

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **OPDIVO® SC**

(op-DEE-voh)

nivolumab for subcutaneous injection 300 mg/2.5 mL (120 mg/mL), 600 mg/ 5 mL (120 mg/mL)

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **Opdivo SC**, talk to a healthcare professional.

Serious warnings and precautions box

Opdivo SC acts on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening.

Opdivo SC given alone can cause serious side effects in parts of your body which can lead to death. These serious side effects may include: inflammation of the lungs (pneumonitis or interstitial lung disease), inflammation of the brain (encephalitis), inflammation of the heart muscle (myocarditis), inflammation of the skin (severe skin problems), and decreased number of red blood cells (autoimmune hemolytic anemia).

It is important to tell your healthcare professional immediately if you have, or develop, any of the symptoms listed under the section *“What are possible side effects from using Opdivo SC and Serious Side Effects and What to do About Them.”*

What Opdivo SC is used for:

Skin Cancer:

Opdivo® SC is a medicine used in adult patients to treat a type of skin cancer (melanoma) to help delay or prevent the cancer from coming back after it and its metastases have been completely removed by surgery.

Opdivo SC may be given to treat a type of skin cancer (melanoma) after complete removal by surgery in adult patients (treatment after surgery is called adjuvant therapy).

Opdivo SC may be given to treat a type of skin cancer that has spread or cannot be removed by surgery (advanced melanoma) in adult patients.

Opdivo SC may also be given to patients following treatment with nivolumab intravenous and ipilimumab combination therapy.

Lung Cancer:

Opdivo SC is used in adult patients to treat a type of advanced stage lung cancer (called non-small cell lung cancer) that has spread or grown after treatment with platinum containing chemotherapy.

Opdivo SC may be given in combination with chemotherapy that contains platinum and another chemotherapy medicine before you have surgery for your lung cancer (non-small cell lung cancer). Treatment prior to surgery is called neoadjuvant therapy.

Kidney Cancer:

Opdivo SC is used in adult patients to treat advanced kidney cancer (called renal cell carcinoma) that has spread or grown after treatment with medicines that block cancer blood vessel growth.

Opdivo SC may be given in adult patients with advanced kidney cancer following treatment with nivolumab intravenous and ipilimumab combination therapy.

Opdivo SC may also be given in combination with cabozantinib in adult patients with advanced kidney cancer that cannot be treated with radiation or surgery or disease that is metastatic, and who have not been treated. It is important that you also read the package leaflet for cabozantinib. If you have any questions about cabozantinib, please ask your doctor.

Head and Neck Cancer:

Opdivo SC is used in adult patients to treat advanced head and neck cancer (called squamous cell carcinoma of the head and neck) when the cancer grows or spreads on or after platinum containing chemotherapy.

Colon or Rectal Cancer:

Opdivo SC is used in adults following first treatment with nivolumab intravenous and ipilimumab combination therapy, for the treatment of colon or rectal cancer that cannot be removed with surgery, or has spread to other parts of the body and is shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Opdivo SC is used in adults following treatment with nivolumab intravenous and ipilimumab combination therapy, for the treatment of colon or rectal cancer that is shown by a laboratory test to be MSI-H or dMMR, and:

- you used the drug fluoropyrimidine in combination with oxaliplatin, or irinotecan and the cancer has spread or grown or you are no longer tolerating the treatment.

Esophageal or Gastroesophageal Junction Cancer:

Esophageal cancer is cancer of the esophagus, the tube that connects your throat to your stomach. Gastroesophageal junction (GEJ) cancer is cancer of the junction between the esophagus and the stomach.

Opdivo SC is used in adult patients who have been treated with chemoradiation followed by surgery to remove the cancer.

Opdivo SC is also used in adult patients who test positive for PD-L1 and have a type of esophageal cancer called squamous cell carcinoma, which cannot be removed with surgery, and has come back or spread to other parts of the body.

Cancer of the stomach, esophagus or the junction between the stomach and esophagus (gastric, esophageal, or gastroesophageal junction cancers):

Opdivo SC may be used in combination with chemotherapy that contains fluoropyrimidine and platinum when your gastric, gastroesophageal junction or esophageal cancer:

- is a type called adenocarcinoma, and
- cannot be removed with surgery

Bladder and Urinary Tract Cancers:

Opdivo SC is used in adult patients to help prevent cancer of the urinary tract from coming back after it was removed by surgery.

