Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is to be supplied upon a physician's prescription only

Rubraca 200 mg film-coated tablets
Rubraca 250 mg film-coated tablets
Rubraca 300 mg film-coated tablets

Active ingredient:
Rubraca 200 mg film-coated tablets contains rucaparib 200 mg
Rubraca 250 mg film-coated tablets contains rucaparib 250 mg
Rubraca 300 mg film-coated tablets contains rucaparib 300 mg

For the list of excipients of the medicine, please see section 6: “Additional information”.

Read the entire leaflet carefully before you start using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, contact the physician or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Rubraca is used for the maintenance treatment of Adults with recurrent epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer who have a complete or partial response to platinum-based chemotherapy.

Therapeutic group: anti-neoplastics, PARP enzyme inhibitors.

2. Before using this medicine

Do not take Rubraca if:
- You are hypersensitive (allergic) to the active ingredient or any of the other ingredients of this medicine (See section 6 'Additional information')
- You are breast-feeding

Special warnings regarding the use of this medicine
Talk to your physician or pharmacist before taking Rubraca if:
- You have the following signs and symptoms of low blood cell counts, which may be caused by Rubraca: 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).

- You are a woman of childbearing age or planning a pregnancy , a pregnancy test is recommended before starting treatment with Rubraca. It is advised to use effective contraception during treatment and for 6 months following the last dose of Rubraca.If you are pregnant, tell your physician immediately.

Children and young people
Rubraca is not intended for use in children and young people under 18 years of age.

Laboratory tests and follow-up
Your physician or nurse will perform blood tests to check your blood cell-counts:
- before treatment with Rubraca
- every month during treatment with Rubraca

Your physician might ask you to perform a pregnancy test before starting treatment with Rubraca.

Drug interactions:
Tell your physician or pharmacist if you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements.
This is because Rubraca can affect the way some other medicines work. Also some other medicines can affect the way Rubraca works.

Tell your physician, 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

Taking this medicine with food
The medicine may be taken with or without food.

Pregnancy, breast-feeding and fertility
Pregnancy
- Rubraca is not recommended during pregnancy. This is because it may harm your unborn baby. You should not become pregnant during treatment with Rubraca.
- 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.

Fertility
Females:
Females 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 physician or pharmacist about the most effective preventive measures.

Males:
- Males with female partners who are pregnant or able to become pregnant should use effective birth control during treatment with Rubraca and for 3 months after the last dose of Rubraca.
- Males should not donate sperm during treatment with Rubraca and for 3 months after the last dose of Rubraca

Driving and using machines
- You may feel sleepy, dizzy or tired while taking Rubraca.
- Do not drive, cycle or use any tools or machines until you know how the medicine affects you.

3. How to use the medicine?
Always take this medicine exactly as your physician has told you. Check with your physician or pharmacist if you are not sure concerning the dosage and manner of treatment.
The dosage and manner of treatment will be determined only by the physician.

- The usual recommended dose is: two 300 mg tablets (600mg) twice a day. This means you take a total of 1,200 mg each day. If you have certain side effects your physician may recommend a lower dose, or temporarily stop your treatment.

Do not exceed the recommended dose.

There is no information regarding crushing, dividing and chewing the tablet.

Rubraca is a long term treatment. Keep using Rubraca until you are istructed otherwise by your physician.

If you have accidentally taken a higher dosage
If you take more Rubraca than you should, tell your physician, pharmacist or nurse straight away. You may need medical help.
If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or a hospital emergency room and bring the package of the medicine with you.

If you forget to take Rubraca
- If you miss a dose, take it as soon as you remember.
- Take your next dose at the time you would normally take it.
- Do not take a double dose to make up for a forgotten dose.
- If you are not sure what to do, ask your physician or pharmacist.

If you are sick (vomit) after taking Rubraca, do not take an extra dose. Take your next dose at your regular time.

Continue with the treatment as recommended by the physician.
Even if there is an improvement in your health condition, do not stop taking this medicine without consulting the physician.

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

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your physician or pharmacist.

4. <u>Side effects</u>
Like all medicines, Rubraca can cause side effects in some users. Do not be alarmed by reading the list of side effects, you may not experience any of them.

<u>Very common side effects (may affect more than 1 in 10 people):</u>
- 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 – these may be signs of a low white blood cell count (neutropenia)

Other side effects include:
<u>Very common side effects (may affect more than 1 in 10 people):</u>
- feeling sick (nausea)

- feeling tired/weak
- being sick (vomiting)
- stomach (abdomen) pain or swelling
- changes in the way food tastes
- changes in liver function tests
- increase in levels of liver enzymes
- loss of appetite
- diarrhoea
- increase in blood creatinine levels
- difficulty breathing
- feeling dizzy
- sunburn
- rash
- peripheral edemas
- insomnia
- headache
- constipation
- upper respiratory tract infection
- indigestion

Common side effects (may affect up to 1 in 10 out of 100 people):

- itching
- mouth sores
- depression
- allergic reaction (e.g. swelling of the face and eyes)

If a side effect appears, if any side effect gets worse or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by using the following link:
https://sideeffects.health.gov.il/
In addition, you can report by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without specific instruction from the physician.
- Do not use the medicine after the expiration date (exp. date) appearing on the bottle label. The expiration date refers to the last day of that month.
- Store below 25°C.

- 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. Additional information

- **In addition to the active ingredient, the medicine also contains:**

Microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate.

Coating
200 mg film-coated tablets:
Polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol/macrogol (E1521), talc (E533b), brilliant blue FCF aluminium lake (E133), indigo carmine aluminium lake (E132).
250 mg film-coated tablets:
Polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol/macrogol (E1521), talc (E533b).
300 mg film-coated tablets:
Polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol/macrogol (E1521), talc (E553b), and iron oxide yellow (E172).

- **What the medicine looks like and contents of the pack**

Rubraca 200 mg: film-coated tablets are blue, round, film-coated tablets with 'C2' marked on one side.
Rubraca 250 mg: film-coated tablets are white, diamond-shaped, film-coated tablets with 'C25' marked on one side.
Rubraca 300 mg: film-coated tablets are yellow, oval, film-coated tablets with 'C3' marked on one side.

The tablets are supplied in plastic bottles. Each bottle contains 60 film-coated tablets.

Manufacturer's name and address: Pharmaand GmbH, Taborstrasse 1
1020 Wien Austria.
Registration holder's name and addrss: Neopharm Ltd., 6 Hashiloach St., P.O.B. 7063, Petach Tikva 4917001, Israel.

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Drug registration numbers in the Ministry of Health's National Drug Registry:
Rubraca 200 mg film-coated tablets: 162-81-35664
Rubraca 250 mg film-coated tablets: 162-83-35666
Rubraca 300 mg film-coated tablets: 162-82-35665