MINNESOTA UROLOGY

TALZENNA® (Tal-ZEN-ah) (talazoparib)capsules

Active ingredient: talazoparib tosylate.
Inactive ingredients: silicified microcrystalline cellulose (sMCC). The capsule shells contain hypromellose (HPMC), yellow iron oxide, red iron oxide and titanium dioxide. The printing ink contains shellac, black iron oxide, potassium hydroxide, ammonium hydroxide, and propylene glycol.

What is the most important information I should know about TALZENNA?
TALZENNA may cause serious side effects, including:
Bone marrow problems called Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML). Some people who have cancer and who have received previous treatment with chemotherapy or certain other medicines for their cancer have developed MDS or AML during or after treatment with TALZENNA.
Symptoms of low blood cell counts are common during treatment with TALZENNA, but can be a sign of serious problems, including MDS or AML. Tell your healthcare provider if you have any of the following symptoms during treatment with TALZENNA:

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

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

- every month during treatment with TALZENNA.
- weekly if you have low blood cell counts that last a long time. Your healthcare provider may stop treatment with TALZENNA until your blood cell counts improve.

What is TALZENNA?
TALZENNA is a prescription medicine used:

- in combination with a medicine called enzalutamide, to treat adults with prostate cancer
    - with certain abnormal inherited or acquired genes called homologous recombination repair (HRR genes) **and**
    - which no longer responds to a hormone therapy or surgical treatment to lower testosterone and has spread to other parts of the body (metastatic).

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

- have kidney problems.
- **Males** with female partners who are pregnant or are able to become pregnant should use effective birth control during treatment with TALZENNA and for at least 4 months after receiving the last dose of TALZENNA.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Taking TALZENNA and certain other medicines can affect how TALZENNA works and may cause side effects.

How should I take TALZENNA?

- Take TALZENNA exactly as your healthcare provider tells you.
- Do not change your dose or stop taking TALZENNA without first talking with your healthcare provider.
- For prostate cancer, take TALZENNA in combination with enzalutamide 1 time a day.
- You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with TALZENNA and enzalutamide unless you have had a surgery to lower the amount of testosterone in your body (surgical castration).
- Take TALZENNA with or without food.
- Swallow TALZENNA capsules whole. Do not dissolve or open TALZENNA capsules.

- If you miss a dose of TALZENNA or vomit, take your next dose at your regular time. Do not take an extra dose to make up for a missed dose.
- If you take too much TALZENNA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of TALZENNA?
TALZENNA may cause serious side effects, including:
The most common side effects of TALZENNA when taken alone include:

low red blood cell counts
low white blood cell counts
low platelet counts
tiredness or weakness
increased blood glucose levels
increased liver function tests
low calcium in the blood
nausea
headache
vomiting
hair loss
diarrhea
decreased appetite

The most common side effects of TALZENNA when taken in combination with enzalutamide include:

low red blood cell counts
low white blood cell counts
tiredness or weakness
low platelet counts
low calcium in the blood
nausea
decreased appetite
low sodium in the blood
low phosphate in the blood
bone injuries
low magnesium in the blood
dizziness
increased bilirubin in the blood
low potassium in the blood
changes in your sense of taste

These are not all of the possible side effects of TALZENNA.
Call your doctor for medical advice about side effects.

How should I store TALZENNA?
Store TALZENNA at 68°F to 77°F (20°C to 25°C).
Keep TALZENNA and all medicines out of the reach of children.
If you have any unused TALZENNA, do not throw it in the trash and do not flush it down the sink or toilet.
Dispose of unused medicines through community take-back disposal programs when available. If no community take-back disposal program is available go to www.fda.gov/drugdisposal for information on how to dispose of medication the right way.

General information about the safe and effective use of TALZENNA.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TALZENNA for a condition for which it is not prescribed. Do not give TALZENNA to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about TALZENNA that is written for health professionals.
If you are unhappy with this service and would like to place a complaint with our management team please contact us at (651) 999-6800 or the Minnesota Secretary of Health and Human Services or Accreditation Commission for Health Care at (855) 937-2242