Opdivo SC may be used in combination with chemotherapy medicines cisplatin and gemcitabine as your first treatment when your urinary tract cancer (urothelial carcinoma) has spread to other parts of the body (metastatic) or cannot be removed by surgery.

Liver Cancer (hepatocellular carcinoma):

Opdivo SC is used in adult patients to help remove cancer of the liver.

Opdivo SC is used after first-line treatment of nivolumab intravenous in combination with ipilimumab as your treatment when your liver cancer cannot be removed with surgery (advanced) or has spread to other parts of the body (metastatic).

For the following indications Opdivo SC has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- Adults with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, following completed treatment with nivolumab intravenous + ipilimumab combination therapy, when your colon or rectal cancer:
 - has come back or spread
 - you have tried treatment with fluoropyrimidine-based therapy in combination with oxaliplatin or irinotecan.
- Adults with bladder or urinary tract cancer at high risk of recurrence when the cancer was removed by surgery and you may have received chemotherapy that contains platinum prior to surgery.

For the following indications Opdivo SC has been approved without conditions. This means it has passed Health Canada's review and can be bought and sold in Canada.

- Adults with skin cancer (advanced melanoma) when used alone or used alone following completed treatment with nivolumab intravenous + ipilimumab combination therapy.
- Adults with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.
- Adults with skin cancer (melanoma) to help delay or prevent the cancer from coming back after it and its metastases have been completely removed by surgery.
- Adults with skin cancer (melanoma) after complete removal by surgery (adjuvant therapy).
- Adults with lung cancer (advanced non-small cell cancer) that has spread or grown after treatment with a platinum-based chemotherapy. Patients with certain lung cancer mutations (EGFR or ALK) should only be treated with Opdivo SC if their cancer grows or spreads during or after treatment with therapies targeting these mutations.
- Adults with lung cancer (advanced non-small cell cancer), if the tumour tests positive for "PD-L1", for patients following treatment with nivolumab intravenous and ipilimumab combination therapy.
- Adults with lung cancer (non-small cell cancer) in combination with chemotherapy before surgery.

- Adults with kidney cancer (advanced renal cell carcinoma) that has spread or grown after treatment with medicines that block vessel growth (anti-angiogenic therapies).
- Adults with kidney cancer (advanced renal cell carcinoma) when used alone following completed treatment with nivolumab intravenous + ipilimumab combination therapy.
- Adults with kidney cancer (advanced renal cell carcinoma) when used together with cabozantinib in patients who have not been treated.
- Adults with cancer of the head and neck (advanced squamous cell carcinoma) when the cancer grows or spreads on or after platinum containing chemotherapy.
- Adults with cancer of the esophagus or junction between the esophagus and the stomach [gastroesophageal junction (GEJ)] who have been treated with chemoradiation followed by surgery to remove the cancer.
- Adults with gastric, gastroesophageal junction or esophageal adenocarcinoma (stomach and gullet cancer). Adults with cancer of the esophagus (advanced squamous cell carcinoma) when used together with chemotherapy in patients who have not been treated and who have tested positive for PD-L1.
- Adults with cancer of the urinary tract (urothelial carcinoma) in combination with cisplatin and gemcitabine chemotherapies as a first treatment for cancer that cannot be removed by surgery or has spread to other parts of the body (unresectable or metastatic).
- Adults with cancer of the liver (hepatocellular carcinoma) when used alone, following completed treatment with nivolumab intravenous + ipilimumab combination therapy as first line treatment, for cancer that cannot be removed by surgery or has spread to other parts of the body (unresectable or advanced).
- Adults with MSI-H or dMMR colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body and who have not been previously treated, when used alone following completed treatment with nivolumab intravenous + ipilimumab combination therapy.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How Opdivo SC works?

Opdivo SC contains the active substance nivolumab which helps your immune system to attack and destroy cancer cells.

Opdivo SC attaches to a target protein called programmed death-1 receptor (PD-1) that can switch off the activity of T cells (a type of white blood cell that forms part of the immune system, the body's natural defences). By attaching to PD-1, nivolumab blocks its action and prevents it from switching off your T cells. This helps increase their activity against the melanoma, lung, kidney, lymphoid, head and neck, liver, colon, rectal or stomach and gullet cancer cells.

