

Package leaflet: Information for the patient

Odomzo 200 mg hard capsules sonidegib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Odomzo may cause severe birth defects. It may lead to the death of a baby before it is born or shortly after being born. You must not become pregnant while taking this medicine. You must follow the contraception instructions contained in this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Odomzo is and what it is used for
2. What you need to know before you take Odomzo
3. How to take Odomzo
4. Possible side effects
5. How to store Odomzo
6. Contents of the pack and other information

1. What Odomzo is and what it is used for

What Odomzo is

Odomzo contains the active substance sonidegib. It is an anti-cancer medicine.

What Odomzo is used for

Odomzo is used to treat adults with a type of skin cancer called basal cell carcinoma. It is used when the cancer has spread locally and cannot be treated with surgery or radiation.

How Odomzo works

The normal growth of cells is controlled by various chemical signals. In patients with basal cell carcinoma, changes occur to genes controlling a part of this process known as the “hedgehog pathway”. This switches on signals that make the cancer cells grow out of control.

Odomzo works by blocking this process, stopping cancer cells from growing and making new cells.

2. What you need to know before you take Odomzo

Read the specific instructions given to you by your doctor, particularly on the effects of Odomzo on unborn babies.

Read carefully and follow the instructions of the patient brochure and reminder card given to you by your doctor.

Do not take Odomzo:

- if you are allergic to sonidegib or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or think you may be pregnant. This is because Odomzo may cause harm or death to your unborn baby (see section “Pregnancy”).
- if you are breast-feeding. This is because it is not known whether Odomzo can pass into your breast milk and cause harm to your baby (see section “Breast-feeding”).
- if you are able to become pregnant but are unable or unwilling to follow the necessary pregnancy prevention measures that are listed in the Odomzo Pregnancy Prevention Programme.

Do not take Odomzo if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Odomzo.

Additional information on the above points can be found in the sections “Pregnancy”, “Breast-feeding”, “Fertility” and “Contraception for women and men”.

Warnings and precautions

- Odomzo may cause muscle problems. Tell your doctor before taking Odomzo if you have a history of muscle cramps or weakness or if you are taking other medicines. Some medicines (e.g. medicines used to treat high cholesterol) might increase the risk for muscle problems. Tell your doctor or pharmacist **immediately** if your muscles hurt or you have unexplained muscle cramps or weakness during treatment with Odomzo. Your doctor may need to change your dose, or stop your treatment temporarily or permanently.
- You should not donate blood while on treatment with Odomzo and for 20 months after ending your treatment.
- If you are male, you should not donate semen at any time during treatment and for 6 months after the final dose.
- Your doctor will check your skin regularly for another type of cancer called cutaneous squamous cell carcinoma (SCC). It is not known whether SCC can be related to treatment with Odomzo.

- Usually this type of cancer appears on sun-damaged skin, does not spread and can be cured. Tell your doctor if you notice any changes in your skin.
- Never give this medicine to anyone else. You should return unused capsules at the end of your treatment. Talk to your doctor or pharmacist regarding where to return the capsules.

Blood tests during treatment with Odomzo

Your doctor will perform blood tests before treatment, and possibly during treatment as well. These tests will check the health of your muscles by measuring the levels of an enzyme in your blood called creatine phosphokinase.

Children and adolescents (under 18 years of age)

Odomzo should not be used in children and adolescents below the age of 18. Problems with growing teeth and bones were seen with this medicine.

Other medicines and Odomzo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Odomzo can affect the way some medicines work. Some other medicines can also affect how Odomzo works, or make it more likely that you will have side effects.

