



Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening and need treatment or withdrawal of OPDIVO.

The following side effects have been reported **with OPDIVO alone**:

**Very common (may affect more than 1 in 10 people)**

- Infections of the upper respiratory tract
- 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)
- Decreased appetite, high sugar levels in the blood (hyperglycaemia)
- Headache
- Shortness of breath (dyspnoea), cough
- Diarrhoea (watery, loose or soft stools), vomiting, nausea, stomach pain, constipation
- Skin rash sometimes with blisters, itching
- Pain in the muscles, bones (musculoskeletal pain) and joints (arthralgia)
- Feeling tired or weak, fever

**Common (may affect up to 1 in 10 people)**

- Serious lung infection (pneumonia), bronchitis
- Reactions related to the infusion of the medicine, allergic reaction (including life-threatening allergic reaction)
- Underactive thyroid gland (which can cause tiredness or weight gain), overactive thyroid gland (which can cause rapid heart rate, sweating and weight loss), swelling of the thyroid gland
- Dehydration, decrease in body weight, low sugar levels in the blood (hypoglycaemia)
- Inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs), dizziness
- Blurred vision, dry eyes
- Fast heart rate, abnormal heart rhythm
- High blood pressure (hypertension)
- Inflammation of the lungs (pneumonitis, characterised by coughing and difficulty breathing), fluid around the lungs
- Inflammation of the intestines (colitis), mouth ulcers and cold sores (stomatitis), dry mouth
- Skin colour change in patches (vitiligo), dry skin, redness of the skin, unusual hair loss or thinning
- Inflammation of the joints (arthritis)
- Kidney failure (including abrupt loss of kidney function)
- Pain, chest pain, oedema (swelling)

**Uncommon (may affect up to 1 in 100 people)**

- Increase in some white blood cells
- Chronic diseases associated with a build-up of inflammatory cells in various organs and tissues, most commonly the lungs (sarcoidosis)
- Decreased secretion of hormones produced by adrenal glands (glands situated above the kidneys), underactive function (hypopituitarism) or inflammation (hypophysitis) of the pituitary gland situated at the base of the brain, diabetes
- Increased acid levels in the blood (metabolic acidosis)
- Damage to nerves causing numbness and weakness (polyneuropathy), inflammation of the nerves caused by the body attacking itself, causing numbness, weakness, tingling or burning pain (autoimmune neuropathy)
- Inflammation of the eye (which causes pain and redness)
- Inflammation of the heart muscle, inflammation of the covering of the heart and accumulation of fluid around the heart (pericardial disorders), changes in the rhythm or rate of the heartbeat
- Fluid in the lungs
- Inflammation of the pancreas (pancreatitis), inflammation of the stomach (gastritis)
- Inflammation of the liver (hepatitis), blockage of bile ducts (cholestasis)

- Skin disease with thickened patches of red skin, often with silvery scales (psoriasis), severe condition of the skin that causes red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body (erythema multiforme), hives (itchy, bumpy rash)
- Inflammation of the muscles causing pain or stiffness (polymyalgia rheumatica)

**Rare (may affect up to 1 in 1000 people)**

- A temporary and reversible non-infectious inflammation of the protective membranes surrounding the brain and spinal cord (aseptic meningitis)
- A disease causing the inflammation or enlargement of a lymph node (Kikuchi lymphadenitis)
- Acid in the blood produced from diabetes (diabetic ketoacidosis), decreased function of the parathyroid gland
- A temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome), loss of the protective sheath around nerves (demyelination), a condition in which the muscles become weak and tire easily (myasthenic syndrome)
- An inflammation of the optic nerve that may cause a complete or partial loss of vision (optic neuritis)
- Inflamation of the brain
- Inflammatory disease of blood vessels
- Ulcer of the small intestines
- Severe and possibly fatal peeling of the skin (toxic epidermal necrolysis or Stevens-Johnson syndrome), skin condition of the face where the nose and cheeks are unusually red (rosacea)
- Disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren’s syndrome), aching muscles, muscle tenderness or weakness, not caused by exercise (myopathy), inflammation of the muscles (myositis), stiffness in muscles and joints, muscle spasm (rhabdomyolysis)
- Inflammation of the kidney, inflammation of the bladder, signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen
- Lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)
- Coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)

**Other side effects that have been reported with frequency not known (cannot be estimated from the available data):**

- A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (called haemophagocytic lymphohistiocytosis)
- Solid organ transplant rejection
- A group of metabolic complications occurring after cancer treatment characterised by high blood levels of potassium and phosphate, and low blood levels of calcium (tumour lysis syndrome)
- An inflammatory disorder (most likely of autoimmune origin) affecting the eyes, skin and the membranes of the ears, brain and spinal cord (Vogt-Koyanagi-Harada syndrome)
- Pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation (myelitis/transverse myelitis)
- Changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (lichen sclerosus or other lichen disorders)

The following side effects have been reported **with OPDIVO in combination with other anti-cancer medicines** (the frequency and severity of side effects may vary with the combination of anti-cancer medicines received):

