

COTELLIC®

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 COTELLIC?

COTELLIC contains the active ingredient cobimetinib. COTELLIC is used to treat a type of skin cancer called melanoma that has spread to other parts of the body and cannot be removed by surgery. For more information, see Section [1. Why am I using COTELLIC?](#) in the full CMI.

2. What should I know before I use COTELLIC?

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

3. What if I am taking other medicines?

Some medicines may interfere with COTELLIC 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 COTELLIC?

- Take COTELLIC exactly as prescribed by your doctor. The recommended dose is three tablets (a total of 60mg) once a day. COTELLIC is taken once daily for 21 days followed by a 7 day treatment break (no medicine) in a 28 day cycle. Start your next COTELLIC treatment cycle after the 7 day treatment break. More instructions can be found in Section [4. How do I use COTELLIC?](#) in the full CMI.

5. What should I know while using COTELLIC?

Things you should do

- Remind any doctor (including a surgeon or anaesthetist), dentist or pharmacist you visit that you are using COTELLIC.
- Tell your doctor straight away if you become

	<p>pregnant or have changes to your vision while taking COTELLIC.</p> <ul style="list-style-type: none"> • Check your skin and tell your doctor right away about any changes. Avoid going out in the sun. • Avoid drinking grapefruit juice. • Tell your doctor if you feel your medicine is not helping your condition.
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop taking COTELLIC or change the dose without first checking with your doctor. • Do not let yourself run out of medicine over the weekend or on holidays.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how COTELLIC affects you. If COTELLIC affects your vision, consult your doctor before driving or operating machinery. COTELLIC may affect your vision.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- Keep the tablets in a cool dry place where the temperature stays below 30°C.
- Do not store COTELLIC 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 COTELLIC?](#) in the full CMI.

6. Are there any side effects?

This medicine helps most people who have melanoma, but it may have unwanted side effects in some people (see the full CMI for more details). Tell your doctor or pharmacist if you notice any of the following and they worry you. Common side effect may include diarrhoea, nausea, vomiting, fever, chills, dehydration, anaemia, sunburn or sun sensitivity, skin problems including rashes, spots, itching, thickened areas of the skin, painful red lumps or warts. 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 swelling of the face, lips, tongue or other parts of the body, shortness of breath or difficulty breathing, rash, itching or hives

on the skin. Some other serious side effects may include blisters or peeling skin, muscle aches/spasms/weakness, dark/reddish urine, bleeding, dizziness, heart problems and/or vision problems.

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

COTELLIC[®] (Kho-teh-lick)

Active ingredient(s): *cobimetinib* (kho-bee-meh-tin'ib)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using COTELLIC?

COTELLIC contains the active ingredient cobimetinib. COTELLIC is belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents.

COTELLIC is used to treat a type of skin cancer called melanoma that has spread to other parts of the body and cannot be removed by surgery.

COTELLIC is used in combination with another medicine called ZELBORAF® (containing the active ingredient vemurafenib).

COTELLIC can only be used if your melanoma has a change (mutation) in the BRAF gene. Your doctor will have tested you for this gene mutation to make sure COTELLIC is suitable for you. The gene mutation has been shown to be involved in the development of melanoma.

COTELLIC targets the "MEK" protein and ZELBORAF targets the changed "BRAF" protein. Both proteins are important in controlling cancer cell growth.

When used together, these medicines slow down the growth of your cancer.

Ask your doctor if you have any questions about why COTELLIC has been prescribed for you. Your doctor may have prescribed it for another reason.

COTELLIC is not addictive. This medicine is available only with a doctor's prescription.

2. What should I know before I use COTELLIC?

Warnings

As COTELLIC is taken together with ZELBORAF, also read the Consumer Medicine Information for ZELBORAF before you take these medicines.

Do not use COTELLIC if:

1. You are allergic to cobimetinib (the active ingredient), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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 or hives on the skin.
2. The package is torn or shows signs of tampering
 3. 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 have any eye problems

- It is important your doctor is aware of any eye problems. You should see your doctor immediately for an eye exam if you experience new or worsening loss in vision or other eye problems while you are taking COTELLIC.

2. You have any heart problems

- Your doctor should do tests before you start taking COTELLIC and during your treatment to check the ability of the heart to pump blood sufficiently.

