

ODOMZO®

sonidegib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ODOMZO. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ODOMZO against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ODOMZO is used for

ODOMZO contains the active ingredient sonidegib.

ODOMZO belongs to a group of medicines called anti-neoplastic (or anti-cancer) medicines. It works by blocking cancer cells from growing and making new cells.

ODOMZO is used to treat adults with a type of skin cancer called advanced basal cell carcinoma. It is used when the cancer:

- has spread to surrounding areas (called "locally advanced" basal cell carcinoma) and your doctor has decided that treatment with surgery or radiation is not appropriate.
- has spread to other parts of the body (called "metastatic" basal cell carcinoma).

Surgery and radiation treatment may not be appropriate because:

- surgery will change the shape of a body part (cause deformity) e.g. face, neck
- surgery may cause you to lose the use of a body part such as an eye or ear
- the cancer has returned after previous surgery and further surgery may not work or is not possible
- radiation was previously not successful or it is not suitable for you to have radiation.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take ODOMZO

When you must not take it

Do not take ODOMZO if you are you are pregnant, think you may be pregnant, or are planning to become pregnant during the course of treatment and for 20 months after your final dose of the medicine.

You must not take this medicine if you are pregnant or plan to become pregnant.

ODOMZO may affect your developing baby if you take it during pregnancy. ODOMZO may cause your baby to die before it is

born or cause your baby to have severe birth defects.

Do not take ODOMZO if you are breast-feeding or plan to breast-feed while on treatment with ODOMZO and for 20 months after your final dose of the medicine.

It is not known if the active ingredient in ODOMZO can pass into breast milk and can cause harm to your baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

You have a history of muscle cramps or weakness or if you are taking other medicines.

ODOMZO may cause muscle pain, cramps or weakness, some medicines (e.g. medicines used to treat high cholesterol) might increase the chance for muscle pain, cramps or weakness.

You plan to donate blood during treatment with ODOMZO or plan to do so in the future.

You should not donate blood while on treatment with ODOMZO and for 20 months after your final dose of the medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking ODOMZO.

Children and adolescents

Do not use ODOMZO in children and adolescents below the age of 18 years.

Fertility preservation

Talk to your doctor about fertility preservation if you plan to have children in the future.

ODOMZO may have an impact on fertility in men and women. Discuss with your doctor fertility preservation before starting treatment with ODOMZO.

Women with the potential to become pregnant

Discuss with 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:

- use two methods of birth control (contraception) including a highly effective method and a barrier method such as a condom, so that you do not become pregnant while on treatment with ODOMZO
- continue to use a highly effective method and barrier method of birth control (contraception) for 20 months after your final dose of the medicine.

Talk to your doctor about the most suitable method of birth control (contraception) for you.

Talk to your doctor about a pregnancy test before starting treatment with ODOMZO.

During treatment and 20 months after treatment, tell your doctor immediately if:

- you believe your contraception has failed for any reason
- your periods stop
- you stop using contraception
- you need to change your contraception.

Men 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. Do this during treatment and for 6 months after your final dose of the medicine.

Do not donate semen while on treatment with ODOMZO and for 6 months after your final dose of the medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ODOMZO may interfere with each other.

These include:

- medicines used to treat high cholesterol; statins and fibric acid derivatives;
- vitamin B3 also known as niacin;
- medicines used to treat infections. These include medicines that treat certain types of bacterial infections (antibiotics such as telithromycin, rifampin, rifabutin) or treat fungal infections such as ketoconazole in formulations other than shampoo, itraconazole, posaconazole or voriconazole;
- medicines used to treat AIDS/HIV, such as ritonavir, saquinavir or zidovudine;
- medicines used to treat acute seizures, such as carbamazepine, phenytoin or phenobarbital;
- chloroquine and hydroxychloroquine, medicines used to treat parasitic infections;
- nefazodone, a medicine used to treat depression;
- penicillamine, a medicine used to treat severe joint problems (rheumatoid arthritis);

- St. John's wort (a herbal medicine also known as Hypericum perforatum used to treat depression)
- Medicines used to treat gastro-oesophageal reflux disease or gastric or duodenal ulcers (such as esomeprazole, omeprazole, ranitidine, cimetidine, famotidine).

These medicines may be affected by ODOMZO or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ODOMZO

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual recommended dose is one 200mg capsule per day.

