

OPDIVO MONOTHERAPY



# Patient information and treatment diary

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For patients being treated with adjuvant  
OPDIVO® (nivolumab) for oesophageal and  
gastro-oesophageal junction cancer

**OPDIVO**®  
*(nivolumab)*

# Introduction

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This booklet is intended as a guide for patients being treated with adjuvant OPDIVO for oesophageal cancer or gastro-oesophageal junction cancer. Here, you can learn more about OPDIVO, and what to expect in conjunction with your treatment. The symptoms of possible side effects, to which you should pay careful attention, are reviewed as well as what to do should you experience any of these symptoms.

For complete information, please see the package leaflet for OPDIVO on [www.fass.se](http://www.fass.se).

## About OPDIVO

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

As this treatment works by activating your immune system, it can result in side effects caused by your immune system becoming overactive and starting to attack healthy cells. It is important that you contact your treating physician or nurse if you experience symptoms or possible signs of side effects. You can find further information on treatment related side effects in the section "Side effects from the treatment" on pages 4-5.

# Before treatment with adjuvant OPDIVO

Prior to treatment, your doctor will perform a general health check. You will also provide **blood samples** during your treatment.

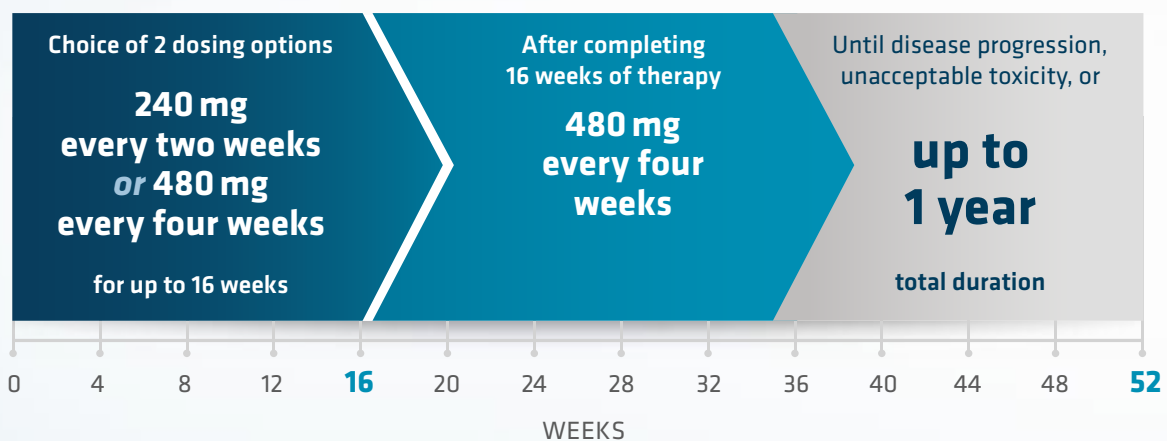
## Before starting the treatment, you and your doctor will go through whether:

- you have an **autoimmune disease** (a condition where the body attacks its own cells)
- you **have previously** received OPDIVO and experienced **serious side effects** from this medicine
- your **cancer has spread to the brain**
- you have previously **had inflammation in the lungs**
- you are taking or have recently taken other **medicines**

**Inform your doctor** if you are, or think you may be, pregnant, if you are planning to have a baby or if you are breastfeeding. **It is important that you protect yourself against pregnancy in conjunction with the treatment.**

# How the adjuvant treatment with OPDIVO will be administered

OPDIVO will be administered over 30 minutes as an infusion (drip) into a vein. The adjuvant treatment with OPDIVO is given every two weeks or every four weeks for the first 16 weeks, followed by every four weeks.



# How the adjuvant treatment with OPDIVO will be administered

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On the day you receive treatment, you may feel generally unwell. In which case, your treating physician and nurse can inform you about how this can be managed. Your doctor will continue to give you OPDIVO for up to 1 year or until you no longer tolerate the treatment. Your doctor will evaluate the treatment, for example, by X-ray examination.

## If you miss a scheduled appointment for treatment

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

## Side effects from the treatment

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

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**It is very important that side effects are detected early to allow treatment and thereby prevent your condition from deteriorating.**

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The majority of side effects related to your treatment can be counteracted. For example, your doctor can decide to give you other drugs to reduce the symptoms and prevent complications, delay the next dose or finish the therapy. Early action to counteract side effects reduces the risk that the therapy will need to be stopped. It is important that you contact your treating clinic early on if you suspect a side effect or you do not feel well.

Side effects can occur at any time during the treatment. Pay attention, because side effects can also arise weeks or months after your last dose.

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**It is important that you contact your treating clinic, if you suspect a side effect.**

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# Pay attention to side effects

In most cases, the side effects can be treated if they are detected early. Therefore, it is important that you contact your doctor or nurse immediately if you experience any of these signs or symptoms:



**Liver problems:** indications and symptoms could be yellow whites of the eye or yellowish skin (jaundice), pain in the right-hand side of the abdominal region or tiredness.



**Diarrhoea:** watery, loose or soft faeces or other symptoms of **intestinal inflammation** (colitis), such as abdominal pains and mucus or blood in the faeces.



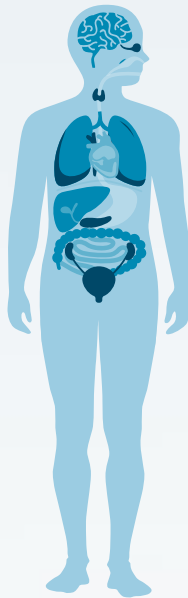
**Kidney problems:** indications and symptoms can be reduced quantity of urine.