3. You have any liver problems

- Your doctor will perform some blood tests before and during your treatment to monitor your liver function. If necessary, your doctor may decide to reduce your dose, interrupt your treatment temporarily or stop it altogether.

4. You have any medical conditions that increase your risk of bleeding

5. You have any muscle problems

6. You have any problems with your kidneys

7. You have allergies to any other medicines, foods, preservatives or dyes

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

Safety and effectiveness of COTELLIC in children younger than 18 years have not been established.

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

Check with your doctor if you are pregnant or intend to become pregnant.

- It is not known whether COTELLIC is harmful to an unborn baby when taken by a pregnant woman. COTELLIC is not recommended during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

- It is not known whether COTELLIC passes into breast milk. Your doctor will discuss the risks and benefits of taking COTELLIC if you are breast feeding or plan to breast feed.

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 COTELLIC and affect how it works. These include:

- itraconazole, voriconazole, posaconazole, fluconazole and miconazole, medicines used to treat fungal infections
- clarithromycin, erythromycin and rifampicin, medicines used to treat bacterial infections
- ritonavir, cobicistat, lopinavir, and fosamprenavir, medicines used to treat HIV infection
- amiodarone, a medicine to treat a heart rhythm problems
- diltiazem and verapamil, medicines used to treat high blood pressure
- imatinib, a medicine used to treat cancer

- carbamazepine and phenytoin, medicines used to treat seizures
- St. John's Wort, a herbal medicine used to treat depression.

These medicines may be affected by COTELLIC 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 COTELLIC.

4. How do I use COTELLIC?

How to use COTELLIC

- Take COTELLIC exactly as your doctor has prescribed.
- The recommended dose is three tablets (a total of 60 mg) once a day.
- COTELLIC is taken once daily for 21 days followed by a 7 day treatment break (no drug) in a 28 day cycle. Start your next COTELLIC treatment cycle after the 7 day treatment break.
- It is recommended you take ZELBORAF, as prescribed, during both the COTELLIC treatment phase AND the 7 day COTELLIC treatment break.

- If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.
- If you experience any side effects, your doctor may need to lower the dose to carry on your treatment.
- Swallow the tablets whole with a glass of water.
- You can take COTELLIC with or without food
- If you vomit after taking COTELLIC, do not take the same dose again. Continue to take COTELLIC as normal, the next day.
- How long you will be treated with COTELLIC depends on how you are responding to treatment. Your doctor will discuss this with you.
- Continue taking COTELLIC until your doctor tells you to stop.

When to use COTELLIC

- Take your medicine 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.

If you vomit after taking COTELLIC

- Do not take the same dose again. Continue to take COTELLIC as normal, the next day.

If you forget to use COTELLIC

- If it is more than 12 hours before your next dose, take the missed dose as soon as you remember.

- If it is less than 12 hours before your next dose, skip the missed dose. Then take the next dose at the usual time.
- Do not take a double dose to make up for the dose that you missed.
- 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 COTELLIC

If you think that you or anyone else has taken too much COTELLIC, you may need urgent medical attention. Keep the following telephone numbers handy.

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 COTELLIC?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking COTELLIC.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking COTELLIC.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Women who can get pregnant should use two effective forms of contraception to prevent pregnancy during treatment and for at least 3 months following the final dose.
- Check your skin and tell your doctor right away about any changes.
- Avoid going out in the sun.
- If you are taking COTELLIC you may become more sensitive to sunlight and get symptoms of sunburn (such as redness, itching, swelling and blistering) more easily or get sunburns that can be severe.
- To help protect against sunburn, if you do plan to go into the sun wear clothing which protects your skin, including head, face, arms and legs. Use a broad spectrum (UVA/UVB) sunscreen and lip balm (minimum of SPF 30+, re-applied every 2 - 3 hours).

- Avoid taking COTELLIC with grapefruit juice. Grapefruit juice can increase the amount of COTELLIC in your blood.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- Tell your doctor if you feel your medicine is not helping your condition.
- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Call your doctor straight away if you:

- Become pregnant while taking COTELLIC.
- You have eye pain, swelling, redness, blurred vision, loss of vision, changes in colour, seeing a blurred outline around objects or other vision changes during your treatment. You should have your eyes immediately examined by your doctor if you experience eye problems while you are taking COTELLIC.
- Notice changes in your skin, such as any crusty, non-healing sores; small lumps that are red, pale or pearly in colour; or new spots, freckles or any moles changing in colour. You may develop new skin cancers or skin lesions which are different from melanoma while taking COTELLIC. These cancers are usually removed by surgery and you can continue your treatment.