In particular tell your doctor or pharmacist if you are taking any of the following:

- medicines such as statins and fibric acid derivatives used to treat high cholesterol and lipids
 - vitamin B3, also known as niacin
 - medicines such as methotrexate, mitoxantrone, irinotecan, or topotecan used to treat certain types of cancers or other diseases such as severe joint problems (rheumatoid arthritis) and psoriasis
 - medicines such as telithromycin, rifampicin or rifabutin used to treat bacterial infections
 - medicines such as ketoconazole (not including shampoos and creams), itraconazole, posaconazole or voriconazole used to treat fungal infections
 - medicines such as chloroquine and hydroxychloroquine used to treat parasitic infections as well as other diseases such as rheumatoid arthritis or lupus erythematosus
 - medicines such as ritonavir, saquinavir or zidovudine used to treat AIDS or HIV
 - medicines such as carbamazepine, phenytoin or phenobarbital used to treat acute seizures
 - a medicine called nefazodone used to treat depression
 - a medicine called penicillamine used to treat rheumatoid arthritis
 - a herbal medicine called St. John’s wort (also known as *Hypericum perforatum*) used to treat depression.
- If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking Odomzo.

These medicines should be used with caution or may need to be avoided during your treatment with Odomzo. If you are taking any of these, your doctor might need to prescribe an alternative medicine for you.

During your treatment with Odomzo, you should also tell your doctor or pharmacist if you are prescribed another medicine that you were not taking before.

Pregnancy

Do not take Odomzo if you are pregnant, think you may be pregnant, or are planning to become pregnant during your treatment or during the 20 months after your treatment has finished. You must stop taking Odomzo and talk to your doctor immediately if you become pregnant or suspect you could be pregnant. Odomzo may cause your baby to have severe birth defects or lead to the death of your unborn baby. Specific instructions (the Odomzo Pregnancy Prevention Programme) given to you by your doctor contain information particularly on the effects of Odomzo on unborn babies.

Breast-feeding

Do not breast-feed during your treatment or during the 20 months after your treatment has finished. It is not known whether Odomzo can pass into your breast milk and cause harm to your baby.

Fertility

Odomzo may have an impact on fertility in men and women. Talk to your doctor if you plan to have children in the future.

Contraception for women and men

Women

Before starting Odomzo treatment, ask your doctor if you are able to become pregnant, even if your periods have stopped (menopause). It is important to check with your doctor whether there is a risk that you could become pregnant.

If you are able to become pregnant:

- you must take precautions so that you do not become pregnant while taking Odomzo,
- you must use 2 methods of contraception, one highly effective method and one barrier method (see the examples below) while you are taking Odomzo,
- you must keep using this contraception for 20 months after you have stopped taking Odomzo because traces of the medicine remain in the body for a long time.

Your doctor will discuss with you the best method of contraception for you.

You must use one highly effective method, such as:

- an intra-uterine device (“the coil” or IUD)
- surgical sterilisation.

You must also use one barrier method, such as:

- a condom (with spermicide, if available)
- a diaphragm (with spermicide, if available).

Your doctor will test you for pregnancy:

- at least 7 days before starting treatment – to make sure that you are not already pregnant
- every month during treatment.

During treatment and during the 20 months after your treatment has finished, tell your doctor straight away if:

- you think your contraception has not worked for any reason
- your periods stop
- you stop using contraception
- you need to change contraception

Men

While you are taking Odomzo, always use a condom (with spermicide, if available) when you have sex with a female partner, even if you have had a vasectomy. You must keep doing this for 6 months after your treatment has finished.

Tell your doctor straight away if your partner becomes pregnant while you are taking Odomzo and for 6 months after your treatment has finished.

You should not donate semen during your treatment and for 6 months after your treatment has finished.

Driving and using machines

Odomzo is not likely to affect your ability to drive or use any tools or machines. Talk to your doctor if you are unsure.

Odomzo contains lactose

Odomzo contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Odomzo

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

The recommended dose is 200 mg (1 capsule) a day.

- Do not eat for 2 hours before taking Odomzo and for 1 hour afterwards.
- Take your capsule at about the same time each day. This will help you to remember when to take your medicine.
- Swallow the capsule whole. Do not open, chew or crush the capsule.