**Lung problems** such as breathing difficulties or coughing. This could be indication of inflammation in the lungs.



**Inflammation in the muscles** such as myocarditis (inflammation of the heart muscle), myositis (inflammation in the muscles) and rhabdomyolysis (stiffness in muscles, joints, muscle cramp). Indications and symptoms of this can be expressed as muscle pain, stiffness, weakness, chest pain or serious fatigue.



**Endocrine gland problems** (including thyroid gland and adrenal glands): indications and symptoms that your glands are not functioning normally can include extreme tiredness, weight change or headache or visual disorders.



**Diabetes** (symptoms such as excessive thirst, greatly increased quantity of urine, increased appetite with weight loss, feeling tired, drowsiness, weakness, depression, irritability and generally feeling unwell) or diabetic ketoacidosis (acid in the blood that originates from the diabetes).



**Skin inflammation** that may cause serious skin reaction (known as toxic epidermal necrolysis and Stevens-Johnson's syndrome). Indications and symptoms of a serious skin reaction (sometimes fatal) can be expressed as rash, itching and peeling of the skin.

Immediately seek medical attention, if you experience indications or symptoms that are mentioned in this booklet or if you have other side effects. Receiving medical treatment at an early stage can prevent the problem from becoming serious.

Do not try to treat your symptoms with other medicines yourself.

**For a complete list of side effects, consult the package leaflet for OPDIVO on [www.fass.se](http://www.fass.se)**

## Your Patient Card

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Your doctor or nurse will give you a patient card. This contains important safety information, which you need to be aware of before, during and after your treatment with OPDIVO. It also contains information that all of the medical personnel need to know about your treatment. For this reason, it is important that you present your patient card to all medical personnel you come into contact with. This is also the case when you visit health centres or hospitals.

If you haven't received a patient card, or if you have lost it, ask your treating physician or nurse for a new one.

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**Always carry the patient card with you and present it if you should need to visit another doctor, e.g. if you are on holiday. It contains important information about symptoms that may need to be treated in consultation with your treating physician.**

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## Your treatment diary

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The purpose of this diary is to make it easier for you, your doctor and your nurse to detect symptoms of potential side effects that may arise during your treatment with OPDIVO at an early stage. If the symptoms are detected early, they can often be treated and managed, preventing the side effect from worsening.

Take the time to fill in the diary and bring it to every appointment with your treating physician or nurse.

Date of treatment.....day on...../.....

..... day on ...../.....	..... day on ...../.....	..... day on ...../.....	..... day on ...../.....	..... day on ...../.....	..... day on ...../.....	..... day on ...../.....
<b>How are you feeling?</b>						
<b>Are you still able to perform your normal activities?</b>						
<b>Are you nauseous and/or vomiting?</b>						
<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
<b>Have you lost your appetite or do you feel less hungry than usual?</b>						
<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
<b>How many defecations do you have each day?</b>						
<b>Are you defecating more often than normal?</b>						
<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
<b>Are your faeces loose or liquid?</b>						
<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
<b>Have you seen blood or mucous in your faeces?</b>						
<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
<b>Are your defecations painful?</b>						
<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
<b>Do you have a new cough or deteriorated cough?</b>						
<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
<b>Do you have breathing difficulties?</b>						
<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
<b>Have you had itching, skin rash, blisters, sores or peeling of the skin?</b>						
<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
<b>Do you have a constant or unusual headache?</b>						
<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
<b>Have you felt extremely tired?</b>						
<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
<b>Have you had changes in your mood or behaviour such as reduced sex drive, irritability or forgetfulness?</b>						
<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
<b>Have you had numbness, pain or weakness in your muscles or difficulty walking?</b>						
<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
<b>Do you have pain or numbness/swelling in your joints or muscles?</b>						
<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
<b>Have you had pain and redness in your eyes, visual problems or blurred vision?</b>						
<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

Contact your treating clinic immediately, if you feel ill during the treatment, so they can help you.

**For further information about  
OPDIVO, please visit the website  
[www.opdivopatient.se](http://www.opdivopatient.se)**



**There is also an informational video:  
“For patients who will receive immunotherapy treatment”  
Ask your nurse if you are interested.**

**OPDIVO®** is an immune therapy used in adults to treat the following:

- advanced colorectal cancer (colon cancer or rectal cancer)
- advanced oesophageal cancer (cancer of the oesophagus, the passage from mouth to stomach)
- oesophageal cancer and gastro-oesophageal junction cancer (cancer at the junction between the stomach and the oesophagus) (adjuvant therapy)
- advanced gastric (stomach) cancer, gastro-oesophageal junction cancer or oesophageal adenocarcinoma

The active substance in Opdivo is called nivolumab.

Opdivo can be given in combination with Yervoy® (ipilimumab) or chemotherapy for advanced oesophageal cancer.

If you receive other medicines in combination with Opdivo, it is important that you also read the package leaflet for those. Ask your doctor, if you have any questions about those medicines.

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

**You must not** treat side effects that are related to Opdivo on your own. 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.

**Strength and packaging:** Opdivo is a concentrate for infusion fluid with the strength 10 mg/ml. The pack size is either 1 injection vial containing 4 ml, 1 injection vial containing 10 ml, 1 injection vial containing 12 ml or 1 injection vial containing 24 ml.

**Further information:** For complete information about Opdivo, carefully read the package leaflet enclosed with the package (it is also available on [www.fass.se](http://www.fass.se)).

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