

COTELLIC[®]

Cobimetinib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COTELLIC. 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 COTELLIC 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 COTELLIC is used for

COTELLIC contains the active ingredient cobimetinib.

COTELLIC 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.

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

Before you take COTELLIC

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

When you must not take it

1. Do not take COTELLIC if you have an allergy to:

- cobimetinib (active ingredient) or
- any of the ingredients listed at the end of this leaflet.

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.

Before you start to take it

Tell your doctor if:

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 are pregnant or plan 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.

8. You are breast feeding or plan to breast feed

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.

9. 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.

Taking other medicines

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

Some medicines and COTELLIC may interfere with each other. These include:

- itraconazole, voriconazole, posaconazole, fluconazole and miconazole, medicines used to treat fungal infections
- clarithromycin, erythromycin and rifampicin, medicines used to treat fungal 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.

How to take COTELLIC

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

They may differ from the information contained in this leaflet.

How much to take

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.

How to take it

Swallow the tablets whole with a glass of water.

You can take COTELLIC with or without food.

When to take it

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 it

If you vomit after taking COTELLIC, do not take the same dose again. Continue to take COTELLIC as normal, the next day.

How long to take it

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.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, telephone 0800 764 766) 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 COTELLIC. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are using COTELLIC

Things you must 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.

Tell your doctor straight away if you become pregnant while taking COTELLIC.

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.

Tell your doctor immediately if you get 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.

Check your skin and tell your doctor right away about any changes.

Tell your doctor if you 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.

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.

Things you must not do

Do not stop taking COTELLIC or change the dose 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.

Things to be careful of

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.

Side effects

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

This medicine helps most people who have melanoma, but it may have unwanted side effects in some 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 list 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:

- diarrhoea
- nausea
- vomiting
- fever
- chills

- symptoms of dehydration, such as dry or sticky mouth, low or no urine output, urine looks dark yellow, no tears or sunken eyes
 - symptoms of anaemia, such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale
 - sunburn or sun sensitivity
 - coughing, difficulty breathing, wheezing
 - skin problems including rashes, spots, itching, dry or scaly skin, hardened or thickened areas of the skin, painful red lumps or warts.
- The above list includes the more common side effects of COTELLIC. Some side effects can only be found when your doctor performs tests from time to time to check your progress, for example;
- 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).

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- A rash that covers a large area of your body, blisters, or peeling skin.
- Symptoms of muscle damage such as:
 - muscle aches
 - muscle spasms and weakness
 - dark, reddish urine.
- Symptoms of a serious bleeding problem such as:
 - red or black stools that look like tar
 - blood in your urine or stools
 - unusual vaginal bleeding

- headaches, dizziness, or feeling weak.
- Symptoms of an allergic reaction which 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.
- Heart problems, including inadequate pumping of the blood by the heart. Signs and symptoms of a decrease in the amount of blood pumped include:
 - persistent coughing or wheezing
 - shortness of breath
 - tiredness
 - increased heart rate
 - swelling of your ankles and feet.
- Any new or worsening problems with your eyes or vision possibly related to a condition called “serous retinopathy” (a build-up of fluid in the eye). These problems may be severe and could lead to blindness.
 - blurred vision, loss of vision or other vision changes
 - changes in colour
 - seeing a blurred outline around objects
 - eye pain, swelling or redness.

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

This is not a complete list of all possible side effects. Other side effects may occur in some people and there may be some others that are not yet known.

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

After using COTELLIC

Storage

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 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 COTELLIC or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

Availability

COTELLIC 20 mg film-coated tablets come in blister packs of 63 tablets.

What COTELLIC looks like

COTELLIC tablets are round and white with “COB” debossed on one side.

Ingredients

COTELLIC tablets contain 20 mg of cobimetinib (as a hemifumarate salt) as the active ingredient.

Inactive ingredients:

- cellulose – microcrystalline (460)
- lactose

- croscarmellose sodium
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide (171)
- macrogol 3350
- talc - purified.

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

Manufacturer

Distributed in New Zealand by:

Roche Products (New Zealand)
Limited

PO Box 109113, Newmarket,
Auckland 1149

NEW ZEALAND

Medical enquiries: 0800 656 464

Distributed in Australia by:

Roche Products Pty Limited

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AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist
for the latest Consumer Medicine
Information.

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