

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 ERIVEDGE?

ERIVEDGE contains the active ingredient vismodegib. ERIVEDGE is used to treat adults with a type of skin cancer called advanced basal cell carcinoma. For more information, see Section [1. Why am I using ERIVEDGE?](#) in the full CMI.

2. What should I know before I use ERIVEDGE?

Do not use if you have ever had an allergic reaction to ERIVEDGE 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 ERIVEDGE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ERIVEDGE 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 ERIVEDGE?

- The recommended dose of ERIVEDGE is one capsule once a day (150mg), taken at about the same time each day.
- Swallow the capsules whole with a full glass of water. Do not crush, open or chew the capsule.
- ERIVEDGE can be taken with or without food.

More instructions can be found in Section [4. How do I use ERIVEDGE?](#) in the full CMI.

5. What should I know while using ERIVEDGE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ERIVEDGE.• Tell your doctor if you have kidney problems.• Women able to have children need to use two acceptable forms of contraception so that a pregnancy does not happen during treatment and for 24 months after the final dose.• For Men, always use a condom (with spermicide, if available), when you have sex during treatment and for 2 months after your final dose of ERIVEDGE.
Things you should not do	<ul style="list-style-type: none">• You must not donate blood while taking ERIVEDGE and for 24 months after your final dose.• You must not donate sperm while taking ERIVEDGE and for 2 months after your final dose.• Do not take ERIVEDGE if you are pregnant, plan to become pregnant and/or breastfeed 24 months after your final dose.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ERIVEDGE affects you. It is not known if ERIVEDGE affects your ability to drive or operate machinery
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in a cool dry place where the temperature stays below 30°C.• Keep your capsules in the bottle, with the cap tightly closed, until it is time to take them.• Do not store ERIVEDGE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

For more information, see [Section 5. What should I know while using ERIVEDGE?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include nausea, diarrhoea, constipation, vomiting, indigestion, stomach pain, fatigue, unusual weakness, weight loss, decreased appetite, change in the way things taste or a loss of taste, dehydration, dry or sticky mouth, low or no urine output, dark urine, no tears, sunken eyes, muscle spasms, hair loss (alopecia), abnormal hair growth, loss of menstrual periods or pain in the chest, back, side, tendons, ligaments, joints, bones or extremities (arms and legs). Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you experience signs or symptoms of a serious allergic reaction such as shortness of breath, difficulty breathing, chest tightness or wheezing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin. 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.

ERIVEDGE® (Eh-rih-vedge)

Active ingredient(s): *vismodegib* (viz-mod-dee-gib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ERIVEDGE. **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 ERIVEDGE.**

Where to find information in this leaflet:

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

1. Why am I using ERIVEDGE?

ERIVEDGE contains the active ingredient vismodegib.

ERIVEDGE belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents.

ERIVEDGE 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 other parts of the body (called "metastatic basal cell carcinoma) or
- 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.

Surgery and radiation treatment may not be appropriate because;

- surgery will change the shape of a body part (cause deformity)
- with surgery, you may lose the use of a body part such as an eye or ear
- the cancer has returned after previous surgeries and further surgery isn't likely to be successful
- radiation was previously unsuccessful or you are not suitable for radiation.

ERIVEDGE works by controlling a key protein involved in this type of cancer. ERIVEDGE may slow or stop the cancer cells from growing, or may kill them. As a result, your skin cancer may shrink.

Research undertaken in the development of ERIVEDGE utilised cell lines derived from human embryos.

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

Your doctor may have given 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 ERIVEDGE?

Warnings

Do not use ERIVEDGE if:

- **You are pregnant, think you may be pregnant, or are planning to become pregnant during the course of treatment or during the 24 months after your final dose of the medicine.**
- **You are a woman who is able to have children but you are unable or unwilling to use two acceptable forms of birth control (contraception) during the course of treatment or during the 24 months after your final dose of the medicine.**

Women able to have children need to use two acceptable forms of contraception so that a pregnancy does not happen during treatment and for 24 months after the final dose.

