

Package leaflet: Information for the patient

Cotellic 20 mg film-coated tablets cobimetinib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 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), 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 any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before taking Cotellic.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cotellic if you have:

- bleeding or are taking any medications that may cause bleeding
- an eye problem
- heart problems
- liver problems
- muscle problems.

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

• Bleeding

Cotellic can cause severe bleeding, especially in your brain or stomach (*see also “Severe bleeding” in Section 4*). Tell your doctor straight away if you have any unusual bleeding or any of these symptoms: headaches, dizziness, feeling weak, blood in the stools or black stools and vomiting blood.

• Eye problems

Cotellic can cause eye problems (*see also “Eye (vision) problems” in Section 4*). 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 (*see also “Heart problems” in Section 4*). 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.

• Muscle problems

Cotellic can cause increased levels of creatine phosphokinase, an enzyme that is found mainly in the muscle, heart, and brain. This can be a sign of muscle damage (rhabdomyolysis) (*see also “Muscle problems” in Section 4*). Your doctor will do blood tests to monitor for this. Tell your doctor straight away if you get any of these symptoms: muscle aches, muscle spasms, weakness, or dark- or red-coloured urine.

• 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.

Children and adolescents

Cotellic is not recommended for children and adolescents. The effects of Cotellic in people younger than 18 years old are not known.

Other medicines and Cotellic

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.

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 breast-feeding

If you are pregnant or breast-feeding, 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 recommended during pregnancy - although the effects of Cotellic have not been studied in pregnant women, 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.
- It is not known if Cotellic passes into breast milk. Your doctor will discuss with you the benefits and risks of taking Cotellic, if you are breast-feeding.

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 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.

Cotellic contain lactose

The tablets contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take Cotellic

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended 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.

If you are sick

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 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.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get side effects your doctor may decide to lower your dose, stop treatment temporarily or permanently.

Please also refer to the Package Leaflet for vemurafenib, which is used in combination with Cotellic.

Serious side effects

Tell your doctor straight away if you notice any of the side effects listed below or if these get worse during treatment.

Severe bleeding (common: may affect up to 1 in 10 people)

Cotellic can cause severe bleeding, especially in your brain or stomach. Depending on the area of the bleeding, symptoms may include:

- headaches, dizziness, or weakness
- vomiting blood
- abdominal pain
- red or black coloured stools.

Eye (vision) problems (very common: may affect more than 1 in 10 people)

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 (common: may affect up to 1 in 10 people)

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.

Muscle problems (uncommon: may affect up to 1 in 100 people)

Cotellic can result in the breakdown of muscle (rhabdomyolysis), symptoms may include:

- muscle aches
- muscle spasms and weakness
- dark- or red-coloured urine.

Diarrhoea (very common: may affect more than 1 in 10 people)

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

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)

- 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.

Common (may affect up to 1 in 10 people)

- 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").

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Cotellic

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cotellic contains

- The active substance is cobimetinib. Each film-coated tablet contains cobimetinib hemifumarate equivalent to 20 mg cobimetinib.
- The other ingredients are:
 - lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate in the tablet core; and
 - polyvinyl alcohol, titanium dioxide, macrogol and talc in the film-coating.

What Cotellic looks like and contents of the pack

Cotellic film-coated tablets are white, round with “COB” debossed on one side. One pack size is available: 63 tablets (3 blisters of 21 tablets).

Marketing Authorisation Holder

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Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.