Do not change your dose without talking to your doctor. Do not exceed the recommended dose prescribed by your doctor. If you vomit after you swallow the capsule, do not take any more capsules until your next scheduled dose.

How long to take Odomzo

Keep taking Odomzo for as long as your doctor tells you. If you have questions about how long to take Odomzo, talk to your doctor or pharmacist.

If you take more Odomzo than you should

If you take more Odomzo than you should, or if someone else accidentally takes your medicine, talk to a doctor or go to a hospital straight away. Take the medicine and its packaging and leaflet with you.

If you forget to take Odomzo

If you forget to take a dose of Odomzo, take it as soon you realise. If more than six hours have passed since the dose was due to be taken, skip the missed dose, then take the next dose at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Odomzo

Do not stop taking Odomzo without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Odomzo may cause severe birth defects, You must not become pregnant while taking this medicine (see “Pregnancy”, “Breast-feeding”, “Fertility” and “Contraception for women and men” in section 2 for more information).

Stop taking Odomzo and tell your doctor straight away if you notice any of the following as these could be signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Some side effects could be serious

Tell your doctor or pharmacist straight away if you notice any of the following:

- severe muscle cramps, muscle pain or muscle weakness. These could be signs of a problem called rhabdomyolysis, which involves the breakdown of muscle tissue.

- dark urine, decreased urine output or no urine output. These could be signs that your muscle fibre is breaking down, which is harmful to your kidneys.

Other possible side effects

If any of these side effects become severe, tell your doctor or pharmacist.

Very common: may affect more than 1 in 10 people

- muscle cramps, muscle pain, pain in the bones, ligaments and tendons
- absence of menstrual periods
- diarrhoea or heartburn
- decreased appetite
- headache
- disturbed sense of taste or strange taste in the mouth
- pain in the belly
- feeling sick
- vomiting
- itching
- hair loss
- tiredness
- pain
- weight loss.

Common: may affect up to 1 in 10 people

- upset stomach or indigestion
- constipation
- rash
- abnormal hair growth
- thirst, not passing much urine, weight loss, dry flushed skin, irritability (possible symptoms of low level of fluids in the body, known as dehydration).

During Odomzo treatment, you may also have some **abnormal blood test results**. These can alert your doctor to possible changes in the function of some parts of your body, for example:

- high levels of the following enzymes: creatine phosphokinase (muscle function), lipase and/ or amylase (pancreas function), alanine aminotransferase (ALT) and/ or aspartate aminotransferase (AST) (liver function)
- high level of creatinine (kidney function)
- high level of sugar in the blood (known as hyperglycaemia)
- low level of haemoglobin (needed to transport oxygen in the blood)
- low level of white blood cells.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Odomzo

- 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 pack and the blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Odomzo contains

- The active substance is sonidegib (as phosphate). Each capsule contains 200 mg sonidegib.
- The other ingredients are:
 - Capsule contents: crospovidone, lactose monohydrate, magnesium stearate, poloxamer (188), silica, colloidal anhydrous (colloidal silicon dioxide), sodium laurilsulfate (sodium lauryl sulfate).
 - Capsule shell: gelatin, red iron oxide (E172), titanium dioxide (E171).
 - Printing ink: black iron oxide (E172), propylene glycol (E1520), shellac.

What Odomzo looks like and contents of the pack

Odomzo 200 mg capsules are pink and opaque. They are imprinted with “SONIDEGIB 200MG” and “NVR”.

Odomzo is provided in perforated unit-dose blisters containing 10 x 1 capsule. It is available in pack sizes of 10 and 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ranbaxy UK Ltd
Tel: +44 (0) 208 848 8688

This leaflet was last revised in 06/2017

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>

As part of the Odomzo Pregnancy Prevention Programme, all patients will receive a:

- Patient Brochure
- Patient Reminder Card

Please refer to these documents for further information.