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Rubraca (*rucaparib*)

An overview of Rubraca and why it is authorised in the EU

What is Rubraca and what is it used for?

Rubraca is a cancer medicine for treating high-grade cancers of the ovary, fallopian tubes (the tubes connecting ovaries to the uterus) and the peritoneum (the membrane lining the abdomen).

It can be used as maintenance treatment in patients whose recurring cancer has cleared (partially or completely) after treatment with platinum-based cancer medicines.

It can also be used if the patient's cancer has returned or is worsening after two treatments with platinum-based medicines and they can no longer have these medicines. For such patients, tests for a genetic mutation (BRCA mutation) should be carried out first to see if Rubraca is likely to work for them.

Rubraca contains the active substance rucaparib.

How is Rubraca used?

Rubraca can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of cancer.

Rubraca is available as tablets of 200, 250 and 300 mg. The recommended dose of Rubraca is 600 mg twice a day. The treatment should continue until the cancer progresses or the patient has unacceptable side effects.

For maintenance treatment, Rubraca should be used no later than 8 weeks after the patient has finished their treatment with platinum-based medicine.

Treatment may be interrupted and doses may be reduced in patients who have certain side effects. For more information about using Rubraca, see the package leaflet or contact your doctor or pharmacist.

How does Rubraca work?

The active substance in Rubraca, rucaparib, blocks the activity of a family of proteins called poly(ADP-ribose) polymerases (PARPs) that help to repair damaged DNA in cells (both normal and cancer cells). In normal cells there is an alternative mechanism for repairing DNA but this alternative mechanism does not work properly in cancer cells with mutations in the BRCA genes. Therefore, when PARP

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

proteins are blocked, the damaged DNA in these cancer cells cannot be repaired, and, as a result, the cancer cells die.

What benefits of Rubraca have been shown in studies?

Rubraca as maintenance treatment was investigated in a study of 564 patients with ovarian cancer which had cleared (partially or completely) after treatment with platinum-based cancer medicines. Patients given Rubraca lived for 11 months without the disease coming back or getting worse compared with 5 months in patients given placebo (a dummy treatment). This benefit with Rubraca was seen in patients with or without the BRCA mutation.

Two other studies looked at 106 patients with ovarian cancer and BRCA mutation whose cancer had come back following at least 2 previous cancer treatments, including in many cases treatment with platinum-based medicines. Of the 79 patients whose disease had responded in the past to platinum-based medicines, 65% (51 patients) had a response to treatment with Rubraca and the response lasted on average 294 days (around 10 months).

What are the risks associated with Rubraca?

The most common side effects with Rubraca (which may affect more than 1 in 5 people) are tiredness or weakness, nausea (feeling sick), increased levels of creatinine (which may indicate kidney problems) and liver enzymes in the blood (which may indicate liver damage), vomiting, anaemia (low red blood cell counts), decreased appetite, dysgeusia (taste disturbances), diarrhoea, thrombocytopenia (low levels of platelets) and abdominal pain (belly ache). For the full list of side effects of Rubraca, see the package leaflet.

Women must not breastfeed during treatment with Rubraca and for at least 2 weeks after treatment. For the full list of restrictions, see the package leaflet.

Why is Rubraca authorised in the EU?

Rubraca has been shown to delay worsening or return of the disease in patients whose cancer had cleared partially or completely after treatment with platinum-based medicines. This benefit was seen in patients with or without the BRCA mutation.

Rubraca was also beneficial to patients whose cancer had come back after 2 previous cancer treatments, although these benefits have only been shown in patients with a BRCA mutation.

Regarding safety, side effects occur frequently but are generally not serious and are manageable with appropriate treatment. In addition, fewer liver and blood-related problems occur with Rubraca than with other existing treatments for these patients.

The European Medicines Agency decided that although further study was needed to better understand the size of the benefit, Rubraca's benefits are greater than its risks and it can be authorised for use in the EU.

Rubraca has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Rubraca?

Since Rubraca has been given conditional authorisation, the company that markets the medicine will provide the results from an ongoing study comparing Rubraca with chemotherapy (another cancer medicine) in patients with high-grade epithelial cancer of the ovary, of the fallopian tubes or of the peritoneum with BRCA mutation whose cancer has come back after chemotherapy treatments.

The company will also provide further data on maintenance treatment, including data on how long patients survived with Rubraca.

What measures are being taken to ensure the safe and effective use of Rubraca?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rubraca have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rubraca are continuously monitored. Side effects reported with Rubraca are carefully evaluated and any necessary action taken to protect patients.

Other information about Rubraca

Rubraca received a conditional marketing authorisation valid throughout the EU on 24 May 2018.

Further information on Rubraca can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Rubraca.

This overview was last updated in 02-2019.