

Getting Started With Rubraca[®] (rucaparib) Tablets

General information about the safe and effective use of Rubraca

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Rubraca for a condition for which it was not prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for more information about Rubraca.

Please see Select Important Safety Information on pages 7-12 and accompanying full Prescribing Information, including Patient Information, in the pocket.

The logo for Rubraca (rucaparib) tablets. It features the word "Rubraca" in a bold, dark teal font with a registered trademark symbol. Above the letters "u" and "a" in "Rubraca" are three small vertical bars of increasing height from left to right. Below "Rubraca" is the text "(rucaparib) tablets" in a smaller, dark teal font, with "rucaparib" in parentheses and "tablets" to the right.

Rubraca[®]
(rucaparib) tablets

A guide to support you through your treatment

This guide is designed to help you and your loved ones during your treatment with Rubraca® (rucaparib) tablets. Inside, you will also find helpful information about *BRCA* testing.

Share the information you learn in this brochure with your caregiver and loved ones. If you have questions, be sure to ask your healthcare team. This brochure is not meant to replace the advice of your healthcare team, but includes information you may want to discuss with them at your next visit.

What you will learn in this brochure:

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What is a *BRCA* mutation and how does it increase the risk of ovarian cancer?

BRCA stands for **B**reast **C**ancer susceptibility gene. Everyone has *BRCA1* and *BRCA2* genes, which play an important role in normal day-to-day functions of cells.

Some women, however, may have changes in their *BRCA* genes, called mutations. *BRCA* mutations increase the likelihood of developing ovarian cancer.

About 1 in 4 women with ovarian cancer may have a *BRCA* mutation; this is known as being *BRCA* mutation positive (*BRCA*^{mut+}).

Women With Ovarian Cancer



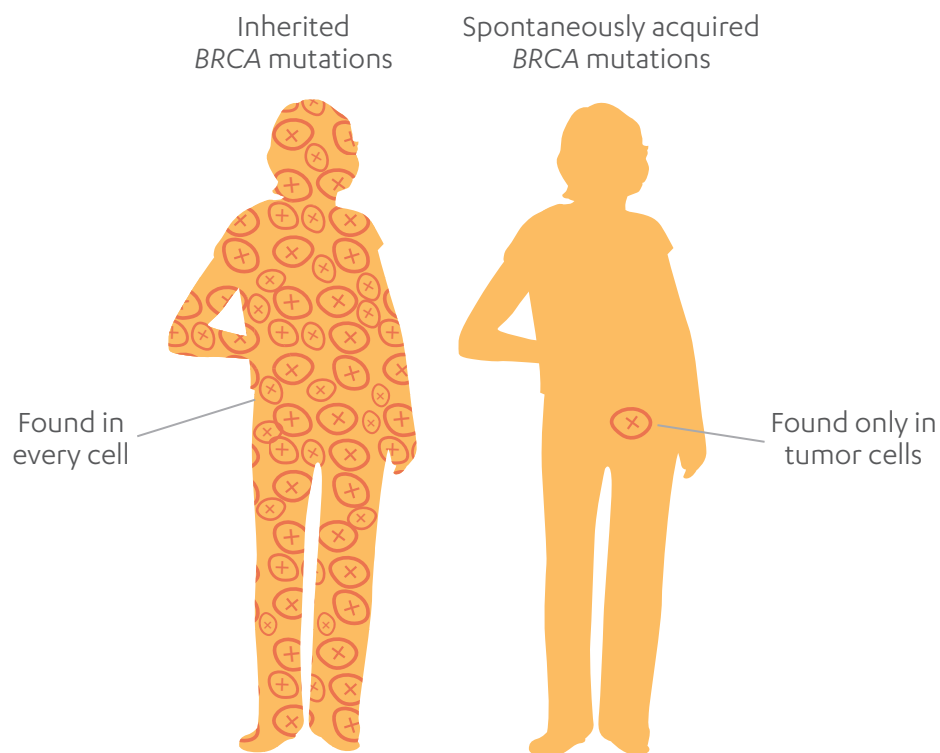
How did I get this mutation?

