PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Cotellic® Film-coated tablets

Cobimetinib

Contains sugar, i.e. lactose monohydrate.

Read all of this leaflet carefully before you start taking Cotellic

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Cotellic has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Cotellic is and what it is used for
2. What you need to know before you take Cotellic
3. How to take Cotellic
4. Possible side effects
5. How to store Cotellic
6. Contents of the pack and other information

1. What Cotellic is and what it is used for

What Cotellic is

Cotellic is an anti-cancer medicine that contains the active substance cobimetinib.

What Cotellic is used for

Cotellic is used to treat adult patients with a type of skin cancer called malignant melanoma that has spread to other parts of the body or cannot be removed by surgery.

- It is used in combination with another anti-cancer medicine called vemurafenib

- It can only be used in patients whose cancer has a change (mutation) in a protein called "BRAF". Before starting treatment, your doctor will test for this mutation. This change may have led to the development of melanoma.

How Cotellic works

Cotellic targets a protein called "MEK" that is important in controlling cancer cell growth. When Cotellic is used in combination with vemurafenib (which targets the changed "BRAF" protein) or with other medicines, it further slows down or stops the growth of your cancer.

2. What you need to know before you take Cotellic

Do not take Cotellic

If you are allergic to cobimetinib or to any of the other ingredients of this medicine, listed in "What Cotellic contains". If you are not sure, talk to your doctor or nurse before taking Cotellic.

Warnings and precautions

Talk to your doctor or healthcare professional before you take Cotellic if you have:

- an eye problem
- heart problems
- liver problems.

If any of the above apply to you (or if you are not sure), talk to your doctor or nurse before taking Cotellic.

- Eye problems

Cotellic can cause eye problems. Tell your doctor straight away if you get the following symptoms: blurred vision, distorted vision, partly missing vision, or any other changes to your sight during treatment. Your doctor should examine your eyes if you have any new or worsening problems with your sight while you are taking Cotellic.

- Heart problems

Cotellic can lower the amount of blood pumped by your heart. Your doctor should do tests before and during your treatment with Cotellic to check how well your heart can pump blood. Tell your

doctor straight away if it feels like your heart is pounding, racing or beating unevenly, or if you experience dizziness, lightheadedness, shortness of breath, tiredness, or swelling in the legs.

- Liver problems

Cotellic can increase the amount of some liver enzymes in your blood during treatment. Your doctor will do blood tests to check these amounts and monitor how well your liver is working.

- Diarrhoea

Tell your doctor straight away if you get diarrhoea. Severe diarrhoea can cause loss of body fluid (dehydration). Follow your doctor's instructions for what to do to help prevent or treat diarrhoea.

Use in children or adolsecents: Cotellic is not recommended for children and adolescents. The effects of Cotellic in people under the age of 18 years old are not known.

Other medicines and Cotellic

Taking other medicines with Cotellic

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Cotellic can affect the way some other medicines work. Also, some other medicines can affect the way Cotellic works.

Talk to your doctor before taking Cotellic if you are taking:

Medicine or active substance	**Purpose of the medicine**
itraconazole, clarithromycin, erythromycin, telithromycin, voriconazole, rifampicin, posaconazole, fluconazole, miconazole	for some fungal and bacterial infections
ritonavir, cobicistat, lopinavir, delavirdine, amprenavir, fosamprenavir	for HIV infection
telaprevir	for hepatitis C
nefadozone	for depression
amiodarone	for an uneven heartbeat

diltiazem, verapamil	for high blood pressure
imatinib	for cancer
carbamazepine, phenytoin	for fits (seizures)
St John's wort	a herbal medicine, used to treat depression. This is available without prescription.

Taking Cotellic with food and drink

Avoid taking Cotellic with grapefruit juice. This is because it could increase the amount of Cotellic in your blood.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Cotellic is not to be taken during pregnancy – it may cause permanent harm or birth defects to an unborn baby.
- If you become pregnant during treatment with Cotellic or in the 3 months after your last dose, tell your doctor straight away.
- Do not breastfeed your baby while taking Cotellic.

Contraception

Women of childbearing potential should use two effective methods of contraception, such as a condom or other barrier method (with spermicide, if available) during treatment and for at least 3 months after treatment has finished. Ask your doctor about the best contraception for you.

Driving and using machines

Cotellic can affect your ability to drive or use machines. Avoid driving or using machines if you have problems with your vision e.g. abnormality of the choroid, blurred vision, or retinal detachment or other problems that might affect your ability e.g. if you feel dizzy or tired. Talk to your doctor if you are not sure.