Opdivo SC may be given in combination with cabozantinib. Please refer to the package leaflet of cabozantinib in order to understand the use of this medicine. If you have questions about this medicine, please ask your doctor.

Opdivo SC may be given in combination with chemotherapy. Please refer to the package leaflets for the chemotherapy medicines in order to understand their use. If you have questions about the chemotherapy medicines given with Opdivo SC, please ask your healthcare professional.

The ingredients in Opdivo SC are:

Medicinal ingredients: nivolumab

Non-medicinal ingredients: histidine, histidine hydrochloride monohydrate, methionine, pentetic acid, polysorbate 80, recombinant human hyaluronidase PH20 (rHuPH20), sodium chloride, sucrose, and water for injection.

Opdivo SC comes in the following dosage form:

Opdivo SC, ready-to-use solution for subcutaneous injection only, 120 mg nivolumab/mL, comes in glass vials containing 300 mg (in 2.5 mL) of nivolumab (overfill of 0.52 mL) and in glass vials containing 600 mg (in 5 mL) of nivolumab (overfill of 0.60 mL).

Do not use Opdivo SC if:

- you are allergic to nivolumab or any of the other ingredients of this medicine. Talk to your healthcare professional if you are not sure.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Opdivo SC. Talk about any health conditions or problems you may have, including if you have:

- **Problems with your hormone producing glands** (including the thyroid, parathyroids, pituitary, adrenal glands, and pancreas) that may affect how these glands work. Signs and symptoms that your glands are not working properly may include fatigue (extreme tiredness), weight change, headache or excessive thirst or lots of urine, decreased blood levels of calcium.
- **Diarrhea** (watery, loose or soft stools) or any symptoms of **inflammation of the intestines** (colitis), such as stomach pain and mucus or blood in stool.
- **Abnormal liver function tests.** Signs and symptoms may include eye or skin yellowing (jaundice), pain on the right side of your stomach area, or tiredness.
- **Problems with your lungs** such as breathing difficulties, or cough. These may be signs of inflammation of the lungs (pneumonitis or interstitial lung disease).
- **Abnormal kidney function tests or problems with your kidneys**, such as decreased volume of urine or inflammation of the kidneys (tubulointerstitial nephritis).
- **Inflammation of the heart muscle (myocarditis).** Signs and symptoms may include chest pain, irregular and/or rapid heartbeat, fatigue, swelling in the ankles or shortness of breath.
- **Inflammation of the muscles (myositis)** that may cause muscle or joint pain, stiffness or weakness.
- **Muscle weakness (myasthenia gravis or myasthenia syndrome)**, a condition in which muscles become weak and tire easily.

- **Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome.** An overlap of either two or three conditions.
- **Had an organ transplant** (such as a kidney transplant).
- **Take other medicines that make your immune system weak.** Examples of these may include steroids, such as prednisone.
- If you are pregnant or plan to become pregnant.
- If you are breast-feeding.

Other warnings you should know about:

Give yourself time after taking Opdivo SC to see how you feel before driving a vehicle or using machinery.

Tell your healthcare professional immediately if you have any of these signs or symptoms or if they get worse. **Do not try to treat your symptoms with other medicines on your own.** Your healthcare professional may:

- give you other medicines in order to prevent complications and reduce your symptoms,
- withhold the next dose of Opdivo SC,
- or, stop your treatment with Opdivo SC.

Please note that these signs and symptoms are **sometimes delayed**, and may develop weeks or months after your last dose. Before treatment, your healthcare professional will check your general health.

Check with your healthcare professional before you are given Opdivo SC if:

- you have an autoimmune disease (a condition where the body attacks its own cells);
- you have melanoma of the eye;
- have experienced side effects with another drug, such as ipilimumab;
- have been told cancer has spread to your brain;
- or, you are on a low salt diet.

