

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**TALZENNA**®

Talazoparib Capsules

Read this carefully before you start taking **TALZENNA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TALZENNA**.

Serious Warnings and Precautions

- Take **TALZENNA** under the care of a doctor who knows how to use anti-cancer drugs.
- **Myelodysplastic Syndrome or Acute Myeloid Leukemia:** Serious bone marrow problems such as Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) have been reported in patients who received PARP inhibitors, including **TALZENNA**. MDS or AML can lead to death.
- **TALZENNA** can harm your unborn baby if you take it when you are pregnant.

What is **TALZENNA** used for?

Breast Cancer:

TALZENNA is taken by itself to treat a specific type of breast cancer (known as human epidermal growth factor receptor 2 [HER2]-negative) in adults:

- who have mutations (changes) in certain genes called BRCA (known as the breast cancer gene),
- who have had previous chemotherapy for your breast cancer and
- whose cancer has spread beyond the original tumor or to other parts or organs of the body.

Prostate Cancer:

TALZENNA is taken with a medicine called enzalutamide, to treat adults with specific type of prostate cancer (known as Castration-resistant prostate cancer [CRPC]):

- whose cancer has spread beyond the original tumor or to other parts or organs of the body.
- who have mutations (changes) in certain genes called homologous recombination repair (HRR) genes.

Before taking **TALZENNA**, a test will be performed. This test is to confirm that your disease is suitable for treatment with this drug.

How does **TALZENNA** work?

TALZENNA is a type of drug called a PARP inhibitor. PARP inhibitors block a protein called poly [adenosine diphosphate-ribose] polymerase (PARP). This protein helps cells to repair their damaged DNA. Blocking PARP activity prevents the repair of damaged DNA in cancer cells leading to cell death.

What are the ingredients in **TALZENNA**?

Medicinal ingredients: talazoparib, as talazoparib tosylate

Non-medicinal ingredients: hydromellose, pharmaceutical grade printing ink, red iron oxide, silicified

microcrystalline cellulose, titanium dioxide and yellow iron oxide

TALZENNA comes in the following dosage forms:

Capsules: 0.1 mg, 0.25 mg, 0.35 mg, 0.5 mg and 1 mg

Do not use TALZENNA if:

- you are allergic to talazoparib tosylate or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TALZENNA. Talk about any health conditions or problems you may have, including if you:

- have or have had liver or kidney problems.

Other warnings you should know about:

Children and adolescents:

- TALZENNA is not recommended for use in patients under the age of 18 years.

Driving and using machines:

- Before you do tasks which may require special attention, wait until you know how you respond to TALZENNA. If you feel dizzy, weak or tired, do not drive or use tools or machines.

Low blood-cell counts:

- TALZENNA may lower your blood cell counts such as your platelets (thrombocytopenia), red blood cells (anemia) and white blood cells (neutropenia).

Pregnancy, breastfeeding and fertility – information for women and men:

- If you or your partner are pregnant, or still able to get pregnant and/or breastfeed, there are specific risks you must discuss with your healthcare professional.

Pregnancy – information for women

- A pregnancy test should be done before you start to take TALZENNA.
- Avoid becoming pregnant while taking TALZENNA. It may harm your unborn child or make you lose the pregnancy.
- If you become pregnant while taking TALZENNA, tell your doctor right away.
- If you plan to get pregnant after taking your dose of TALZENNA, ask your doctor for advice. This is because TALZENNA may remain in your body after the last dose.

Pregnancy – information for men

- If your partner becomes pregnant while you are taking TALZENNA, tell your partner's doctor right away.

Birth Control – information for women and men

- Use an effective method of birth control while taking TALZENNA.
- Talk to your doctor about birth control methods that may be right for you.
- Men taking TALZENNA must use a condom because the drug may pass into the sperm. Do NOT donate sperm while taking TALZENNA.
- Women should NOT donate eggs while taking TALZENNA.

- **After you finish treatment with TALZENNA:**
 - **Women who are able to become pregnant:** Keep using birth control and do NOT donate eggs for 7 months after taking your last dose.
 - **Males with female partners who are pregnant or able to become pregnant:** Keep using birth control and do NOT donate sperm for 4 months after taking your last dose.

Breastfeeding – information for women

- TALZENNA may pass into breast milk. Do not breast-feed while you are taking it and for 1 month after taking your last dose of TALZENNA. Talk to your doctor about the best way to feed your baby.