**Very common (may affect more than 1 in 10 people)**

- Infections of the upper respiratory tract
- 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)
- Underactive thyroid gland (which can cause tiredness or weight gain), overactive thyroid gland (which can cause rapid heart rate, sweating and weight loss)
- Decreased appetite, decrease in body weight, high (hyperglycaemia) or low (hypoglycaemia) sugar levels in the blood
- Inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs), headache, dizziness, altered sense of taste
- High blood pressure (hypertension)
- Shortness of breath (dyspnoea), cough, abnormal speaking sound (dysphonia)
- Diarrhoea (watery, loose or soft stools), constipation, vomiting, nausea, stomach pain, mouth ulcers and cold sores (stomatitis), indigestion (dyspepsia)
- Skin rash sometimes with blisters, itching, pain of the hands or soles of the feet: rash or redness of the skin, tingling and tenderness developing to symmetrical redness, swelling and pain primarily on the palm of the hand and sole of the foot (palmar-plantar erythrodysaesthaesia syndrome)
- Pain in the joints (arthralgia), pain in the muscles and bones (musculoskeletal pain), muscle spasm
- Excess protein in urine
- Feeling tired or weak, fever, oedema (swelling)

**Common (may affect up to 1 in 10 people)**

- Serious lung infection (pneumonia), bronchitis, inflammation of the eye (conjunctivitis)
- Increase in some white blood cells, decrease in neutrophils with fever
- Allergic reaction (including life-threatening allergic reaction), reactions related to the infusion of the medicine
- Decreased secretion of hormones produced by adrenal glands (glands situated above the kidneys), underactive function (hypopituitarism) or inflammation (hypophysitis) of the pituitary gland situated at the base of the brain, swelling of the thyroid gland, diabetes
- Dehydration, decreased levels of albumin in the blood, decreased levels of phosphate in the blood
- Sensations like numbness and tingling (paraesthesia)
- Hearing a persistent sound in your ear when no sound exists (tinnitus)
- Blurred vision, dry eye
- Fast heart rate, abnormal heart rhythm
- Formation of a blood clot within a blood vessel (thrombosis), inflammatory disease of blood vessels
- Inflammation of the lungs (pneumonitis, characterised by coughing and difficulty breathing), fluid around the lungs, blood clots, nose bleeding
- Inflammation of the intestines (colitis), inflammation of the pancreas (pancreatitis), dry mouth, inflammation of the stomach (gastritis), oral pain, haemorrhoids (piles)
- Inflammation of the liver
- Skin colour change in patches (including vitiligo), redness of the skin, unusual hair loss or thinning, hair colour change, hives (itchy rash), discolouration or abnormal darkening of the skin (skin hyperpigmentation), dry skin
- Inflammation of the joints (arthritis), muscle weakness, aching muscles
- Kidney failure (including abrupt loss of kidney function)
- Pain, chest pain, chills
- Feeling generally unwell (malaise)

**Uncommon (may affect up to 1 in 100 people)**

- Acid in the blood produced from diabetes (diabetic ketoacidosis)
- Increased acid levels in the blood
- A temporary inflammation of the nerves that causes pain, weakness and paralysis in the extremities (Guillain-Barré syndrome); damage to nerves causing numbness and weakness (polyneuropathy); foot drop (peroneal nerve palsy); inflammation of the nerves caused by the body attacking itself, causing numbness, weakness, tingling or burning pain (autoimmune neuropathy); muscle weakness and tiredness without atrophy (myasthenia gravis or syndrome)
- Inflammation of the brain
- Inflammation of the eye (which causes pain and redness)
- Changes in the rhythm or rate of the heartbeat, slow heart rate, inflammation of the heart muscle
- Intestinal perforation, inflammation of the duodenum, burning or painful sensation in the tongue (glossodynia)
- Severe and possibly fatal peeling of the skin (Stevens-Johnson syndrome), skin disease with thickened patches of red skin, often with silvery scales (psoriasis), severe condition of the skin that causes red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body (erythema multiforme), changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (other lichen disorders)
- Muscle tenderness or weakness, not caused by exercise (myopathy), inflammation of the muscles (myositis), stiffness in muscles and joints, inflammation of the muscles causing pain or stiffness (polymyalgia rheumatica), bone damage in the jaw, abnormal opening between two body parts, such as an organ or blood vessel and another structure (fistula)
- Inflammation of the kidney, inflammation of the bladder, signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen

**Rare (may affect up to 1 in 1000 people)**

- Temporary and reversible non-infectious inflammation of the protective membranes surrounding the brain and spinal cord (aseptic meningitis)
- Chronic diseases associated with a build-up of inflammatory cells in various organs and tissues, most commonly the lungs (sarcoidosis)
- Decreased function of the parathyroid gland
- A group of metabolic complications occurring after cancer treatment characterised by high blood levels of potassium and phosphate, and low blood levels of calcium (tumour lysis syndrome)
- An inflammatory disorder (most likely of autoimmune origin) affecting the eyes, skin and the membranes of the ears, brain and spinal cord (Vogt-Koyanagi-Harada syndrome)
- An inflammation of the optic nerve that may cause a complete or partial loss of vision (optic neuritis)
- Inflamation of the nerves
- Pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation (myelitis/transverse myelitis)
- Severe and possibly fatal peeling of the skin (toxic epidermal necrolysis), changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (lichen sclerosus)
- Chronic disease of joints (spondyloarthropathy), disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren’s syndrome), muscle spasm (rhabdomyolysis)

- Lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)
- Coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)

**Other side effects that have been reported with frequency not known (cannot be estimated from the available data):**

- A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (called haemophagocytic lymphohistiocytosis)
- Solid organ transplant rejection
- Inflamation of the covering of the heart and accumulation of fluid around the heart (pericardial disorders)

**Tell your doctor immediately** if you get any of the side effects listed above.

Do not try to treat your symptoms with other medicines on your own.