Pregnancy and Breast-feeding:

- you are pregnant or plan to become pregnant. You should not become pregnant while you are getting Opdivo SC, Opdivo SC can cause harm or death to your unborn baby.
- you must use effective contraception while you are being treated with Opdivo SC and for at least 5 months after the last dose of Opdivo SC if you are a woman who could become pregnant.
- you are breast-feeding. Opdivo SC may pass into your breast milk. You and your doctor should decide if you will take Opdivo SC or breast-feed. You should not do both.

Always update your healthcare professional on your medical conditions.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Opdivo SC:

No drug-drug interaction studies have been conducted with nivolumab.

How to take Opdivo SC:

Your healthcare provider will give you Opdivo SC by injection under the skin, in the stomach area (abdomen) or in the thigh area.

Opdivo SC is injected over 3 to 5 minutes.

Your healthcare provider will decide the time between doses as well as how many treatments you will receive.

Your healthcare provider will do blood tests to check you for side effects.

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

Usual dose:

- When Opdivo SC is given on its own, the recommended dose is either 600 mg of nivolumab every 2 weeks or 1200 mg given every 2 weeks every 4 weeks. Your healthcare professional will discuss with you and help choose the appropriate dose.
- When Opdivo SC is given on its own following nivolumab intravenous in combination with ipilimumab for the treatment of skin cancer, the recommended dose is either 600 mg of nivolumab every 2 weeks or 1200 mg given every 2 weeks every 4 weeks. Your healthcare professional will discuss with you and help choose the appropriate dose.
- When Opdivo SC is given on its own following nivolumab intravenous in combination with ipilimumab for the treatment of advanced kidney cancer or with a previously treated type of colon or rectal cancer (colorectal cancer), the recommended dose is either 600 mg of nivolumab every 2 weeks or 1200 mg given every 2 weeks every 4 weeks. Your healthcare professional will discuss with you and help choose the appropriate dose.
- When Opdivo SC is given on its own following nivolumab intravenous in combination with ipilimumab as a first treatment of colon or rectal cancer, the recommended dose is either 600 mg of nivolumab every 2 weeks or 1200 mg given every 2 weeks every 4 weeks.
- When Opdivo SC is given in combination with cabozantinib for the treatment of advanced kidney cancer, the recommended dose of Opdivo SC is 600 mg of nivolumab every 2 weeks, or 1200 mg every 4 weeks and cabozantinib 40 mg is given once daily by mouth.
- When Opdivo SC is given in combination with chemotherapy before surgery for non-small cell lung cancer, the recommended dose of Opdivo SC is 900 mg every 3 weeks for 3 cycles only.
- When Opdivo SC is given in combination with chemotherapy for the treatment of advanced gastric, gastroesophageal junction or esophageal adenocarcinoma cancer, the recommended dose of Opdivo SC is 600 mg of nivolumab every 2 weeks or 900 mg of nivolumab every 3 weeks.

- When Opdivo SC is given in combination with chemotherapy for the treatment of metastatic esophageal cancer, the recommended dose of Opdivo is 600 mg or 1200 mg Q4W in combination with fluoropyrimidine- and platinum-based chemotherapy, until disease progression, unacceptable toxicity, or up to 24 months.
- When Opdivo SC is given in combination with cisplatin and gemcitabine chemotherapies for the treatment of unresectable or metastatic urothelial carcinoma, the recommended dose of Opdivo SC is 900 mg every 3 weeks for up to 6 cycles followed by Opdivo SC monotherapy at either 600 mg every 2 weeks or at 1,200 mg every 4 weeks, until disease progression, unacceptable toxicity, or up to 24 months.
- When Opdivo SC is given on its own following nivolumab intravenous in combination with ipilimumab for the treatment of liver cancer, the recommended dose is either 600 mg of nivolumab every 2 weeks or 1200 mg given every 2 weeks every 4 weeks.

Overdose:

If you think you, or a person you are caring for, have taken too much Opdivo SC, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

If you stop using Opdivo SC:

Stopping your treatment may stop the effect of the medicine. Do not stop treatment with Opdivo SC unless you have discussed this with your healthcare professional.

If you have any further questions about your treatment or on the use of this medicine, ask your healthcare professional.

When Opdivo SC is given in combination with chemotherapy you will first be given Opdivo SC followed by chemotherapy.

Please refer to the package leaflet of your prescribed chemotherapy in order to understand the use of these medicines. If you have questions about these medicines, please ask your healthcare professional.