Some women are born with a *BRCA* mutation that they have inherited from one of their parents (this is known as a germline mutation). For other women, mutations in *BRCA* are acquired spontaneously during their lives without an obvious cause (this is known as a somatic mutation).

If you're *BRCA* mutation positive (*BRCA*^{mut+}), you have the *BRCA* mutation either by inheriting it **or** by acquiring it spontaneously.

Inherited *BRCA* mutations are found in every cell of the body and can be passed down to children. In contrast, *BRCA* mutations that are acquired spontaneously are only found in the tumor cells and are not passed down to children.


In fact, 44% of women with *BRCA* mutation positive (*BRCA*^{mut+}) ovarian cancer have no family history of the disease.



Women with ovarian cancer who are *BRCA*^{mut+} have either inherited the mutation **or** spontaneously acquired it

How do I know what my *BRCA* status is?

After you are diagnosed with advanced ovarian cancer, your doctor may order a *BRCA* test. This test can be done in several ways, and one way is by testing tumor cells. Tumor cells can be obtained from archived (frozen) tumor tissue.

Testing source	What it looks for	Information it provides
	Detects both <ul style="list-style-type: none"> • Inherited <i>BRCA</i> mutations • Acquired <i>BRCA</i> mutations 	<ul style="list-style-type: none"> • Whether you may be a candidate for certain treatments

Tests that detect *BRCA* mutations can provide information for you, your family, and your doctor

As mentioned earlier, mutations that are acquired spontaneously are only found in the tumor cells. This is why testing your tumor cells for a *BRCA* mutation is important. Tests that use tumor tissue can detect *BRCA* mutations from both origins—those that are inherited as well as those that are acquired spontaneously. If you've never been tested for *BRCA* before, or if your tumor cells were not tested for *BRCA*, speak to your doctor about testing for *BRCA* mutations in your tumor cells.

Questions to consider asking your doctor about your *BRCA* status

- Have I had a *BRCA* mutation test? If so, what is my status?
- Have my tumor cells been tested for *BRCA* mutations?
- Have I had a test that identifies *BRCA* mutations that I could have been born with and those that I could have acquired?

Why is it important to know my *BRCA* status?

Knowing your *BRCA* status may help your doctor select an appropriate treatment for you

Testing your tumor cells may help your doctor understand what is causing your cancer to grow. Knowing this may then help your doctor choose a treatment.

A *BRCA* mutation may affect the way ovarian cancer responds to treatments, and knowing if you're *BRCA* mutation positive (*BRCA*^{mut+}) may inform you and your doctor's treatment decisions. If you're *BRCA* mutation positive, you may respond to a type of treatment called a poly (ADP-ribose) polymerase, or PARP, inhibitor. In the following sections of this guide, we will talk about a PARP inhibitor called Rubraca® (rucaparib) tablets and how it may help some women with *BRCA* mutation positive advanced ovarian cancer who have received previous treatment with 2 or more chemotherapy medicines for their cancer.

What is Rubraca and who is it for?

Rubraca is a pill-based PARP inhibitor therapy used by itself

Rubraca is a PARP inhibitor that works by making it difficult for the tumor to fix or repair its DNA, a process that is needed for tumor cells to survive. Rubraca may also impact other cells and tissues.



The starting dose of 600 mg (two 300-mg tablets), to be taken twice daily with or without food, is shown. Tablets shown are actual size

Rubraca is a prescription medicine used to treat people with advanced ovarian cancer who:

- have certain “*BRCA*” gene mutations, either inherited (germline) or acquired (somatic), and
- have received previous treatment with 2 or more prior chemotherapy medicines for their cancer

Your doctor will perform a test to make sure Rubraca is right for you. It is not known if Rubraca is safe and effective in children.

