



Patient special information card

This card contains important safety information, that you should be aware of, before starting and during treatment with Cotellic (Cobimetinib) for the treatment of skin cancer.



For the full information about the medicine, read the patient leaflet as approved by the ministry of health before use.

Cotellic is an anti-cancer medicine that contains the active substance cobimetinib. Cotellic is intended for the treatment of a type of skin cancer called metastatic melanoma, or melanoma which can not be surgically removed, in combination with vemurafenib in patients with the V600 mutation in the protein called BRAF.

How does the medicine work?

The medicine targets a protein called “MEK” that is important in regulating the development of the cancer cell. When Cotellic is given in combination with vemurafenib (a medicine which targets the mutated “BRAF” protein), it further slows down or stops the development of the cancer.

Special warnings regarding use of the medicine

Before and during treatment with Cotellic, inform the doctor if you have:

- problem in the eyes
- heart problems
- liver problems

If these medical conditions apply to you (or if you are not sure), refer to your doctor, before starting or during treatment with Cotellic.

The warnings are specified below:

Eye (vision) problems (very common side effects which may affect more than one in ten users): Cotellic can cause eye problems, some of which may be a result of a condition called “serous retinopathy”, which results from a build-up of fluid under the retina in the eye. Tell your doctor **immediately** if the following symptoms occur: blurred vision, vision disturbances or distortions, partial vision loss or any other change to your vision during treatment. Your doctor will examine your eyes in the event of new problems, or worsening of your preexisting vision problems, during the course of treatment with Cotellic.

Heart problems (common side effects which may affect up to one in ten users):

Cotellic can lower the amount of blood pumped by your heart.

Your doctor will instruct you to perform tests before and during treatment with Cotellic to test the ability of your heart to pump blood. Tell your doctor **immediately** if it feels like your heart is pounding strongly, racing or beating unevenly, or if you experience dizziness, light-headedness, shortness of breath, tiredness, or swelling in the legs.

Liver problems (very common side effects which may affect more than one in ten users): Cotellic can increase the levels of certain liver enzymes in your blood during treatment. Your doctor will instruct you to perform blood tests to check the levels of these enzymes and to monitor your liver function.

Diarrhea (very common side effect which may affect more than one in ten users):

Tell your doctor **immediately** if you get diarrhea. Severe diarrhea can cause loss of body fluids (dehydration). Follow your doctor’s instructions to know what to do to prevent or treat diarrhea.

Reporting side effects

If any side effects occur, contact your doctor, pharmacist or nurse.

Side effects can be reported to the Ministry of Health via the online form for reporting side effects, found on the Ministry of Health homepage (www.health.gov.il) or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il> In addition, a report can be made directly to Roche e-mail: israel.drugsafety@roche.com

How should you use the medicine?

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Always use this medicine according to the doctor’s instructions.

You should check with your doctor or pharmacist if you are not sure.

Usual dosage

The dosage and treatment regimen will be determined by the doctor only.

The usual dose is generally three tablets (a total of 60 mg) per day.

- Take the tablets every day for 21 days (called a “treatment cycle”).
- After 21 days, do not take any Cotellic tablets for 7 days. During this 7 day break in Cotellic treatment, keep taking the medicine vemurafenib as instructed by your doctor.
- Start your next Cotellic treatment cycle (21 days of treatment) after the 7 day break.
- If you have side effects, your doctor may decide to lower your dosage, to temporarily or permanently stop the treatment.

Always take the medicine exactly as your doctor instructs you.

If you vomit after taking the medicine, do not take an additional dose of Cotellic on the same day. Continue taking the medicine as normal, the next day.

If you accidentally took a Cotellic dosage higher than instructed by the doctor, refer to the doctor **immediately**. Take the medicine package and this leaflet with you.

If you forget to take Cotellic at the scheduled time, follow the instructions below:

- If it is more than 12 hours before the time for taking the next dose, take the missed dose as soon as you remember.
- If there is less than 12 hours until the time for taking the next dose, do not take the missed dose; skip it. Wait and take the next dose at the usual time.
- If you forgot to take this medicine at the scheduled time, do not take a double dose, in order to make up for a missed dose.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Tests and follow-up

- Your doctor will instruct you to perform tests before and during treatment with Cotellic, to assess your heart’s ability to pump blood.
- Your doctor will instruct you to perform blood tests to check the levels of liver enzymes, and in order to monitor your liver function.
- Your doctor will check your eyes to determine if you have any new or worsening problems with your sight, during treatment with Cotellic.

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