When Opdivo SC is given in combination with cabozantinib, you will first be given Opdivo SC followed by cabozantinib.

Please refer to the package leaflet of cabozantinib in order to understand the use of this medicine. If you have questions about this medicine, please ask your healthcare professional.

Opdivo SC is not authorised for the use in combination concurrently with ipilimumab.

Missed dose:

It is very important for you to keep all your appointments to receive Opdivo SC. If you miss an appointment, ask your healthcare professional when to schedule your next dose.

Possible side effects from using Opdivo SC:

These are not all the possible side effects you may have when taking Opdivo SC. If you experience any side effects not listed here, tell your healthcare professional.

Very common side effects (may affect more than 1 in 10 people):

The most common side effects of Opdivo SC when used alone are:

- Feeling tired
- Skin rash, itching
- Pain in muscles, bones and joints
- Cough

Injection site reactions: Skin reactions at or near the injection site (local), including injection site reactions, may happen with Opdivo SC. Symptoms may include pain, itching, swelling or redness around site of injection.

Opdivo SC acts on your immune system and may cause redness, warmth (fever), swelling and pain (inflammation) in parts of your body. This may cause serious damage to your body and some conditions may be life-threatening. You may need treatment to reduce the inflammation and Opdivo SC may be stopped.

If you get any serious side effects with Opdivo SC when used alone (monotherapy) or in combination with chemotherapy (combination) (see table below), talk to your healthcare professional. Side effects may be very common (may affect more than 1 in 10 people), common (may affect less than 1 in 10 but more than 1 in 100 people), uncommon (may affect less than 1 in 100 but more than 1 in 1,000 people), or rare (may affect less than 1 in 1,000 people).

Serious side effects and what to do about them

Frequency/Side Effect/Symptom		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
COMMON	Inflammation of the intestines (colitis) <i>Symptoms may include:</i> • diarrhea (watery, loose, or soft stools) or more bowel movements than usual. Do not treat the diarrhea yourself • blood or mucous in stools, or dark, tarry, sticky stools stomach pain (abdominal pain) or tenderness		√	
COMMON	Inflammation of the thyroid, adrenal or pituitary glands <i>Symptoms may include:</i>		√	

Frequency/Side Effect/Symptom		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	- headaches that will not go away or unusual - unusual tiredness or sleepiness - weight changes (weight gain or weight loss) - changes in mood or behaviour such as less sex drive, being irritable or forgetful, or depression - dizziness or fainting			
UNCOMMON	Inflammation of the liver (hepatitis) <i>Symptoms may include:</i> - extreme tiredness - yellowing of your skin (jaundice) or the whites of your eyes - severe nausea or vomiting - pain on the right side of your stomach (abdomen) - bruise easily		√	
UNCOMMON	Inflammation of the kidney (nephritis) <i>Symptoms may include:</i> - changes in urine output (increase or decrease) - dark urine (tea-coloured) - swelling of extremities		√	
COMMON	Inflammation of the lung (pneumonitis) <i>Symptoms may include:</i> - trouble breathing, shortness of breath - cough (new or worsening) with or without mucus		√	
UNCOMMON	Eye problems <i>Symptoms may include:</i> - changes in eyesight - eye pain or redness - blurred or blurry vision, or		√	

Frequency/Side Effect/Symptom		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	other vision problems			
UNCOMMON	Blood sugar problems (diabetes or ketoacidosis) <i>Symptoms may include:</i> • hunger or excessive thirst • need to urinate more often • increased appetite with weight loss, or loss of appetite • muscle weakness • sleepiness or drowsiness • depression • irritability feeling unwell		√	
COMMON	Inflammation of the skin (severe skin problems) <i>Symptoms may include:</i> • severe skin reactions or rash • itching • skin blistering and peeling • ulcers in the mouth or other mucous membranes • raised skin lumps/bumps (skin nodules) • dry skin		√	
UNCOMMON	Inflammation of the skin (severe skin problems) <i>Symptoms may include:</i> changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (other lichen disorders)		√	
UNCOMMON	Inflammation of the brain (encephalitis) <i>Symptoms may include:</i> • headache • fever • confusion • memory problems		√	

