

OPDIVO[®] *(nivolumab)*

Patient information and treatment diary

To you who are being treated with
OPDIVO[®] (nivolumab)

Introduction

This is a booklet intended as guidance for you who are being treated with OPDIVO. Here you will learn more about this medicine and what you can expect in relation to your treatment. The symptoms of possible side effects are described here, to which you should pay attention, as well as what to do should you experience such symptoms.

For complete information, please see the package leaflet for OPDIVO at www.fass.se.

About OPDIVO

The immune system consists of a number of different cells, including T-cells, which are part of the body's natural defence. T-cells find and destroy cells that the body considers to be alien, such as bacteria, viruses and cancer cells. Occasionally cancer cells can find a way to hide from the body's defence system which leads to the cancer being able to grow and spread. OPDIVO helps by stopping the cancer cells' blocking mechanism towards the immune system's T-cells.

As this treatment works by activating your immune system it can result in side effects caused by the fact that your immune system becomes overactive and starts attacking healthy cells. It is important to contact your doctor or nurse treating you early if you experience symptoms or signs of side effects. You can read more information about side effects related to treatment in section "Side effects from the treatment".

OPDIVO can be used to treat several different types of cancer and can also be given in combination with YERVOY® (ipilimumab).

Before treatment with OPDIVO

Before treatment, your doctor will check your general health. You will also give blood samples during your treatment.

Before treatment you and your doctor will go through whether:

- you have an autoimmune disease (a condition where the body attacks its own cells)
- you have melanoma in your eye
- you have previously been given YERVOY and had severe side effects from this medicine
- your cancer has spread to your brain
- you have previously had inflammation in your lungs
- you are taking or have taken other medicines

Inform your doctor if you are, or if you think you are, pregnant, if you plan to have a child or if you are breast-feeding. It is important to protect yourself against pregnancy.

How OPDIVO is administered

OPDIVO will be administered via an infusion (drip) into the blood.

On the day that you receive treatment, you may experience a general sense of illness. The doctor and nurse treating you can inform you about how this can be treated.

Your doctor will continue to give you OPDIVO so long as you benefit from it or until you no longer tolerate the treatment. It is your doctor who evaluates the treatment with, for example, an X-ray examination.

If you miss an appointment for treatment

It is very important that you come to your appointments to receive OPDIVO. If you miss a treatment, your doctor will plan when to give you your next dose.

Side effects from the treatment

Like all medicines, this medicine can cause side effects, but not everybody experiences them. OPDIVO affects your immune system and can cause inflammation in parts of the body. Inflammation can cause serious injury in the body and some inflammatory conditions can be life-threatening and may need treatment or may need you to discontinue your treatment with OPDIVO.

Most side effects related to your treatment can be treated. For example, your doctor can decide to give you other medicines in order to decrease the symptoms and prevent complications, give your next dose at a later date or discontinue the treatment. Early measures to counteract side effects decrease the risk of having to discontinue the treatment with OPDIVO. It is important that you contact your treating outpatient clinic early if you suspect an side effect or if you are not feeling well.

Side effects from OPDIVO can occur at any time during treatment. Be attentive as side effects can occur also weeks or months after your last dose.

It is important that you contact your treating outpatient clinic if you suspect an side effect. It is very important that side effects are detected early to allow treatment and thereby prevent your condition from deteriorating.

Immediately contact your doctor or nurse if you experience any of these signs or symptoms:



Problems with you liver: signs and symptoms can be yellow whites of your eyes or yellowish skin (jaundice), pain in the right part of your stomach or fatigue.



Diarrhoea: watery, thin or soft stools or other symptoms of inflammation in the bowels (colitis), like stomach pain and mucus or blood in the stools.



Problems with your kidneys: signs and symptoms can be decreased urine volume.



Problems with your lungs such as breathing difficulties or coughing. This can be a sign of inflammation of your lungs.



Inflammation in your muscles like myocarditis (inflammation of your heart muscle), myositis (inflammation of the muscles) and rhabdomyolysis (stiffness of the muscles and joints, muscular cramps). Signs and symptoms of this can be muscular pain, stiffness, weakness, chest pain or intense fatigue.



