</strong></th>
<th><strong>MANAGEMENT</strong></th>
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</thead>
<tbody>
<tr>
<td>Rare</td>
<td>Tell your nurse if this happens while you are receiving Interferon. Go to your local Emergency Room immediately if this happens after you leave the clinic.</td>
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**Allergic reactions** may rarely occur. Signs of an allergic reaction are dizziness, confusion and wheezing or difficulty breathing. This reaction can occur immediately or several hours after receiving Interferon.

### OTHER SIDE EFFECTS

<table>
<thead>
<tr>
<th><strong>How common is it?</strong></th>
<th><strong>MANAGEMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncommon</td>
<td>• Apply cool compresses or soak in cool water for 15-20 minutes several times a day.</td>
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</table>

**Pain or tenderness** may occur where the needle was placed.

**A flu-like illness** may occur shortly after your treatment. You may have fever, chills, headache, muscle aches and joint aches. Flu-like symptoms usually disappear on their own.

**Nausea and vomiting** may occur during treatment.

**Uncommon**

- You may be given a prescription for antinausea drug(s) to take before your treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred.
- Drink plenty of liquids.
- Eat and drink often in small amounts.
- Try the ideas in *Food Choices to Control Nausea.*
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| Skin rashes may occur.          | Uncommon         | To help itching:  
• You can use calamine lotion  
• If very irritating, call your doctor during office hours  
• Otherwise make sure to mention it at your next visit |
| 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 During Chemotherapy. |
| Sugar control may be affected in diabetics. | Very rare        | • Check your blood sugar regularly if you are diabetic.  
                                                                                                                                                 |
| You may have trouble sleeping.  | Uncommon         | • Talk to your doctor if your trouble in sleeping continues to bother you.  
• This will return to normal when you stop taking interferon. |
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| Taste alteration may occur. | Uncommon | To help reduce the impact of taste changes on your ability to get good nutrition and avoid weight loss:  
• Rinse mouth with water before eating.  
• Eat small, frequent meals and healthy snacks.  
• Eat meals when hungry rather than at set mealtimes.  
• Have others prepare the meal.  
• Substitute poultry, fish, eggs and cheese for red meat.  
• Eat meat with a marinade or sauce; try something sweet.  
• Use plastic utensils if food tastes like metal.  
• Use mints, lemon drops or chewing gum to mask the bitter or metallic taste.  
• Chilled or frozen food may be more acceptable than warm or hot food.  
• Try tart foods, such as citrus fruits or lemonade, unless you have mouth sores.  
• Avoid bad odours, as these may affect your appetite. |
| Tiredness and lack of energy may occur. | Very common | • Do not drive a car or operate machinery if you are feeling tired.  
• Try the ideas in Your Bank of Energy Savings: How People with Cancer Can Handle Fatigue. |
| Hair loss sometimes occurs with interferon. Your hair will grow back once you stop treatment with interferon. Colour and texture may change. | Uncommon | • Use a gentle shampoo and soft brush.  
• Care should be taken with use of hair spray, bleaches, dyes and perms. |
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<td><strong>Loss of appetite</strong> and <strong>weight loss</strong> are common and may persist long after discontinuation of interferon.</td>
<td>Common</td>
<td>• Try ideas in <em>High Energy High Protein Ideas</em> and in <em>Healthy Eating Using High Energy, High Protein Foods</em>.</td>
</tr>
</tbody>
</table>
| **Increase** in **triglycerides** (one of the types of fat in the blood) may occur. | Rare | Discuss this with your doctor if you have:  
• A history of heart disease.  
• High blood pressure.  
• Elevated triglycerides.  
You may need to have your **triglyceride** level checked a few months after starting interferon. |
| **Emotional changes** (e.g., feelings of depression) may sometimes occur. | Common | • Discuss these symptoms with your doctor if they occur. |
THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP USING INTERFERON AND 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 heart beat, face swelling or breathing problems.
- Signs of heart problems (rare) such as fast or uneven heartbeat.

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

- Signs of anemia such as unusual tiredness or weakness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Numbness or tingling in feet or hands.
- Changes in eyesight (rare).
- Ringing in your ears or hearing problems.
- Trouble in walking.

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

- Uncontrolled nausea, vomiting or diarrhea.
- For diabetics: uncontrolled blood sugars.
- Headache not controlled with acetaminophen.
- Easy bruising or minor bleeding.
- Redness, swelling, pain or sores where the needle was placed.
- Redness, swelling, pain or sores on your lips, tongue, mouth or throat.
- Skin rash or itching.

If you experience symptoms or changes in your body that have not been described above but worry you, or in any symptoms are severe, contact:

__________________________ at telephone number: ____________________

BC Cancer Agency Protocol Summary (Patient Version) SMAJIFN
Developed: 1 Oct 2009
Revised: 1 July 2011