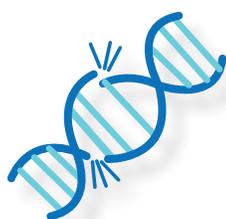


### About Rubraca (rucaparib)

Rubraca® (rucaparib) tablets are a prescription medicine used in adults for the treatment of castration-resistant prostate cancer (prostate cancer that no longer responds to medical or surgical treatment that lowers testosterone): that has spread to other parts of the body, and has a certain type of inherited (germline) or acquired (somatic) abnormal *BRCA* gene, and you have been treated with certain medicines for your cancer. Rubraca was approved based on response rate and how long patients' responses lasted. There are ongoing studies to confirm the clinical benefit of Rubraca. Your healthcare provider will perform a test to make sure Rubraca is right for you. It is not known if Rubraca is safe and effective in children.

### How does Rubraca work?



There are two major ways to repair DNA damage in cells. If one method fails, the other method can make up the difference and repair DNA. Rubraca is a PARP inhibitor that interrupts (or prevents) one DNA repair system from working. Cells with mutations in genes like *BRCA1* and *BRCA2* have a decreased ability to repair DNA damage in the other system. If both ways to repair the DNA in a tumor cell are stopped, DNA damage adds up and that causes the tumor cells to die.

### What are the potential side effects of Rubraca?

Common side effects include:

- Weakness/fatigue
- Nausea
- Decreased red blood count
- Changes in liver function tests
- Decreased appetite
- Constipation, rash, decreased platelet count
- Vomiting and diarrhea
- Bone marrow problems (myelodysplastic syndrome and acute myeloid leukemia) have been reported with Rubraca, although no cases have been reported in prostate cancer patients.



If you are interested in Rubraca as an option for your prostate cancer treatment, talk to your health care team.

### What else should I know?

For males with a female partner who can become pregnant, birth control should be used during treatment and for three months after receiving the last dose of therapy. Men should not donate sperm during use and for three months after the last dose.

Your health care team will conduct blood tests before and while you are receiving therapy to monitor your blood cell counts.



## How long may I be on Rubraca?

In the clinical trial, 44% of men who were studied (27 of 62) had their tumors shrink by a meaningful amount. Patient responses ranged from 1.7 to more than 24 months. More than half of the patients who responded had a confirmed response to treatment of more than six months.



## How do I take Rubraca?

Rubraca tablets are taken by mouth twice a day about 12 hours apart. You can take it with or without food.

## What questions should I ask my health care team?

If you are interested in Rubraca as a treatment option, talk to your health care team.

- Does my cancer have a *BRCA1* or *BRCA2* mutation? What test will you use to find out? What does a positive test mean for my family and me?
- Is Rubraca a treatment for my type of prostate cancer?
- Which side effects are associated with Rubraca? How are these side effects managed?
- How will my health care team check and monitor for side effects?
- Are there options to help me pay for this medicine?

## Where can I find specific information about this treatment?

Additional information can be found at [www.rubraca.com](http://www.rubraca.com) and [www.rubracaconnections.com](http://www.rubracaconnections.com).

### BRCA Mutations in Prostate Cancer

- Everyone has *BRCA1* and *BRCA2* genes. These genes are important in every day functions of your cells. Some men may have damaged or “broken” *BRCA* genes, called mutations. *BRCA* mutations occur in two ways.
  - They are inherited from a parent (called germline mutation) and are present in every cell in your body.
  - They are acquired at some point during your life (called somatic mutations). Somatic mutations are only present in your tumor and can’t be passed on your children.
- Tests can determine if you have a germline or somatic *BRCA* mutation.
- About 12% of men (1 in 8 men) with advanced prostate cancer have a mutation in the *BRCA1* or *BRCA2* genes.
- If the *BRCA* mutation is a germline mutation, family members may have an increased risk of developing prostate or other types of cancer, like breast or ovarian cancer.

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5. National Cancer Institute. Dictionary of Cancer Terms. Germline mutation. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/germline-mutation>. Accessed August 4, 2020.

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9. Abida W, Patnaik A, Campbell D, et al. Rucaparib in Men With Metastatic Castration-Resistant Prostate Cancer Harboring a *BRCA1* or *BRCA2* Gene Alteration. *J Clin Oncol.* 2020; 38:1-8.

## **INDICATION**

### **What is Rubraca used for?**

Rubraca® (rucaparib) tablets are a prescription medicine used in adults for the treatment of castration-resistant prostate cancer (prostate cancer that no longer responds to medical or surgical treatment that lowers testosterone): that has spread to other parts of the body, and has a certain type of inherited (germline) or acquired (somatic) abnormal *BRCA* gene, and you have been treated with certain medicines for your cancer.

Rubraca was approved based on response rate and how long patients' responses lasted. There are ongoing studies to confirm the clinical benefit of Rubraca. Your healthcare provider will perform a test to make sure Rubraca is right for you.

It is not known if Rubraca is safe and effective in children.

## **SELECT IMPORTANT SAFETY INFORMATION**

### **What Warnings should I know about Rubraca?**

Rubraca tablets may cause serious side effects including bone marrow problems called Myelodysplastic Syndrome (MDS) or a type of cancer of the blood called Acute Myeloid Leukemia (AML). Some people who have ovarian cancer and who have received previous treatment with chemotherapy or certain other medicines for their cancer have developed MDS or AML during or after treatment with Rubraca, although MDS or AML was not observed in men with prostate cancer during the clinical study. MDS or AML may lead to death. If you develop MDS or AML, your healthcare provider will stop treatment with Rubraca.

If you are a male with a female partner who is pregnant or able to become pregnant, effective birth control should be used during treatment and for 3 months after the last dose of Rubraca. Do not donate sperm during use and for 3 months after the last dose of Rubraca.

### **What other important information should I know about Rubraca?**

Your healthcare provider will do blood tests before, and every month during treatment with Rubraca to monitor your blood cell counts. Weekly blood tests will be performed if you have low blood cell counts for a long time. Your healthcare provider may stop treatment with Rubraca until your blood cell counts improve.

Avoid spending time in sunlight while on Rubraca since your skin may become more sensitive to the sun and may sunburn more easily. You should wear a hat and clothes that cover your skin and use sunscreen to help protect against sunburn if you have to be in the sunlight.

### **What are the side effects of Rubraca?**

The most common side effects for men in Rubraca clinical studies were weakness/fatigue, nausea, decreased red blood cell count, changes in liver function tests, decreased appetite, constipation, rash, decreased platelet count, vomiting, and diarrhea.

### **What other medications might interact with Rubraca?**

Rubraca can increase the amounts of other medications you may be taking which can increase the risk of side effects. Tell your healthcare provider about all of your medical conditions and all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

You may report side effects to the FDA at 1-800-FDA-1088 or <http://www.fda.gov/medwatch>. You may also report side effects to Clovis Oncology, Inc. at 1-415-409-7220 (US toll) or 1-844-CLVS-ONC (1-844-258-7662; US toll-free).