Frequency/Side Effect/Symptom		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	- sleepiness or drowsiness - seeing things that are not really there (hallucinations) - seizures (fits) - stiff neck			
UNCOMMON	Inflammation of the nerves (demyelination) <i>Symptoms may include:</i> - muscle weakness - muscle stiffness - numbness - loss of reflexes uncoordinated movements		√	
UNCOMMON	Muscle weakness (myasthenia gravis or myasthenic syndrome) <i>Symptoms may include:</i> - difficulty walking and climbing stairs - difficulty lifting objects or raising the arms - drooping eyelids chewing or swallowing problems		√	
RARE	Inflammation of the muscles (myositis), inflammation of the heart muscle (myocarditis), or breakdown of skeletal muscle (rhabdomyolysis): <i>Symptoms may include:</i> - muscle or joint pain, stiffness, or weakness - chest pain, irregular heartbeat, or palpitations - confusion or memory problems - severe fatigue difficulty walking		√	

Frequency/Side Effect/Symptom		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
UNCOMMON	Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome: <i>Overlap of two or three of the following Symptoms:</i> • Inflammation of the heart muscle (myocarditis) • inflammation of the muscles (myositis) • muscles become weak and tire easily (myasthenia gravis)		√	
RARE	Problems with other organs <i>Symptoms may include:</i> • loss of nerve function or sensation of paralysis • swollen lymph nodes • numbness or tingling in hands or feet • swelling in extremities • abdominal pain, nausea or vomiting (pancreatitis) indigestion or heartburn		√	
RARE	Inflammation of the spinal cord (myelitis and transverse myelitis) <i>Symptoms may include:</i> • Pain, numbness, tingling, or weakness in the arms, legs or torso • Bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation		√	

Other serious side effects that have been reported (frequency not known) with Opdivo SC alone and/or Opdivo (IV formulation) in combination with ipilimumab include:

- A condition where the immune system makes too many infection fighting cells called

histiocytes and lymphocytes that may cause various symptoms (haemophagocytic lymphohistiocytosis).

- A condition where the immune system mistakenly destroys red blood cells (oxygen carrying cells) and results in decreased number of red blood cells (autoimmune hemolytic anemia).
- A condition where your body stops producing enough new blood cells (aplastic anemia).

Complications of stem cell transplant that uses donor stem cells (allogeneic) after treatment with Opdivo SC. These complications can be severe and can lead to death. Your healthcare professional will monitor you for signs of complications if you have an allogeneic stem cell transplant. If you are having a stem cell transplant, tell your transplant doctor that you have received Opdivo and/or Opdivo SC in the past.

Also tell your healthcare professional before you are given Opdivo SC if you have received an allogeneic stem cell transplant.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Changes in test results

Opdivo SC may cause changes in the results of tests carried out by your healthcare professional. These include:

- Abnormal liver function tests (increased amounts of the liver enzymes aspartate aminotransferase, alanine aminotransferase or alkaline phosphatase in your blood, higher blood levels of bilirubin).
- Abnormal kidney function tests (increased amounts of creatinine in your blood).
- A decreased number of red blood cells (which carry oxygen), white blood cells (which are important in fighting infection) or platelets (cells which help the blood to clot).
- An increased level of the enzyme that breaks down fats and of the enzyme that breaks down starch.
- Increased or decreased amount of calcium or potassium.
- Increased or decreased blood levels of magnesium or sodium.

Tell your healthcare professional immediately if you get any of the side effects listed above. Do not try to treat your symptoms with other medicines on your own.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

It is unlikely that you will be asked to store Opdivo SC yourself. It will be stored in the hospital or clinic where it is given to you.

Keep out of reach and sight of children.

Do not use Opdivo SC after the expiry date which is stated on the label and carton after EXP.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original package in order to protect from light.

Storage in Syringe

Once withdrawn into the syringe, Opdivo SC should be used immediately. If not used immediately, the syringe can be stored in the refrigerator at 2°C to 8°C, protected from light for up to 7 days and/or at room temperature 15°C to 25°C and room light for up to 8 hours. Discard if storage time exceeds these limits. Do not freeze.

If you want more information about Opdivo SC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [<https://www.bms.com/ca/en>], or by calling Bristol-Myers Squibb Canada at: 1-866-463-6267

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