EMA/469708/2023
EMEA/H/C/004272

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 the ovaries to the uterus) and the peritoneum (the membrane lining the abdomen).

It is used as maintenance treatment in patients newly diagnosed with advanced cancer or in patients whose cancer has come back, and in whom the cancer has cleared (partially or completely) after treatment with platinum-based chemotherapy. 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 to be taken twice a day. Treatment should continue until the cancer progresses or the patient has unacceptable side effects, and no longer than 2 years for patients newly diagnosed with advanced cancer. Treatment with Rubraca should be started no later than 8 weeks after the patient has finished their treatment with platinum-based chemotherapy.

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

What benefits of Rubraca have been shown in studies?

Rubraca was investigated in a main study of 564 patients with recurring ovarian cancer which had cleared (partially or completely) after treatment with platinum-based chemotherapy. 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).

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Another study looked at 538 patients with newly diagnosed advanced ovarian cancer which had cleared (partially or completely) after treatment with platinum-based chemotherapy. Patients given Rubraca lived for 20 months without the disease coming back or getting worse compared with 9 months in patients given placebo.

What are the risks associated with Rubraca?

For the full list of side effects and restrictions with Rubraca, see the package leaflet.

The most common side effects with Rubraca (which may affect more than 1 in 5 people) include tiredness or weakness, nausea (feeling sick), vomiting, anaemia (low red blood cell counts), abdominal pain (belly ache), dysgeusia (taste disturbances), increased levels of liver enzymes in the blood (which may indicate liver damage), decreased appetite, diarrhoea, neutropenia (low levels of neutrophils, a type of white blood cell that fights infection) and thrombocytopenia (low levels of platelets).

Women must not breastfeed during treatment with Rubraca and for at least 2 weeks after treatment.

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 chemotherapy. 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 Rubraca's benefits are greater than its risks and it can be authorised for use in the EU.

Rubraca was originally given 'conditional authorisation' because there was more evidence to come about the use of Rubraca outside maintenance treatment of patients. This use has since been restricted.[1] The authorisation has therefore been switched from a conditional to a standard marketing authorisation.

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

The company that markets Rubraca will provide final results to confirm the effectiveness of Rubraca as a maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer whose cancer has cleared (partially or completely) after treatment with platinum-based chemotherapy.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rubraca have also 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.

[1] Following a review carried out in 2022, the use of Rubraca in patients whose cancer has returned or worsened after two treatments with platinum-based chemotherapy is no longer recommended.

Other information about Rubraca

Rubraca received a conditional marketing authorisation valid throughout the EU on 24 May 2018. This was switched to a standard marketing authorisation on 9 November 2022.

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 11-2023.