Things you should not do

- Do not stop using this medicine suddenly without first checking with your doctor.
- Do not use COTELLIC to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- 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 with a pharmacist.

Driving or using machines

- Be careful before you drive or use any machines or tools until you know how COTELLIC affects you.
- Be careful driving or operating machinery until you know how COTELLIC affects you. If COTELLIC affects your vision, consult your doctor before driving or operating machinery.
- COTELLIC may affect your vision.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Keep the tablets in a cool dry place where the temperature stays below 30°C.

- Do not store COTELLIC or any other medicine in the bathroom, near a sink, on a window sill or in the car. Heat and dampness can destroy some medicines.
- Follow the instructions in the carton on how to take care of your medicine properly.
- 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
<ul style="list-style-type: none">● fever● chills <p>Signs and symptoms of low iron in your blood (anaemia):</p> <ul style="list-style-type: none">● tiredness● headaches● being short of breath when exercising● dizziness● looking pale <p>Signs and symptoms of dehydration:</p> <ul style="list-style-type: none">● dry or sticky mouth● low or no urine output● urine looks dark yellow● no tears● sunken eyes <p>Signs and symptoms of skin problems:</p> <ul style="list-style-type: none">● sunburn or sun sensitivity● rashes● spots	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● itching ● dry or scaly skin ● hardened or thickened areas of the skin ● painful red lumps or warts <p>Signs and symptoms of respiratory problems:</p> <ul style="list-style-type: none"> ● coughing <p>Signs and symptoms of gastro-intestinal problems:</p> <ul style="list-style-type: none"> ● diarrhoea ● nausea ● vomiting ● sore mouth or mouth ulcers, inflammation to the lining of the mouth (stomatitis) <p>Some side effects can only be found when your doctor performs tests from time to time to check your progress, for example:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● increased levels of liver enzymes or sugars in the blood ● decreased levels of sodium or phosphate in the blood ● increased levels of blood creatine phosphokinase, a marker of tissue damage ● increased blood pressure (hypertension) 	

Serious side effects

Serious side effects	What to do
<p>Signs and symptoms of severe skin problems:</p> <ul style="list-style-type: none"> ● a rash that covers a large area of your body ● blisters ● peeling skin <p>Signs and symptoms of muscle damage:</p> <ul style="list-style-type: none"> ● muscle aches ● muscle spasms and weakness 	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> ● dark, reddish urine <p>Signs and symptoms of a serious bleeding problem:</p> <ul style="list-style-type: none"> ● red or black stools that look like tar ● blood in your urine or stools ● unusual vaginal bleeding ● headaches, dizziness, or feeling weak <p>Signs and symptoms of an allergic reaction:</p> <ul style="list-style-type: none"> ● shortness of breath ● wheezing or difficulty breathing ● swelling of the face, lips, tongue or other parts of the body ● rash, itching or hives on the skin <p>Signs and symptoms of heart problems:</p> <ul style="list-style-type: none"> ● persistent coughing or wheezing ● shortness of breath ● difficulty breathing 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● tiredness ● increased heart rate ● swelling of your ankles and feet <p>Signs and symptoms of severe eye or vision problems:</p> <ul style="list-style-type: none"> ● blurred vision, loss of vision or other vision changes ● changes in colour ● seeing a blurred outline around objects ● eye pain, swelling or redness 	

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 COTELLIC contains

Active ingredient (main ingredient)	cobimetinib (as a hemifumarate salt)
Other ingredients (inactive ingredients)	microcrystalline cellulose (460) croscarmellose sodium magnesium stearate polyvinyl alcohol titanium dioxide (171) macrogol 3350 purified talc

Potential allergens	lactose monohydrate
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Do not take this medicine if you are allergic to any of these ingredients.

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

What COTELLIC looks like

COTELLIC tablets are round and white with "COB" debossed on one side. (AUST R 237017).

Who distributes COTELLIC

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

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