If you have advanced ovarian cancer, are *BRCA* mutation positive (*BRCA*^{mut+}), and have finished 2 chemotherapy medicines, speak to your doctor about Rubraca

Select Important Safety Information

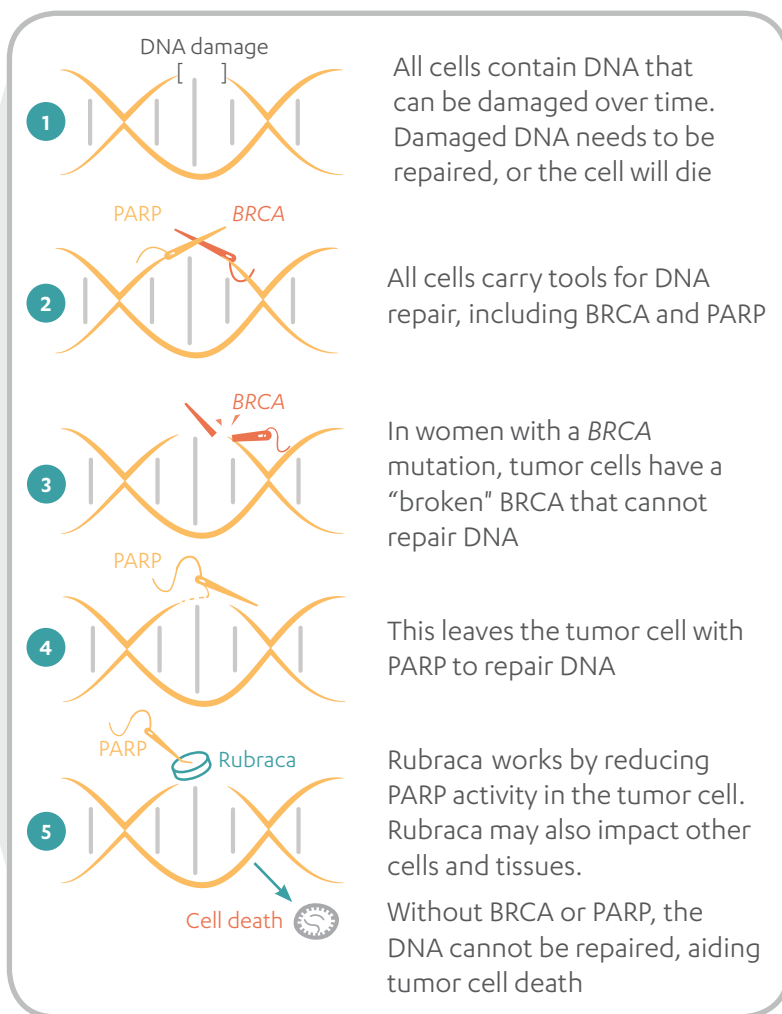
Rubraca may cause serious side effects including bone marrow problems called Myelodysplastic Syndrome (MDS) or a type of cancer of the blood called Acute Myeloid Leukemia (AML). Some people who have ovarian cancer and who have received previous treatment with chemotherapy or certain other medicines for their cancer have developed MDS or AML during or after treatment with Rubraca.

How does Rubraca work?

Rubraca makes it difficult for tumor cells to repair DNA

By reducing DNA repair in the tumor, Rubraca makes it difficult for your tumor to continue to grow. Rubraca may also impact other cells and tissues

Rubraca® (rucaparib) tablets takes advantage of the fact that your cancer has a *BRCA* mutation, regardless of whether you were born with the *BRCA* mutation or if you acquired the mutation spontaneously.



What are the possible benefits of taking Rubraca?

Rubraca works when your tumor starts to grow again

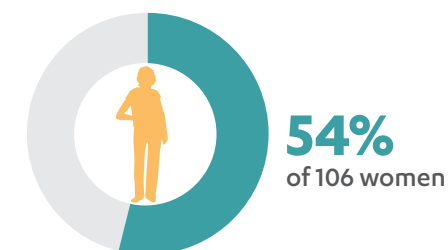
The effectiveness of Rubraca was evaluated in 106 women from 2 clinical studies.