- **You are breast-feeding or intend to breast-feed in the future.**
- **The package is torn or shows signs of tampering.**

If the package is damaged, return it to your pharmacist for disposal.

- **The expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

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

Check with your doctor if you:

1. **You plan to donate blood or blood products during treatment with ERIVEDGE or you plan to do so in the future.**

If a pregnant woman receives your donated blood, the baby may develop birth defects.

You must not donate blood while taking ERIVEDGE and for 24 months after your final dose.

2. **You plan to donate sperm during treatment with ERIVEDGE or you plan to do so in the future.**

If a woman receives your donated sperm, the baby may develop birth defects.

You must not donate sperm while taking ERIVEDGE and for 2 months after your final dose.

3. **You have kidney problems.**
4. **You are allergic (hypersensitive) to vismodegib or any of the ingredients listed at the end of this leaflet or allergic to any other medicines, foods, preservatives or dyes.**

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, redness or hives on the skin

- chills and shivering
- feeling sick (nausea) or being sick (vomiting).

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

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

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

The active ingredient in ERIVEDGE may pass into breast milk and there is a possibility that your baby may suffer serious growth defects.

You must not breast-feed while taking ERIVEDGE and for 24 months after the last dose.

ERIVEDGE may affect your developing baby if you take it during pregnancy. ERIVEDGE may cause your baby to die before it is born (stillborn) or cause your baby to have severe birth defects.

Use in Children

ERIVEDGE should not be used in children and adolescents. The safety and effectiveness in people younger than 18 years old have not been established. Premature fusion of the growth plates has been reported in paediatric patients exposed to ERIVEDGE. In some cases, fusion progressed after drug discontinuation.

Fertility preservation

If you are a female patient and want to have children after treatment with ERIVEDGE, talk to your doctor about fertility preservation.

It is not known whether ERIVEDGE causes infertility. In clinical trials, some female patients no longer experienced their menstrual period after starting treatment.

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.

Tell your pharmacist or doctor if you are taking antibiotics or any herbal medicines (such as St. John's wort), because they can make female birth control (contraception) less effective.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ERIVEDGE.

ERIVEDGE may interfere with some medicines. These include:

- ezetimibe and statins, such as atorvastatin, fluvastatin, pravastatin, rosuvastatin, simvastatin – medicines used to treat high cholesterol
- bosentan, a medicine used to treat high blood pressure in the vessels between the heart and the lungs
- glibenclamide, a medicine used to treat diabetes

- valsartan and olmesartan, medicines used to treat high blood pressure and heart problems.

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

4. How do I use ERIVEDGE?

How much to take

- The recommended dose of ERIVEDGE is one capsule once a day.
- Follow the instructions provided and use ERIVEDGE until your doctor tells you to stop.
- Swallow the capsules whole with a full glass of water.
- Do not crush, open or chew the capsule.
- ERIVEDGE can be taken with or without food.

When to take ERIVEDGE

- Take ERIVEDGE 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.

- Continue taking ERIVEDGE for as long as your doctor tells you.

How long you will be treated with ERIVEDGE depends on how you are responding to treatment. Your doctor will discuss this with you.

If you forget to take ERIVEDGE

ERIVEDGE should be taken regularly at the same time each day. If you miss your dose at the usual time and 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.

If you use too much ERIVEDGE

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.

5. What should I know while using ERIVEDGE?

Things you should do

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

Tell all 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 have children need to take precautions so that a pregnant woman is not exposed to ERIVEDGE. You need to do this for 24 months after stopping

treatment if you are a woman and for 2 months after stopping treatment if you are a man.

ERIVEDGE may cause severe birth defects. It may also lead to the death of a baby before it is born or shortly after being born.

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

Call your doctor straight away if:

- You or your partner becomes pregnant or your partner thinks they are pregnant while taking ERIVEDGE.

Remind any doctor, dentist or pharmacist you visit that you are using ERIVEDGE.

Things you should not do

- Do not stop taking ERIVEDGE or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.
- Do not give ERIVEDGE to anyone else even if they have the same condition as you.

