Package leaflet: Information for the patient

Rubraca® 300 mg film-coated tablets

rucaparib

xx-xxx-xxxxxxxxx

The name of your medicine is Rubraca 300 mg film-coated tablets but will be referred to as Rubraca throughout this leaflet.
Please note that the leaflet also contains information about other strengths.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rubraca is and what it is used for

What Rubraca is and how it works

Rubraca contains the active substance rucaparib. Rubraca is an anti-cancer medicine, also known as a 'PARP (poly adenosine diphosphate-ribose polymerase) inhibitor'.

Patients with changes (mutations) in genes called BRCA are at risk of developing a number of types of cancer. Rubraca blocks an enzyme that repairs damaged DNA in the cancer cells, resulting in their death.

What Rubraca is used for

Rubraca is used to treat a type of cancer of the ovary. It is used as maintenance therapy immediately after a course of chemotherapy that has caused the tumour to shrink.

2. What you need to know before you take Rubraca

Do not take Rubraca
- if you are allergic to rucaparib or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding

If you are not sure, talk to your doctor, pharmacist or nurse before taking Rubraca.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before or during taking Rubraca.

Blood tests

Your doctor or nurse will perform blood tests to check your blood cell-counts:
- before treatment with Rubraca
- every month during treatment with Rubraca

This is because Rubraca can cause low blood counts of:
- red blood-cells, white blood-cells, or platelets. See section 4 for more information. The signs and symptoms of low blood cell counts include fever, infection, bruising or bleeding.
- a low blood-cell count may be a sign of a serious bone marrow problem - such as 'myelodysplastic syndrome' (MDS) or 'acute myeloid leukaemia' (AML). Your doctor may test your bone marrow to check for any problems.

Your doctor may also do weekly tests, if you have low blood cell counts for a long time. They may stop treatment with Rubraca until your blood cell counts improve.

Take care in direct sunlight

You may get sunburn more easily during treatment with Rubraca. This means you should:
- keep out of direct sunlight and not use sunbeds while you are taking Rubraca
- wear clothing that covers your head, arms and legs
- use a sunscreen and lip balm with a sun protection factor (SPF) of 50 or higher.

Symptoms you should be aware of

Talk to your doctor if you feel sick (nauseous), have been sick (vomiting) or you have had diarrhoea or abdominal pain. These may be signs and symptoms that Rubraca is affecting your stomach or bowels.

Children and adolescents

Children under 18 years of age should not be given Rubraca. This medicine has not been studied in this age group.

Other medicines and Rubraca

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines. This is because Rubraca can affect the way some other medicines work. Also some other medicines can affect the way Rubraca works.

Tell your doctor, pharmacist or nurse if you are taking any of the following medicines:
- anticoagulant medicines which helps the blood flow freely, such as warfarin
- anticonvulsant medicines used to treat fits (seizures) and epilepsy - such as phenytoin
- medicines to lower blood cholesterol levels - such as rosuvastatin
- medicines to treat stomach problems - such as cisapride, omeprazole
- medicines which suppress the immune system - such as ciclosporin, sirolimus or tacrolimus
- medicines to treat migraines and headaches - such as dihydroergotamine or ergotamine
- medicines to treat severe pain - such as alfentanil or fentanyl
- medicines used to treat uncontrolled movement or mental disorders - such as pimozide
- medicines to lower blood sugar levels and treat diabetes - such as metformin
- medicines to treat irregular heartbeats - such as digoxin or quinidine
- medicines to treat allergic reactions - such as astemizole or terfenadine
- medicines used to cause sleepiness or drowsiness - such as midazolam
- medicines used to relax muscles - such as tizanidine
- medicines used to treat asthma - such as theophylline

Pregnancy, breast-feeding and contraception

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

Pregnancy
- Rubraca is not recommended during pregnancy. This is because it may harm your unborn baby.
- For women who are able to become pregnant, a pregnancy test is recommended before starting treatment with Rubraca.

Breast-feeding
- Do not breast-feed during treatment with Rubraca, and for two weeks after taking the last dose. This is because it is not known if rucaparib passes into breast milk.

Contraception
- Women who are able to become pregnant must use effective birth control (contraception):
  – during treatment with Rubraca and
  – for 6 months after taking the last dose of Rubraca.

This is because rucaparib may affect the unborn baby.
- Talk to your doctor or pharmacist about the most effective methods of contraception.

Driving and using machines

Rubraca may affect your ability to drive or use tools or machines. Take care if you feel tired or feel sick (nauseous).

Rubraca contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Rubraca

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

How much to take

- The usual recommended dose is 600 mg twice a day. This means you take a total of 1 200 mg each day. If you have certain side effects your doctor may recommend a lower dose, or temporarily stop your treatment.
- Rubraca is available as either 200 mg, 250 mg or 300 mg tablets.

Taking this medicine

- Take the tablets once in the morning and once in the evening, approximately 12 hours apart.
- You can take the tablets with or without food.
- If you are sick (vomit) after taking Rubraca, do not take an extra dose. Take your next dose at your regular time.

If you take more Rubraca than you should

If you take more tablets than you should, tell your doctor, pharmacist or nurse straight away. You may need medical help.

If you forget to take Rubraca

- If you forget to take a dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Rubraca

- It is important to keep taking Rubraca every day – as long as your doctor prescribes it for you.
- Do not stop taking this medicine without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

Very common (may affect more than 1 in 10 people):

- being short of breath, feeling tired, having pale skin, or fast heart beat - these may be signs of a low red blood cell count (anaemia)
- bleeding or bruising for longer than usual if you hurt yourself - these may be signs of a low blood platelet count (thrombocytopenia)
- fever or infection – these may be signs of a low white blood cell count (neutropenia)

Other side effects include:

Very common (may affect more than 1 in 10 people):

- feeling sick (nausea)
- feeling tired
- being sick (vomiting)
- pain in the stomach
- changes in the way food tastes
- abnormal blood tests - increase in levels of liver enzymes
- loss of appetite
- diarrhoea
- abnormal blood tests - increase in blood creatinine levels
- difficulty breathing
- feeling dizzy
- sunburn
- heartburn
- high cholesterol levels
- rash

Common (may affect up to 1 in 10 people):

- dehydration
- itching
- allergic reaction (e.g. swelling of the face and eyes)
- redness, swelling, and pain on the palms of the hands and, or the soles of the feet
- red patches on the skin
- blockage in the gut or bowel
- serious bone marrow problem, such as “myelodysplastic syndrome” (MDS) or “acute myeloid leukaemia” (AML) (see section 2)
- mouth sores

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rubraca

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rubraca contains

- The active substance is rucaparib.

Each film-coated tablet contains rucaparib camsylate corresponding to 300 mg of rucaparib.

- The other ingredients are:
  - Tablet content: Microcrystalline cellulose, sodium starch glycolate (Type A), colloidal anhydrous silica and magnesium stearate.
  - Tablet coating: Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), and iron oxide yellow (E172).

What Rubraca looks like and contents of the pack

- Rubraca 300 mg film-coated tablets are yellow, oval, film-coated tablets with “C3” marked on one side.

Rubraca is supplied in plastic bottles. Each bottle contains 60 film-coated tablets.

Product Licence Holder and Manufacturer

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