In women with *BRCA* mutation positive (*BRCA*^{mut+}) advanced ovarian cancer who had received at least 2 prior chemotherapy medicines,

As reported by the studies' doctors:

More than half of women saw their tumors shrink with Rubraca treatment

- Rubraca caused tumors to shrink in 54% of patients
- Not all women saw their tumors shrink or responded to Rubraca treatment



Median* length of response to treatment with Rubraca was 9.2 months

- In women who participated in the rucaparib clinical trials, of those who responded to Rubraca, half showed a response to treatment that was less than 9.2 months while half of the women showed a response that was longer than 9.2 months. The majority of these women had a response that lasted between 6.6 and 11.6 months



In a separate review by independent doctors not involved in the clinical studies, Rubraca caused tumors to shrink in 42% of patients. Of those who responded, half showed a response to treatment that was less than 6.7 months while half of the women showed a response that was longer than 6.7 months. The majority of these women had a response that lasted between 5.5 and 11.1 months.

*Median is a middle point in a range of numbers, half of which are above the middle point, half of which are below it.

Select Important Safety Information (continued)

MDS or AML may lead to death. If you develop MDS or AML, your doctor will stop treatment with Rubraca.

What is the most important information I should know about Rubraca?

Rubraca 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® (rucaparib) tablets. MDS or AML may lead to death. If you develop MDS or AML, your doctor will stop treatment with Rubraca.

Symptoms of low blood cell counts are common during treatment with Rubraca, but can be a sign of serious problems, including MDS or AML. **Tell your doctor if you have any of the following symptoms during treatment with Rubraca:**

- Weakness
- Weight loss
- Fever
- Frequent infections
- Blood in urine or stool
- Shortness of breath
- Feeling very tired
- Bruising or bleeding more easily

Your doctor will do blood tests to check your blood cell counts:

- **Before treatment with Rubraca**
- **Every month during treatment with Rubraca**
- **Weekly if you have low blood cell counts for a long time. Your doctor may stop treatment with Rubraca until your blood cell counts improve**

What are the possible side effects of Rubraca?

The most common side effects of Rubraca include:

- Nausea
- Fatigue
- Vomiting
- Stomach-area pain
- Changes in how food tastes
- Constipation
- Decreased appetite
- Diarrhea
- Shortness of breath
- Decrease in hemoglobin (anemia)
- Low blood cell counts
- Changes in liver or kidney function blood tests
- Increased cholesterol levels



These are not all of the possible side effects of Rubraca. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may also report side effects to the FDA at 1-800-FDA-1088.

What should I tell my doctor before taking Rubraca?

Before you take Rubraca, tell your doctor about all of your medical conditions, including if you:


- are pregnant or plan to become pregnant. Rubraca® (rucaparib) tablets can harm your unborn baby and may cause loss of pregnancy (miscarriage). You should not become pregnant during treatment with Rubraca
 - If you are able to become pregnant, your doctor may do a pregnancy test before you start treatment with Rubraca
 - Females who are able to become pregnant should use effective birth control during treatment and for 6 months after the last dose of Rubraca. Talk to your doctor about birth control methods that may be right for you
 - Tell your doctor right away if you become pregnant
- are breastfeeding or plan to breastfeed. It is not known if Rubraca passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after the last dose of Rubraca

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



How should I take Rubraca?

Take Rubraca 2 times per day, with or without food



 Each dose should be taken about 12 hours apart. The starting dose is 600 mg (two 300-mg tablets) taken twice daily.


If you miss a dose of Rubraca:

- Take your next dose at your usual scheduled time
- Do not take an extra dose to make up for a missed dose
-  If you vomit after taking a dose of Rubraca, do not take an extra dose. Take your next dose at your usual time.
-  If you take too much Rubraca, call your doctor or go to the nearest emergency room right away.