How to take it

ODOMZO capsules are to be taken by mouth on an empty stomach.

Swallow the capsules whole with a full glass of water.

When to take it

Take ODOMZO once a day at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take ODOMZO on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of this medicine.

How long to take it

Continue taking your medicine 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 forget to take it

If it is more than 6 hours since your last ODOMZO dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON, 0800 764 766 in NZ) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ODOMZO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers for these places handy.

While you are using ODOMZO

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ODOMZO.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Both men and women (who are able to become pregnant) need to take precautions so that a pregnant woman is not exposed to ODOMZO. You will need to do this for 20 months after stopping treatment if you are a woman and for 6 months after stopping treatment if you are a man.

ODOMZO may cause your baby to have severe birth defects or lead to the death of your unborn baby.

Talk to your doctor immediately if you have unprotected sex or if you think your contraception has failed.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests (such as checking muscle function, liver, kidney and pancreas function) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Women taking ODOMZO

Women who are able to become pregnant will need to show a negative pregnancy test done by your doctor before starting treatment with ODOMZO.

If you become pregnant while taking this medicine or suspect you could be pregnant, stop taking ODOMZO and tell your doctor immediately.

Women who are able to get pregnant must use two methods of birth control (contraception), a highly effective method and a

barrier method. This applies during treatment and for 20 months after your final dose of the medicine.

Men 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. Do this during treatment and for 6 months after your final dose of the medicine.

Do not donate semen while on treatment with ODOMZO and for 6 months after your final dose of the medicine.

Tell your doctor immediately if your partner becomes pregnant or thinks she is pregnant while you are taking ODOMZO.

Things you must not do

Do not take ODOMZO to treat any other complaints unless your doctor tells you to.

Do not give ODOMZO to anyone else, even if they have the same condition as you.

Do not stop taking ODOMZO or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how ODOMZO affects you.

This medicine may cause tiredness in some people. If you feel tired, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ODOMZO.

This medicine helps most people with advanced basal cell carcinoma, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- muscle pain, weakness, spasms or cramps, pain in the bones, ligaments and tendons
- absence of menstrual periods
- diarrhoea, heartburn
- decreased appetite
- headache
- disturbed sense of taste or strange taste in the mouth
- stomach (abdominal) pain
- feeling sick (nausea)
- hair loss (alopecia)
- tiredness (fatigue)
- pain
- weight loss
- vomiting
- upset stomach, indigestion
- constipation
- rash
- itching
- abnormal hair growth

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- unexpected muscle pain, tenderness or weakness not caused by exercise

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth, tongue, throat or neck which may cause difficulty in swallowing or breathing
- unexpected muscle pain, tenderness or weakness not caused by exercise, particularly if you also feel unwell or have a fever.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

During ODOMZO treatment, you may also have some abnormal blood test results such as high levels of creatine phosphokinase (muscle function), high levels of lipase and/or amylase (pancreas function), high level of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (liver function), high level of creatinine (kidney function), high level of sugar in the blood, low level of hemoglobin (needed to transport oxygen in the blood) and low level of white blood cells.

The above side effects may be serious. You may need urgent medical attention. Serious side effects are generally rare.

After using ODOMZO

Storage

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store ODOMZO or any other medicine in the bathroom

or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ODOMZO capsules have an opaque pink body with "SONIDEGIB 200MG" printed in black ink and an opaque pink cap with "NVR" printed in black ink.

ODOMZO is available in blister packs of 10 and 30 capsules and bottles of 30 capsules.

Not all pack sizes may be marketed.

Ingredients

ODOMZO contains 200 mg of sonidegib (as phosphate) as the active ingredient.

It also contains the following inactive ingredients:

- crospovidone
- lactose monohydrate
- magnesium stearate
- poloxamer (188)
- butylated hydroxytoluene
- anhydrous colloidal silica
- sodium lauryl sulfate.

The capsule shell contains:

- gelatin
- iron oxide red
- titanium dioxide
- ammonium hydroxide
- iron oxide black

- propylene glycol
- shellac.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

ODOMZO is supplied in Australia by:

Sun Pharma ANZ Pty Ltd
12 Waterloo Road
Macquarie Park NSW 2113
Australia

® = Registered Trademark

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ODOMZO 200mg capsules

AUST R 292262 (bottles);

AUST R 226544 (blisters)