Fertility – information for women and men

- TALZENNA may affect your fertility. Talk to your doctor if this is a concern for you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TALZENNA:

- clarithromycin, erythromycin – used to treat bacterial infections
- itraconazole, ketoconazole – used to treat fungal infections
- darunavir, indinavir, lopinavir, saquinavir, ritonavir, tipranavir – used to treat viral infections, primarily HIV
- amiodarone, dronedarone, propafenone – used to treat illnesses with rapid heart beat
- verapamil, carvedilol – used to treat high blood pressure
- quinidine – used to treat abnormal heart rhythms
- lapatinib – used to treat certain types of cancer
- carbamazepine – used to treat seizures and epilepsy
- St John’s Wart (*Hypericum perforatum*) – an herbal remedy used mainly for depression
- rifampin – used to treat bacterial infections, primarily tuberculosis
- curcumin – an herbal supplement
- cyclosporine – used to suppress the immune system

How to take TALZENNA:

- Take TALZENNA exactly as your healthcare professional has told you. Check with your doctor, pharmacist or nurse if you are not sure.
- Do not change your dose or stop taking TALZENNA without first talking with your doctor.
- Take TALZENNA with or without food at about the same time each day.
- Swallow TALZENNA capsules whole. Do NOT chew, crush, open or dissolve TALZENNA capsules.
- Do NOT touch or handle crushed or broken TALZENNA capsules.
- If you vomit after taking your dose, take your next dose at your regular time.

Usual dose:**Usual adult dose:**For breast cancer

1 mg: Take 1 mg by mouth once a day.

For prostate cancer

0.5 mg: Take 0.5mg by mouth once a day in combination with enzalutamide

Your doctor may change your dose of TALZENNA or tell you to stop taking it. This may happen if:

- you have certain side effects while taking TALZENNA.
- you are taking medicines that may interact with TALZENNA.

Reduced adult dose:For breast cancer

Dose Reductions	Dose Level
First dose reduction	0.75 mg once daily
Second dose reduction	0.5 mg once daily
Third dose reduction	0.25 mg once daily

For prostate cancer

Dose Reductions	Dose Level
First dose reduction	0.35 mg once daily
Second dose reduction	0.25 mg once daily
Third dose reduction	0.1 mg once daily

Overdose:

If you think you have taken too much TALZENNA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take TALZENNA, take your next dose at your regular time. Do not take an extra dose to make up for a missed dose.

What are possible side effects from using TALZENNA?

These are not all the possible side effects you may feel when taking TALZENNA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects of TALZENNA may include:

- decreased appetite
- diarrhea
- nausea (feeling the need to vomit)
- vomiting (throwing up)

- dizziness
- changes in the way food tastes
- indigestion or heartburn
- upset stomach
- hair loss
- fatigue (feeling tired or weak)
- inflamed and sore mouth

TALZENNA can cause abnormal blood test results. This includes decreased blood cell counts. Your healthcare professional will test your blood before you start treatment with TALZENNA. They will then test your blood every month while you are taking TALZENNA for the first year. Your doctor will tell you if your test results are abnormal and may adjust your treatment to correct these side effects.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (low red blood cell count): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness, headaches, dizziness.		X	
Leukopenia (low white blood-cell count: leukophils): fever or infection, fatigue, aches and pains, and flu-like symptoms.		X	
Lymphopenia (low white blood-cell count: lymphocytes): Get infections more easily.		X	
Neutropenia (low white blood-cell count): infections, chills, fever, fatigue, aches, pains and flu-like symptoms.		X	
Thrombocytopenia (low blood platelet count): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.		X	
COMMON			
Headache	X		
Abdominal Pain: pain in the stomach.	X		
UNCOMMON			

Myelodysplastic Syndrome or Acute Myeloid Leukemia (a group of diseases in which the body produces large numbers of abnormal blood cells): Fever, infection, bruising or bleeding easily, breathlessness, blood in urine or stool.			X
Venous Thromboembolic Events (blood clot in a vein which may move to your lungs): Pain or tenderness or swelling in your arm or leg, skin that is red or warm, coldness, tingling or numbness, pale skin, muscle pain or spasms, weakness. Chest pain that may increase with deep breathing, coughing up bloody sputum, shortness of breath.			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store between 15°C to 30°C. Maintain in original bottle to protect from light.
- Do not use after the expiry date stated on the bottle after EXP.
- Do not throw away any medicines via wastewater or household waste. Ask your healthcare provider or pharmacist about the right way to throw away outdated or unused TALZENNA. These measures will help protect the environment.
- **Keep out of reach and sight of children.**

If you want more information about TALZENNA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (www.pfizer.ca), or by calling 1-800-463-6001.

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