Make sure to take Rubraca exactly as your doctor tells you:

- Your doctor may temporarily stop treatment with Rubraca or change your dose of Rubraca if you have side effects. Do not change your dose or stop taking Rubraca unless your doctor tells you to

What should I avoid while taking Rubraca?

 Avoid spending time in sunlight. You may sunburn more easily during treatment with Rubraca. 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.

How should I store Rubraca?

 Store Rubraca at room temperature at 68°F to 77°F (20°C to 25°C).
Keep Rubraca and all medicines out of the reach of children.

What should I do if I have side effects?

Always report side effects to your healthcare team

Your doctor may temporarily stop treatment with Rubraca® (rucaparib) tablets or change your dose if you have side effects. This may make it easier for you to keep taking Rubraca. Always follow the instructions from your doctor.

Write down your experience

You may find it useful to keep a journal about your Rubraca treatment experience. Ask your doctor for the *Rubraca Patient Journal*, or create one of your own.



Remember to always tell your healthcare team if you think you're experiencing a side effect. Partnering with your healthcare team is important to help manage side effects.




How do I get Rubraca?

Rubraca is not available at your local drugstore or pharmacy.

Talk to your doctor to find out if you will get your Rubraca treatment from his or her office or from a specialty pharmacy (a mail order pharmacy that sells specialty drugs).

Rubraca Connections—personalized support from day 1

If you need help understanding how to get your Rubraca treatment or if you experience delays, contact Rubraca Connections. This is a support program designed to help you:

-  **Start Rubraca**
We can work with you and your doctor's office to identify the specialty pharmacy that will help make sure your Rubraca gets delivered where and when you need it.
-  **Afford Rubraca**
We can help you understand your insurance coverage, find programs that can help you pay for Rubraca, and see if you qualify for the Rubraca \$0 Co-Pay Program, which may assist with the cost of your Rubraca treatment.
-  **Continue Rubraca**
We can connect you with a specialty pharmacy team for 24/7 support with side effects, lifestyle/diet, and dosage adjustments that can help you continue your Rubraca treatment plan, as prescribed by your doctor.*

Rubraca
(rucaparib) tablets

connections

Get more information on what Rubraca Connections can do for you at [RubracaConnections.com](https://www.RubracaConnections.com). Or call 1-844-779-7707, Monday through Friday 8 AM-8 PM EST. We're here to help answer any questions you may have.

You do not need to enroll in Rubraca Connections to get Rubraca.

*Their support does not replace direction given by your healthcare provider; 24/7 support is only offered by participating specialty pharmacies.

Where can I find information about ovarian cancer and support?

In this section, you will find a list of additional resources for information on ovarian cancer as well as support and advocacy groups

Information about ovarian cancer

American Cancer Society

- A comprehensive resource for information, support, and ways to become involved in the fight against cancer
-

National Cancer Institute

- Learn about clinical trials, research, and news
-

OncoLink

- Find out about cancer treatment, blogs, and support
-

Support and advocacy groups for patients with ovarian cancer

CancerCare

- Provides telephone, online, and face-to-face counseling, support groups, education, publications, and financial assistance
-

CaringBridge

- Connect with your family, friends, and other patients who want to share their personal stories
-

Clarity Foundation

- Helps eligible women obtain and understand the molecular profile of their tumor
-

Facing Our Risk of Cancer Empowered (FORCE)

- Education, advocacy, and research specific to hereditary breast and ovarian cancer
-

Inspire

- Join a community to share and learn about ovarian cancer, treatment, and support
-

National Ovarian Cancer Coalition (NOCC)

- Learn how you can support cancer organizations, get medical information, and find future events
-

Ovarian Cancer Research Fund Alliance (OCRFA)

- A support network that connects survivors, women at risk, and caregivers
-

This is not a comprehensive list of patient resources.

My notes

Please see Select Important Safety Information on pages 7-12 and accompanying full Prescribing Information, including Patient Information, in the pocket.

