PATIENT INFORMATION LEAFLET

ZEJULA 100 mg, 200 mg, or 300 mg film-coated tablets

niraparib

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

In this leaflet

1. What ZEJULA is and what it is used for

What ZEJULA is and how it works

ZEJULA contains the active substance niraparib. Niraparib is a type of anti-cancer medicine called a PARP inhibitor. PARP inhibitors block an enzyme called poly [adenosine diphosphate-ribose] polymerase (PARP). PARP helps cells repair damaged DNA so blocking it means that the DNA of cancer cells cannot be repaired. This results in tumour cell death, helping to control the cancer.

What ZEJULA is used for

ZEJULA is used in adult women for the treatment of cancer of the ovary, the fallopian tubes (part of the female reproductive system that connects the ovaries to the uterus), or the peritoneum (the membrane lining the abdomen).

It is used after the cancer has:

- responded to the first treatment with platinum-based chemotherapy, or
- come back (recurred) after the cancer has responded to previous treatment

withstandard platinum-based chemotherapy.

2. Before you take ZEJULA

Don’t take ZEJULA

- if you are allergic to niraparib or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding (see Pregnancy and breast-feeding section)

Take special care with ZEJULA

Talk to your doctor, pharmacist or nurse before or while taking this medicine if any of the following could apply to you:

Low blood-cell counts

ZEJULA lowers your blood-cell counts, such as your red blood-cell count (anaemia), white blood-cell count (neutropenia), or blood-platelet count (thrombocytopenia). Signs and symptoms you need to look out for include fever or infection, and abnormal bruising or bleeding (see section 4 for more information). Your doctor will test your blood regularly throughout your treatment.

Myelodysplastic syndrome/acute myeloid leukaemia

Rarely, low blood-cell counts may be a sign of more serious problems with the bone marrow such as ‘myelodysplastic syndrome’ (MDS) or ‘acute myeloid leukaemia’ (AML). Your doctor may want to test your bone marrow to check for these problems.

High blood pressure

ZEJULA can cause high blood pressure, which in some cases, could be severe. Your doctor will measure your blood pressure regularly throughout your treatment. He or she may also give you medicine to treat high blood pressure and adjust your ZEJULA dose, if necessary.

Your doctor may advise home blood pressure monitoring and instruction on when to contact him or her in case of a rise in blood pressure.

Posterior Reversible Encephalopathy Syndrome (PRES)

A rare neurological side effect named Posterior Reversible Encephalopathy Syndrome (PRES) has been associated with ZEJULA treatment. If you have headache, vision changes, confusion or seizure with or without high blood pressure, please contact your doctor.

Other medicines and ZEJULA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

ZEJULA should not be taken during pregnancy as it could harm your baby. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you are a woman who could become pregnant you must use highly effective contraception while you are taking ZEJULA, and you must continue to use highly effective contraception for 6 months after taking your last dose. Your doctor will ask you to confirm that you are not pregnant with a pregnancy test before starting your treatment. Contact your doctor straightaway if you become pregnant while you are taking ZEJULA.

ZEJULA should not be taken if you are breast-feeding as it is not known if it passes into breast milk. If you are breast-feeding, you must stop before you start taking ZEJULA and you must not begin breast-feeding again until 1 month after taking your last dose. Ask your doctor for advice before taking this medicine.

Driving and using machines

When you are taking ZEJULA it may make you feel weak, unfocused, tired or dizzy and therefore influence your ability to drive and use machines. Observe caution when driving or using machines.

3. How to take ZEJULA

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

How much to take

For ovarian cancer that has responded to the first treatment with platinum-based chemotherapy
The recommended starting dose is 200 mg, taken once a day, with or without food. If you weigh ≥ 77 kg and have platelet count ≥ 150,000/μL before starting treatment, the recommended starting dose is 300 mg, taken together once a day, with or without food.

For ovarian cancer that has come back (recurred)
The recommended starting dose is 300 mg, taken once a day, with or without food. Take ZEJULA at approximately the same time each day. Taking ZEJULA at bedtime may help you to manage nausea.

Your doctor may recommend a different dose if you have problems with your liver.

How to take ZEJULA

Swallow ZEJULA whole with some water. Do not chew or crush the tablets.

Your doctor may recommend a lower dose if you experience side effects (such as nausea, tiredness, abnormal bleeding/bruising, anaemia).

Your doctor will check you on a regular basis, and you will normally continue to take ZEJULA as long as you experience benefit, and do not suffer unacceptable side effects.

If you forget to take ZEJULA

Do not take an additional dose if you miss a dose or vomit after taking ZEJULA. Take your next dose at its scheduled time. Do not take a double dose to make up for a forgotten dose.

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

If you take too much ZEJULA

If you take more than your normal dose, contact your doctor immediately.

4. Possible side effects

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

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

- Bruising or bleeding for longer than usual if you hurt yourself -- these may be signs of a low blood platelet count (thrombocytopenia).
- Being short of breath, feeling very tired, having pale skin, or fast heartbeat -- these may be signs of a low red blood cell count (anaemia).
- Fever or infection – low white blood cell count (neutropenia) can increase your risk for infection. Signs may include fever, chills, feeling weak or confused, cough, pain or burning feeling when passing urine. Some infections can be serious and may lead

to death. Low neutrophil counts may be associated with neutropenic infection, febrile neutropenia or neutropenic sepsis (see side effects with lower frequency below).
- Decrease in the number of white blood cells called leukocytes that fight infection (leukopenia). Low leukocyte counts may decrease your ability to fight infections.