Women taking ERIVEDGE

- Women who are able to have children will need to show a negative pregnancy test (conducted under medical supervision) before starting treatment with ERIVEDGE. You should then have a medically-supervised pregnancy test each month during treatment.
- Women who are able to get pregnant must use two forms of acceptable contraception (a barrier and a non-barrier form). This applies during treatment and for 24 months after your final dose.
- Use one non-barrier form of contraception from this list:
 - combination hormonal contraceptives e.g. Yasmin, Yaz, Levlen or vaginal ring e.g. Nuvaring
 - Microlut, Provera
 - subcutaneous hormonal implant e.g. Jadelle, Implanon NXT, Implanon
 - birth control patch
 - birth control injections e.g. Depo-Provera
 - tubal sterilisation
 - vasectomy (surgery performed on male partner)
 - intrauterine device (IUD e.g. Copper TT38 Slimline, Multiload-Cu375, Mirena).
- In addition, use one barrier form of contraception from this list:
 - any male condom (with spermicide, if available)
 - diaphragm (with spermicide, if available).

If you have stopped menstruating during the course of treatment you must still use 2 forms of acceptable contraception during treatment and for 24 months after your last dose.

Men taking ERIVEDGE

Always use a condom (with spermicide, if available), when you have sex during treatment and for 2 months after your final dose of ERIVEDGE.

A vasectomy does not give enough protection without a condom.

Do not donate sperm while taking ERIVEDGE and for 2 months after your final dose.

Talk to your doctor about the best contraception for you.

Tell your doctor if, for any reason, you have not taken ERIVEDGE exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel ERIVEDGE is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Driving or using machines

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

It is not known if ERIVEDGE affects your ability to drive or operate machinery.

Looking after your medicine

- Keep your capsules in a cool dry place where the temperature stays below 30°C.
- Keep your capsules in the bottle, with the cap tightly closed, until it is time to take them.

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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine, your doctor tells you to stop taking this medicine or the expiry date has passed, 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 following information 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
<ul style="list-style-type: none">• feeling sick, also called nausea• feeling tired, also called fatigue• unusual weakness• weight loss• decreased appetite• a change in the way things taste or a loss of taste• pain in your chest, back, side or extremities (arms and legs)• hair loss, also called alopecia• loss of eyelashes• abnormal hair growth	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> loss of menstrual periods <p>Signs and symptoms of gastro-intestinal problems:</p> <ul style="list-style-type: none"> vomiting indigestion stomach pain diarrhoea constipation <p>Signs and symptoms of dehydration:</p> <ul style="list-style-type: none"> such as dry or sticky mouth low or no urine output urine looks dark yellow no tears or sunken eyes <p>Signs and symptoms of muscle damage:</p> <ul style="list-style-type: none"> aching muscles, muscle tenderness or weakness, not caused by exercise muscle, tendon, ligament, joint or bone pain muscle spasms <p>ERIVEDGE may be associated with abnormalities in your blood test results.</p>	

Serious side effects

Serious side effects	What to do
<p>Signs and symptoms of an allergic reaction:</p> <ul style="list-style-type: none"> shortness of breath difficulty breathing chest tightness wheezing swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin 	<p>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.</p>

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.

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 ERIVEDGE contains

Active ingredient (main ingredient)	vismodegib
Other ingredients (inactive ingredients)	microcrystalline cellulose (460) sodium lauryl sulphate povidone sodium starch glycolate purified talc (553) magnesium stearate lactose monohydrate
Other ingredients (capsule shell)	gelatin titanium dioxide (171) iron oxide red (CI77491, 172) iron oxide black (CI77499, 172) shellac (904)
Potential allergens	lactose sulfites

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 ERIVEDGE looks like

ERIVEDGE capsules have a pink body with "150mg" printed in black ink and a grey cap with "VISMO" printed in black ink. (AUST R 214475).

ERIVEDGE is available in a bottle of 28 capsules.

Who distributes ERIVEDGE

Roche Products Pty Ltd
ABN 70 000 132 865
Level 8, 30 – 34 Hickson Road
Sydney NSW 2000
AUSTRALIA
Medical enquiries: 1800 233 950

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