**Changes in test results**

OPDIVO alone or in combination may cause changes in the results of tests carried out by your doctor. These include:

- Abnormal liver function tests (increased amounts of the liver enzymes aspartate aminotransferase, alanine aminotransferase, gamma-glutamyltransferase, or alkaline phosphatase in your blood, higher blood levels of the waste product bilirubin)
- Abnormal kidney function tests (increased amounts of creatinine in your blood)
- 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
- Increased amount of thyroid stimulating hormone
- Increase in blood triglyceride levels in the blood
- Increase in cholesterol levels in the blood

**Reporting of side effects**

If you get any side effects, **talk to your doctor**. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme Website: http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

## 5. How to store OPDIVO

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and the vial label after EXP. The expiry date refers to the last day of that month.

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

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

The unopened vial can be stored at controlled room temperature up to 25°C with room light for up to 48 hours.

Do not store any unused portion of the infusion solution for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

### 6. Contents of the pack and other information

**What OPDIVO contains**

- The active substance is nivolumab. Each mL of concentrate for solution for infusion contains 10 mg of nivolumab. Each vial contains either 40 mg (in 4 mL), 100 mg (in 10 mL) or 120 mg (in 12 mL) of nivolumab.
- The other ingredients are sodium citrate dihydrate, sodium chloride (see section 2 “OPDIVO contains sodium”), mannitol (E421), pentetic acid, polysorbate 80 (E433), sodium hydroxide, hydrochloric acid and water for injections.

**What OPDIVO looks like and contents of the pack**
OPDIVO concentrate for solution for infusion (sterile concentrate) is a clear to opalescent, colourless to pale yellow liquid that may contain few light particles.

It is available in packs containing either 1 vial of 4 mL, 1 vial of 10 mL or 1 vial of 12 mL.

**Manufacturer**

Swords Laboratories Unlimited Company t/a Bristol-Myers Squibb
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PL 45763/0823

**POM**

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company

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For any information about this medicine, please contact the local representative of the Product Licence Holder:
Abacus Medicine Ltd., tel: +44(0)2036301244, email: MedInfo@abacusmedicine.co.uk or drugsafetyuk@abacusmedicine.co.uk

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### Administration

OPDIVO infusion must not be administered as an intravenous push or bolus injection.

Administer the OPDIVO infusion **intravenously over a period of 30 or 60 minutes depending on the dose.**

OPDIVO infusion should not be infused at the same time in the same intravenous line with other agents. Use a separate infusion line for the infusion.

Use an infusion set and an in-line, sterile, non-pyrogenic, low protein binding filter (pore size of 0.2 µm to 1.2 µm).

OPDIVO infusion is compatible with:

- PVC containers
- Polyolefin containers
- Glass bottles
- PVC infusion sets
- In-line filters with polyethersulfone membranes with pore sizes of 0.2 µm to 1.2 µm.

After administration of the nivolumab dose, flush the line with sodium chloride 9 mg/mL (0.9%) solution for injection or 50 mg/mL (5%) glucose solution for injection.

**Storage conditions and shelf life**

Unopened vial

OPDIVO must be **stored in a refrigerator** (2°C to 8°C). The vials must be kept in the original package in order to protect from light. OPDIVO should not be frozen. The unopened vial can be stored at controlled room temperature up to 25°C with room light for up to 48 hours. Do not use OPDIVO after the expiry date which is stated on the carton and on the vial label after EXP. The expiry date refers to the last day of that month.

OPDIVO infusion

Chemical and physical in-use stability from the time of preparation has been demonstrated as follows (times are inclusive of the administration period):

Infusion preparation	Chemical and physical in-use stability	
	Storage at 2°C to 8°C protected from light	Storage at room temperature (≤ 25°C) and room light
Undiluted or diluted with sodium chloride 9 mg/mL (0.9%) solution for injection	30 days	24 hours (of total 30 days storage)
Diluted with 50 mg/mL (5%) glucose solution for injection	7 days	8 hours (of total 7 days storage)

From a microbiological point of view the prepared solution for infusion, regardless of the diluent, should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 7 days at 2°C to 8°C or 8 hours (of the total 7 days of storage) at room temperature (≤ 25°C). Aseptic handling should be ensured during the preparation of infusion.

### Disposal

Do not store any unused portion of the infusion solution for reuse.

Any unused medicine or waste material should be disposed of in accordance with local requirements.