Common (may affect up to 1 in 10 people)
- Infection due to low white blood cell counts (neutropenic infection)
- Low blood cell counts due to a problem in the bone marrow or blood cancer startingfrom the bone marrow (MDS or AML)
- Allergic reaction (hypersensitivity, including anaphylaxis).
- Life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) (anaphylaxis)

Uncommon (may affect up to 1 in 100 people)
- Fever with low white blood cell count (febrile neutropenia)
- Decrease in the number of all types of blood cells (pancytopenia)
- Severe life-threatening infection associated with low blood pressure and possible organ failure (for example, heart, kidney and/or liver) due to low blood pressure (neutropenic sepsis)
    - Symptoms may include: fever, feeling of low blood pressure (lightheadedness, dizziness), decreased urination, rapid pulse, rapid breathing (signs of neutropenic sepsis).

Rare (may affect up to 1 in 1000 people)
- A sudden increase in blood pressure, which may be a medical emergency that could lead to organ damage or can be life-threatening (hypertensive crisis).
- A brain condition with symptoms including seizures, headache, confusion, and changes in vision (posterior reversible encephalopathy syndrome [PRES])

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

Very common side effects

These may affect **more than 1 in 10** people:

- Stomach pain (abdominal pain)
- Indigestion (dyspepsia)
- Cough
- Painful and frequent urination (urinary tract infection)
- Headache
- Feeling weak (asthenia)
- Lack of energy (fatigue)
- Dizziness
- Joint pain (arthralgia)
- Back pain

- Difficulty passing stool (constipation)
- Feeling sick (nausea)
- Vomiting
- Frequent watery stools (diarrhoea)
- Shortness of breath (dyspnoea)
- Runny or stuffy nose (nasopharyngitis)
- Difficulty in sleeping (insomnia)
- Decreased appetite
- Fast or irregular heart beats (palpitations)
- High blood pressure

Common side effects

These may affect **up to 1 in 10** people:

- Inflammation of the eye (conjunctivitis)
- Dry mouth
- Swelling of lower legs and feet (peripheral oedema)
- Nose bleed (epistaxis)
- Feelings of sadness, depressed (depression)
- Muscle pain (myalgia)
- Decrease in weight
- Decrease in potassium in the blood. Low potassium may cause an irregular heart beat (hypokalaemia)
- Inflammation or swelling of the air passages between the mouth and nose and the lungs (bronchitis)
- Sore, red mouth (mucositis/stomatitis)
- Rash
- Increased sensitivity of the skin to sunlight (photosensitivity)
- Feelings of worry, nervousness or unease (anxiety)
- Impaired concentration, understanding, memory and thinking (cognitive impairment)
- Fast heart beat (tachycardia), which may cause dizziness, chest pain or breathlessness
- Increased level of creatinine in your blood (blood creatinine increase), which may be a sign of kidney damage
- Abnormal taste in mouth (dysgeusia)
- Abnormally high levels of enzymes in the blood produced by the liver meaning that your liver may not be functioning properly and can cause fatigue, nausea and abdominal pain. Although this is usually mild and reversible, this can be serious or life threatening. Specific enzymes are:
    - aspartate transaminase ("AST")
    - alanine aminotransferase ("ALT")
    - gamma glutamyl transferase increased ("GGT") and/or
    - alkaline phosphatase (ALP)

Uncommon side effects

These may affect **up to 1 in 100** people:

• Confusion (confusional state/disorientation)
• Seeing or hearing things that are not really there (hallucination)
• Inflammation of the lungs which can cause shortness of breath and difficulty breathing (non-infectious pneumonitis)

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5. How to Store ZEJULA

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 carton and blister after EXP. The expiry date refers to the last day of that month.

The storage conditions are detailed on the packaging.

Do not use this medicine if you notice any damage or signs of tampering to the pack.

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. Further information

What ZEJULA contains

The active substance is niraparib.

Each film-coated tablet contains 159.3 mg, 318.7 mg, or 478.0 mg niraparib tosylate monohydrate equivalent to 100 mg, 200 mg, or 300 mg, respectively, niraparib as the active ingredient.

The other ingredients (excipients) are crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and silicon dioxide. The film-coating consists of Opadry II Gray (100 mg), Opadry II Blue (200 mg), or Opadry II Green (300 mg), and purified water.

What ZEJULA looks like and contents of the pack

ZEJULA 100 mg tablet is gray, oval-shaped, film-coated tablet debossed with “100” on one side and “Zejula” on the other.

ZEJULA 200 mg tablet is blue, oval-shaped, film-coated tablet debossed with “200” on one side and “Zejula” on the other.

ZEJULA 300 mg tablet is green, oval-shaped, film-coated tablet debossed with “300” on one side and “Zejula” on the other.

Not all presentations are available in every country.

Product Registrant

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