ODOMZO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ODOMZO?

ODOMZO contains the active ingredient sonidegib diphosphate. 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.

For more information, see Section 1. Why am I using ODOMZO? in the full CMI.

2. What should I know before I use ODOMZO?

Do not use if you have ever had an allergic reaction to ODOMZO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ODOMZO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ODOMZO and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ODOMZO?

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

More instructions can be found in Section 4. How do I use ODOMZO? in the full CMI.

5. What should I know while using ODOMZO?

Things you should do	Remind any doctor, dentist or pharmacist, surgeon or anaesthetist that you are taking ODOMZO.
Things you should 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.
Driving or using machines	Be careful driving or operating machinery until you know how ODOMZO affects you.
Looking after your medicine	Keep your capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

Common side effects: 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.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ODOMZO®

Active ingredient(s): *Sonidegib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ODOMZO. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ODOMZO.

Where to find information in this leaflet:

1. Why am I using ODOMZO?
2. What should I know before I use ODOMZO?
3. What if I am taking other medicines?
4. How do I use ODOMZO?
5. What should I know while using ODOMZO?
6. Are there any side effects?
7. Product details

1. Why am I using ODOMZO?

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.

2. What should I know before I use ODOMZO?

Warnings

Do not use ODOMZO if:

- you are allergic to sonidegib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.
- 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.
- children and adolescents below the age of 18 years.
- the expiry date printed on the pack has passed 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.

Check with 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.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

See section Warnings.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with ODOMZO and affect how it works.

- 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, omeprazol, 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ODOMZO.

4. How do I use ODOMZO?

How much to take

- The usual recommended dose is one 200mg capsule per day.
- Follow the instructions provided and use ODOMZO until your doctor tells you to stop.

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

When to take ODOMZO

- ODOMZO should be taken 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.

How to take ODOMZO

- ODOMZO capsules are to be taken by mouth on an empty stomach.
  Swallow the capsules whole with a full glass of water.
- 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 use ODOMZO

ODOMZO should be used regularly at the same time each day. If you miss your dose at the usual time, and 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.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose 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 use too much ODOMZO

If you think that you have used too much ODOMZO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 POISON, 0800 764 766 in NZ**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using ODOMZO?

Things you should 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ODOMZO affects you.

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

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• unexpected muscle pain, tenderness or weakness not caused by exercise • 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.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 aspartame 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ODOMZO contains

Active ingredient (main ingredient)	sonidegib (as phosphate)
Other ingredients (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.

Do not take this medicine if you are allergic to any of these ingredients.

What ODOMZO 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.

AUST R 292262 (bottles);

AUST R 226544 (blisters)

Who distributes ODOMZO in Australia

Sun Pharma ANZ Pty Ltd

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