



Provincial Health Services Authority

For the Patient: **SMAVFIPI**

Other Names: Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab

SM = Skin and Melanoma

AV = Advanced

IPI = Ipilimumab

ABOUT THIS MEDICATION

What is this drug used for?

- Ipilimumab (ip" i lim' ue mab) is a drug that is used to treat a type of skin cancer called melanoma, that has spread to other parts of the body or cannot be removed by surgery.
- It is for adults whose disease has failed to respond to or has relapsed from other systemic treatment, such as chemotherapy.

How does this drug work?

- Ipilimumab is a type of therapy called immunotherapy. It is an antibody designed to help your own body's immune system target cancer cells to stop them from growing.

INTENDED BENEFITS

- Ipilimumab is being given to destroy and/or limit the growth of melanoma cells. It may improve your current symptoms, and delay or prevent the onset of new ones.
- It may take several treatments before your doctor can judge whether or not this treatment is helping. Treatment is continued as long as there is benefit and side effects are tolerable.

TREATMENT SUMMARY

How is this drug given?

- Ipilimumab will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 90 minutes. If you tolerate the first two treatments well, your nurse may give the remainder infusions over 30 minutes.

- You will be treated with Ipilimumab once every 3 weeks. This 3 weeks period is called a “cycle”. The cycle is repeated up to a total of 4 times, depending on your response to treatment.

What will happen while I am being treated?

- A blood test (lab work) and other tests are done before starting each treatment cycle.
- Treatment may be interrupted based on your test results and/or side effects.

INSTRUCTIONS FOR THE PATIENT

It is very important to report side effects immediately to your doctor. Do not manage side effects at home without speaking with your doctor. Be aware that symptoms may be delayed and can develop months after your last dose. If other doctors are involved in your care it is important they know you are on these treatments and the autoimmune side effects they can cause.

What other drugs or foods can interact with Ipilimumab?

- Other drugs may interact with ipilimumab. Check with your doctor or pharmacist before you start or stop taking any other drugs including all prescription and non-prescription medicines, steroids or other medicines that lower your immune response, vitamins, and herbal supplements.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of ipilimumab.

Other important things to know:

- **Before you are given Ipilimumab**, talk to your doctor or pharmacist if you:
 - have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn’s disease, lupus, or sarcoidosis.
 - take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone or dexamethasone.
 - had an organ transplant, such as a kidney transplant.
 - have liver damage from diseases or drugs.
 - have any other medical conditions.
- It is very important to tell your doctor immediately if you have, or develop, any of the symptoms listed under **Serious Side Effects. Do not try to treat or diagnose symptoms yourself.**
- You may have a **transient worsening of disease** before the tumour shrinks. Tumour response will be assessed after completion of treatment (ie, 4 cycles).
- Ipilimumab may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with ipilimumab. Tell your doctor right away if you or your partner becomes pregnant.
- Ipilimumab may pass into your breast milk. **Do not breastfeed** during treatment
- **Tell** doctors or dentists that you are being treated with ipilimumab before you receive

any treatment from them. You should carry the BC Cancer **wallet card** for ipilimumab or checkpoint inhibitor to alert health providers.

- **Do not receive any immunizations before discussing with your doctor.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Ipilimumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.

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.

What is the most important information I should know about SERIOUS SIDE EFFECTS?

- Ipilimumab can cause serious side effects in many parts of your body. These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment with ipilimumab.
- **Tell** your doctor as soon as possible if you have any of serious side effects listed in the table below or your symptoms get worse.
- **Do not try to treat or diagnose symptoms yourself.** Getting medical treatment right away may keep the problem from becoming more serious.

SERIOUS SIDE EFFECTS	How common is it?
<p>Inflammation of the INTESTINES (COLITIS) <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself. • constipation • blood in stools or dark, tarry, sticky stools • stomach pain (abdominal pain) or tenderness • fever 	Common
<p>Inflammation of the LIVER (HEPATITIS) <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • yellowing of your skin or the whites of your eyes, • dark urine, tiredness, nausea or vomiting, loss of appetite, pain on the right side of your stomach, or bruise easily 	Very Rare
<p>Inflammation of the SKIN <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • rash on your skin, mouth blisters, or peeling skin 	Common
<p>Inflammation of the NERVES <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • weakness of legs, arms or face • numbness or tingling in hands or feet 	Very Rare
<p>Inflammation of certain GLANDS (pituitary, adrenal glands, or thyroid) so they do not make enough hormone. <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • headaches or unusual tiredness or sleepiness • changes in behavior such as less sex drive, being irritable or forgetful • dizziness or fainting 	Rare

SERIOUS SIDE EFFECTS	How common is it?
<p>Inflammation in other parts of the body including EYES, KIDNEYS, PANCREASE or LUNG. <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • blurry vision, double vision, or other vision problems • eye pain or redness 	Rare
<p>Infusion reaction. <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • shortness of breath or trouble breathing, cough, chest tightness • dizziness, fainting, rapid or weak heartbeat • itching, hives, or feeling warm • swelling of the throat, tongue, or face • hoarse voice, throat tightness or trouble swallowing 	Very Rare