Important information about some of the ingredients of Cotellic

Cotellic contains lactose monohydrate. Patients with the rare hereditary conditions of lactose intolerance should not take Cotellic. Cotellic contains sugar (lactose monohydrate) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take Cotellic

Do not share medicines prescribed for you with any other person.

Always take Cotellic exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 3 tablets (a total of 60 mg) once a day.

- Take the tablets every day for 21 days (called a “treatment period”).
- After the 21 days, do not take any Cotellic tablets for 7 days. During this 7 day break in Cotellic treatment, you should keep taking vemurafenib as told by your doctor.
- Start your next Cotellic 21 day treatment period after the 7 day break.
- If you get side effects, your doctor may decide to lower your dose, stop treatment temporarily or permanently. Always take Cotellic exactly as your doctor or pharmacist has told you.

Taking the medicine:

- Swallow the tablets whole with water.
- Cotellic can be taken with or without food.

Your doctor will tell you how long your treatment with Cotellic will last. Do not stop treatment early if you are sick (vomit) after taking Cotellic. Do not take an extra dose of Cotellic on that day. Continue to take Cotellic as normal, the next day.

If you have the impression that the effect of Cotellic is too strong or too weak, tell your doctor or pharmacist.

If you take more Cotellic than you should:

If you take more Cotellic than you should, talk to a doctor straight away. Take the medicine package and this leaflet with you.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take 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 a missed dose.

If you stop taking Cotellic:

It is important to keep taking Cotellic for as long as your doctor prescribes it.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Cotellic can have side effects.

Not all side effects reported for Cotellic are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side-effects - *Tell your doctor or nurse straight away, if you notice any of the following side effects:*

Frequent

Eye (vision) problems

Cotellic can cause eye problems. Some of these eye problems may be a result of “serous retinopathy” (a build-up of fluid under the retina in the eye). Symptoms of serous retinopathy include:

- blurred vision
- distorted vision
- partly missing vision
- any other changes to your sight.

Heart problems

Cotellic can lower the amount of blood pumped by your heart. Symptoms may include:

- feeling dizzy
- feeling light-headed
- feeling short of breath
- feeling tired
- feeling like your heart is pounding, racing or beating unevenly
- swelling in the legs.

Diarrhoea

Tell your doctor straight away if you get diarrhoea and follow your doctor's instructions for what to do to help prevent or treat diarrhoea.

Other side effects include:

Tell your doctor or nurse immediately if you notice any of the side effects:

Frequent

- increased skin sensitivity to sunlight
- skin rash
- feeling sick (nausea)
- fever
- chills
- increased liver enzymes (shown in blood tests)
- abnormal blood test results related to creatine phosphokinase, an enzyme found mainly in heart, brain and skeletal muscle
- vomiting
- skin rash with a flat discoloured area or raised bump like acne
- high blood pressure
- anaemia (a low level of red blood cells)
- bleeding
- abnormal thickening of the skin.

- some types of skin cancer such as basal cell carcinoma, cutaneous squamous cell carcinoma and keratoacanthoma
- dehydration, when your body does not have enough fluid
- decreased levels of phosphate or sodium (shown in blood tests)
- increased sugar level (shown in blood tests)
- increased liver pigment (called “bilirubin”) in the blood. Signs include yellowing of the skin or eyes
- inflammation of the lungs that may cause difficulty breathing, and can be life-threatening (called “pneumonitis”).
- dry skin
- itchy skin
- swelling in your lower legs or hands

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Cotellic.

5. How to store Cotellic

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package.

Keep the container in the outer carton.

There are no special storage instructions for this medicine.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Cotellic contains

- The active substance is cobimetinib.

The other ingredients are:

- Croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose in the tablet core; and
- Macrogol, polyvinyl alcohol, titanium dioxide, and talc in the film-coating.

Contains sugar (36,48 mg lactose monohydrate).

What Cotellic looks like and contents of the pack

White, round film-coated tablets of approximately 6,6 mm diameter, with “COB” debossed on one side.

Transparent PVC/PVDC blisters containing 21 tablets. Each pack contains 63 tablets (3 x blisters of 21 tablets), placed in an outer carton.

Holder of Certificate of Registration

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Roche Ethical Assistance Line toll-free: 0800 21 21 25

This leaflet was last revised on

Registration number: 51/32.16/0871