Problems with hormone-producing glands (including the thyroid gland and the adrenal glands): signs and symptoms that your glands do not work normally can be extreme fatigue, weight changes or headache and visual disturbances.



Diabetes (symptoms like exaggerated thirst, large increase in urine volume, increased appetite with weight loss, sensation of fatigue, drowsiness, weakness, depression, irritability and a general sensation of illness) or diabetic ketoacidosis (acid in the blood caused by the diabetes).



Inflammation in the skin which can cause serious skin reactions (known as toxic epidermal necrolysis and Stevens-Johnson syndrome). Signs and symptoms of serious skin reaction (sometimes lethal) can express itself as rash, itching and skin detachment.

Immediately contact the health care staff if you experience signs, symptoms described in this booklet, or if you have other adverse reactions. Receiving medical care at an early stage can prevent the problem from becoming serious. Do not try to treat your symptoms with other medicines on your own.

For a complete list of side effects, please see the package leaflet for OPDIVO at www.fass.se.

Your patient card

Your doctor or your nurse will give you a patient card. It contains important safety information that you need to know before, during and after your treatment with OPDIVO. It also contains information that all medical staff need to know about your treatment. Therefore, it is important that you show your patient card to all other health care staff that you meet. This is also valid for your visit to a primary care centre or a hospital.

If you have not been given a patient card or if you have lost it, ask the doctor or nurse treating you for a new one.

Always bring the patient card with you and show it if you need to visit another doctor, for example when you are travelling. It contains important information about symptoms that may need to be treated in agreement with your treating doctor.

Your treatment diary

This diary is created to make it easier for you, your doctor and your nurse to detect symptoms of side effects early, which may occur with your treatment with OPDIVO. If the symptoms are detected in time they can often be treated and can prevent the side effects from worsening.

Take time to fill in the diary and bring it to every visit to your treating doctor or nurse.

Date for treatment: day on /

..... day on/..... day on/..... day on/..... day on/..... day on/..... day on/..... day on/.....
How are you feeling?						
Are you still able to perform your normal activities?						
Are you nauseous and/or vomiting?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you lost your appetite or do you feel less hungry than usually?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
How many defecations do you have each day?						
Are your defecations more numerous than normally?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Are your stools thin or watery?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you seen blood or mucus in your stools?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Are your defecations painful?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you got a new cough or deteriorated cough?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have breathing problems?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you had itching, skin rash, blisters, ulcers or peeling of the skin?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have a constant or unusual headache?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you felt extremely tired?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you had changes of your mood or your behaviour such as decreased sex drive, irritability or forgetfulness?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you had numbness, pain or weakness in your muscles or difficulties walking?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have pain or numbness/swelling in joints or muscles?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you had pain or redness in your eye, visual problems or blurred vision?						
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO

Immediately contact the outpatient clinic if you feel ill during the treatment so that they can help you.

▼ This medicine is subject to increased supervision

OPDIVO® is an immunotherapy that is used to treat adults with:

- advanced melanoma (a type of skin cancer)
- melanoma that has been completely removed with surgery (treatment after operation is called adjuvant treatment)
- advanced non-small cell lung cancer (a type of lung cancer)
- advanced renal cell cancer
- Hodgkin's lymphoma
- advanced head and neck cancer
- advanced urothelial cell cancer (cancer in the urine bladder and in the urinary tract)

Opdivo can be administered in combination with ipilimumab for advanced melanoma or advanced renal cell cancer. It is important that you also read the package leaflet for Yervoy®. Ask your doctor if you have questions about Yervoy.

The active substance in Opdivo is called nivolumab.

Do not use Opdivo if you are allergic to nivolumab or any other excipient in this medicine.

You must not treat side effects that are related to Opdivo on your own and must always contact your doctor. Note that side effects may occur at any time during the treatment and sometimes weeks or months after your last dose.

Potency and package: Opdivo is a concentrate for infusion fluid with potency 10 mg/ml. The package size is either 1 injection bottle at 4 ml or 1 injection bottle at 10 ml or 1 injection bottle at 24 ml.

Further information: For complete information about Opdivo, carefully read the package leaflet contained in the package (it can also be found at www.fass.se).

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