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	Very Rare	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Nausea and vomiting may occur after your treatment. Most people have little or no nausea.	Uncommon	<ul style="list-style-type: none"> • 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, so follow directions closely. <ul style="list-style-type: none"> ○ Drink plenty of fluids. ○ Eat and drink often in small amounts. • Try the ideas in <i>Food Choices to Help Control Nausea</i>.* • If nausea and vomiting is persistent and you have other symptoms of hepatitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Fever may sometimes occur.	Rare	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. • If you have other symptoms of colitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Constipation may sometimes occur.	Very Rare	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Suggestions for Dealing with Constipation</i>.* • If you have other symptoms of colitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Headache may sometimes occur.	Very Rare	<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. • If headache is persistent and you have other symptoms of inflammation of glands or Inflammation of the nerves , tell your doctor as soon as possible. (see the table above for serious side effects.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Loss of appetite and weight loss sometimes occur.	Uncommon	<ul style="list-style-type: none"> • Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i>. • If loss of appetite is persistent and you have other symptoms of hepatitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Tiredness and lack of energy may sometimes occur.	Common	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in <i>Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue</i>.* • If tiredness is persistent and you have other symptoms of hepatitis or inflammation of glands, tell your doctor as soon as possible. (see the table above for serious side effects.)
Hair loss is rare with ipilimumab.	Very Rare	If hair loss is a problem, refer to <i>For the Patient: Hair Loss Due to Chemotherapy</i> .*

***Please ask your oncologist or pharmacist for a copy.**

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: _____



Provincial Health Services Authority

MEDICAL ALERT

NAME _____

has received

IPILIMUMAB: Immune-Mediated Adverse Reactions

ALWAYS CARRY THIS CARD AND SHOW TO PHYSICIANS INCLUDING ANESTHETISTS

SEVERE IMMUNE-MEDIATED ADVERSE REACTIONS
Including enterocolitis, intestinal perforation, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, endocrinopathy, pneumonitis, myositis, myocarditis and toxicities in other organ systems. Duration of risk after treatment is unknown.

FOR MORE INFORMATION:

- BC Cancer - Abbotsford 604-851-4710
- BC Cancer - Kelowna 250-712-3900
- BC Cancer - Prince George..... 250-645-7300
- BC Cancer - Surrey 604-930-4055
- BC Cancer - Vancouver..... 604-877-6000
- BC Cancer - Victoria..... 250-519-5500

www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual

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To Whom It May Concern:

RE: _____

Medical Oncologist _____

Immunotherapy Regimen _____

This patient is receiving **immunotherapy** at the BC Cancer and is at risk of **immune-related toxicities** which may be life threatening and require urgent management.

Immunotherapy toxicities are different from those encountered with standard chemotherapy or targeted therapies. The immune system may become dysregulated during immunotherapy treatment, leading to symptoms and findings which mimic autoimmune disorders. Adverse events can occur during or following treatment and can be life threatening. Any organ system in the body is at risk including, but not limited to:

- Lungs (pneumonitis, pleuritis, sarcoidosis)
- Gastrointestinal (colitis, ileitis, pancreatitis)
- Liver (hepatitis)
- Skin (rash, Stevens-Johnson syndrome)
- Endocrine (hypophysitis, adrenal insufficiency, hypo/hyperthyroidism, type 1 diabetes mellitus)
- Renal (interstitial nephritis)
- Blood (hemolytic anemia, thrombocytopenia, neutropenia)
- Neurologic (encephalitis, Guillain-Barré syndrome, meningitis, myasthenia gravis, neuropathy)
- Musculoskeletal (myositis, arthritis)
- Cardiovascular (pericarditis, myocarditis, vasculitis)
- Ophthalmologic (uveitis, scleritis, episcleritis, conjunctivitis, retinitis)

Management of immune-related toxicities necessitates prompt coordination with a medical oncologist with **initiation of high dose corticosteroids**, and may require referral to the appropriate subspecialty. If you suspect your patient is presenting with immune-related toxicity, **please contact the patient's medical oncologist** directly or if after hours contact the on-call physician, or as per your local centre's process (next page). Additional information on immunotherapy toxicity treatment algorithms is located at the end of the above posted protocol at www.bccancer.bc.ca.

BC CANCER CENTRES	CONTACT INFORMATION AND PROCESS
Abbotsford	Contact the patient's medical oncologist immediately by calling the Abbotsford Regional Hospital and Cancer Centre (ARHCC) switchboard at (604) 851-4700 and ask for the on-call medical oncologist (24-hour call system).
Kelowna	Between 8:30 am – 5:00 pm, call (250) 712-3900 (press "8" to speak to the Kelowna Centre receptionist) and have an oncologist paged. Outside these hours, call the Kelowna General Hospital switchboard at (250) 862-4000 and ask for the on-call medical oncologist.
Prince George	Between 8:30 am – 4:00 pm Monday to Friday, call (250) 645-7313. Outside these hours, go to the emergency department at the University Hospital of Northern British Columbia (UHNBC).
Surrey	Between 8:30 am – 4:00 pm Monday to Friday (except Statutory holidays), call the Nursing Phone Line at (604) 930-4053. Outside these hours, call the Surrey Memorial Hospital switchboard at (604) 581-2211 and ask for the Fraser Valley on-call medical oncologist.
Vancouver	Between 8:30 am – 4:30 pm Monday to Friday, call the Patient Nurse Line at (604) 877-6025. Outside these hours, call the inpatient unit at (604) 877-6000 and press 1, and ask for the on-call medical oncologist.
Victoria	Between 8:30 am – 4:30 pm Monday-Friday (except Statutory holidays), call (250) 519-5500, and press 1 then 4 to speak with a registered nurse. Outside these hours, call the Royal Jubilee Hospital switchboard at (250) 370-8000 and ask for the on-call medical oncologist.