

PATIENT INFORMATION
ZEJULA™ (zuh-JOO-luh)
(niraparib)
capsules

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

ZEJULA 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 treatment with ZEJULA. MDS or AML may lead to death. If you develop MDS or AML, your healthcare provider will stop treatment with ZEJULA.

Symptoms of low blood cell counts (low red blood cells, low white blood cells, and low platelets) are common during treatment with ZEJULA, but can be a sign of serious bone marrow problems, including MDS or AML. Symptoms may include:

- weakness
- feeling tired
- weight loss
- frequent infections
- fever
- shortness of breath
- blood in urine or stool
- bruising or bleeding more easily

Your healthcare provider will do blood tests to check your blood cell counts:

- before treatment with ZEJULA
 - weekly for the first month of treatment with ZEJULA
 - every month for the next 11 months, then as needed during treatment with ZEJULA
- **High blood pressure.** High blood pressure is common during treatment with ZEJULA, and can become serious. Your healthcare provider will check your blood pressure and heart rate monthly for the first year and as needed thereafter during your treatment with ZEJULA.

See “What are the possible side effects of ZEJULA?” for more information about side effects.

What is ZEJULA?

ZEJULA is a prescription medicine used for the maintenance treatment of adults with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, when the cancer comes back. ZEJULA is used after the cancer has responded (complete or partial response) to treatment with platinum-based chemotherapy.

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

Before taking ZEJULA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have high blood pressure.
- are pregnant or plan to become pregnant. ZEJULA can harm your unborn baby and may cause loss of pregnancy (miscarriage).
 - If you are able to become pregnant, your healthcare provider may perform a pregnancy test before you start treatment with ZEJULA.
 - Females who are able to become pregnant should use effective birth control

PATIENT INFORMATION
ZEJULA™ (zuh-JOO-luh)
(niraparib)
capsules

(contraception) during treatment with ZEJULA and for 6 months after the last dose of ZEJULA. Talk to your healthcare provider about birth control methods that may be right for you.

- Tell your healthcare provider right away if you become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if ZEJULA passes into your breast milk. Do not breastfeed during treatment with ZEJULA and for 1 month after the last dose of ZEJULA. Talk to your healthcare provider about the best way to feed your baby during this time.

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

How should I take ZEJULA?

- Take ZEJULA exactly as your healthcare provider tells you to.
- Take ZEJULA 1 time each day, at the same time each day.
- ZEJULA may be taken with or without food.
- ZEJULA capsules should be swallowed whole.
- Taking ZEJULA at bedtime may help relieve any nausea symptoms you may have.
- Do not stop taking ZEJULA without first talking with your healthcare provider.
- If you miss a dose of ZEJULA, take your next dose at your scheduled time. Do not take an extra dose to make up for a missed dose.
- If you vomit after taking a dose of ZEJULA, do not take an extra dose. Take your next dose at your scheduled time.
- If you take too much ZEJULA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ZEJULA?

ZEJULA can cause serious side effects, including:

- See “What is the most important information I should know about ZEJULA?”

The most common side effects of ZEJULA include:

- | | |
|-------------------------------|--|
| ● heart not beating regularly | ● changes in liver function blood tests |
| ● nausea | ● pain in your joints, muscles, and back |
| ● constipation | ● headache |
| ● vomiting | ● dizziness |
| ● pain in the stomach area | ● change in the way food tastes |
| ● mouth sores | ● trouble sleeping |
| ● diarrhea | ● anxiety |
| ● indigestion or heartburn | ● sore throat |
| ● dry mouth | ● shortness of breath |
| ● tiredness | ● cough |
| ● loss of appetite | ● rash |
| ● urinary tract infection | |

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with

PATIENT INFORMATION
ZEJULA™ (zuh-JOO-luh)
(niraparib)
capsules

ZEJULA, if you have certain side effects.

These are not all the possible side effects of ZEJULA. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZEJULA?

Store ZEJULA at room temperature between 68° to 77°F (20° to 25°C).

Keep ZEJULA and all medicines out of the reach of children.

General information about the safe and effective use of ZEJULA.

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

What are the ingredients in ZEJULA?

Active ingredient: niraparib

Inactive ingredients:

Capsule fill: magnesium stearate and lactose monohydrate

Capsule shell: titanium dioxide and gelatin in the white capsule body and FD&C Blue #1, FD&C Red #3, FD&C Yellow #5 and gelatin in the purple capsule cap.

The black printing ink: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide and black iron oxide.

The white printing ink: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, sodium hydroxide, povidone and titanium oxide.

Manufactured for: TESARO, Inc. 1000 Winter St., #3300, Waltham, MA 02451

ZEJULA is a trademark of TESARO, Inc. All other trademarks referenced herein are the property of their respective owners. ©2017 TESARO, Inc. All rights reserved. 117648

For more information, call 1-844-483-7276 or go to www.tesarobio.com

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: March 2017