

TALZENNA HARD CAPSULES

Talazoparib (0.25 mg, 1 mg)

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What Talzenna is used for

Talzenna is an anticancer drug used for treating adult patients with mutations/changes in the genes (BRCA1/2 mutation and HER2-negative locally advanced or metastatic breast cancer) which are responsible for breast cancer. Patients should have been treated prior with another anticancer drug such as anthracycline or a taxane. Patients with breast cancer due to changes in the hormones should be first treated with a hormone-based therapy, or identified to be unsuitable for hormone-based therapy.

How Talzenna works

Talzenna inhibits the activity of PARP (PARP1, and PARP2) enzymes which is involved in development of cancer.

Before you use Talzenna

- When you must not use it

Do not take Talzenna

- If you are allergic to talazoparib or any of the other ingredients in Talzenna.
- If you are breastfeeding

Pregnancy and lactation

Your doctor may do a pregnancy test before you start treatment with Talzenna and may also suggest you to use effective birth control (contraception) during treatment and for at least 7 months after your last

dose of Talzenna. Talk to your doctor about birth control methods that may be right for you during this time.

You should not become pregnant during treatment with Talzenna because this medicine could harm the baby. If you become pregnant while taking this medicine, you should immediately talk to your doctor.

It is not known if Talzenna passes into your breast milk. Breast-feeding is contraindicated during treatment with Talzenna and for at least 1 month after the final dose.

- Before you start to use it

Before taking Talzenna, tell your doctor if you:

- have low levels of red blood cells, white blood cells or platelets
- have cancer or abnormality affecting bone marrow
- are pregnant or planning to get pregnant

- Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Some medicines may reduce how well Talzenna works, while some medications may become harmful when being taken with Talzenna. Especially tell your doctor if you take:

- medicines used to treat fungal infections such as itraconazole, ketoconazole
- antibacterial medicine such as rifampicin, clarithromycin, erythromycin
- medicines like carbamazepine, phenytoin, and St. John's wort, curcumin
- medicine used to prevent organ rejection such as cyclosporine

- cardiovascular medicines such as amiodarone, carvedilol, dronedarone, propafenone, quinidine, ranolazine
- medicines to treat HIV/AIDS like cobicistat, indinavir, lopinavir, darunavir, ritonavir, saquinavir, tipranavir
- medicine used to treat cancer such as lapatinib
- medicine used to treat Hepatitis C like telaprevir
- medicine used to treat low blood pressure such as verapamil

How to use Talzenna

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose is 1 mg Talzenna once daily.

You can take Talzenna with food or between meals. Swallow the capsule whole with a glass of water. Do not chew or crush the capsules. Do not open the capsules. Contact with the capsule content should be avoided.

Tell your doctor if you notice any side effects. Your doctor may suggest you to modify your dose or stop Talzenna as appropriate.

Your doctor will do a complete blood test before the start of treatment and will monitor it during the treatment to ensure if any dose reductions are required.

- When to use it

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

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- How long to use it

Take Talzenna for as long as your doctor tells you to i.e. until disease progression or unacceptable toxicity occurs.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you vomit or miss a dose, an additional dose should not be taken. The next prescribed dose should be taken at the usual time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The effects of Talzenna overdose have not been established.

In case of overdosage, your doctor will suggest you to discontinue medication and may consider to follow the procedure for emptying your gastrointestinal tract.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Talzenna.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Talzenna to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using machines

Talzenna may have a minor influence on your ability to drive and use machines. You may experience dizziness/tiredness after taking Talzenna.

Side effects

Like all medicines, Talzenna can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Side effects are divided according to the frequency it appears while treating for different conditions.

Very common side effects (may affect more than 1 in 10 people) include:

- low levels of platelets
- low levels of red blood cells
- low levels of white blood cells
- decreased appetite
- dizziness
- headache
- diarrhoea
- nausea
- vomiting
- abdominal pain
- hair loss
- tiredness

Common side effects (may affect up to 1 in 10 people) include:

- low levels of white blood cells (Lymphocytes)
- impaired taste
- inflammation of lips, cheeks, gums, tongue, and throat (inflammation inside mouth)
- indigestion

These are not all of the possible side effects of Talzenna. For more information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Talzenna

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Talzenna 0.25 mg hard capsule is an opaque, size #4 hard capsule with an ivory cap (printed with “Pfizer” in black) and a white body (printed with “TLZ 0.25” in black).

Talzenna 1 mg hard capsule is an opaque, size #4 hard capsule with a light red cap (printed with “Pfizer” in black) and a white body (printed with “TLZ 1” in black).

- Ingredients

- Active ingredient

Talazoparib

- Inactive ingredients

Capsule content

Silicified microcrystalline cellulose (microcrystalline cellulose and silicone dioxide)

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Talazoparib (0.25 mg, 1 mg)

0.25 mg capsule shell

Hypromellose

Yellow iron oxide (E172)

Titanium dioxide (E171)

1 mg capsule shell

Hypromellose

Red iron oxide (E172)

Yellow iron oxide (E172)

Titanium dioxide (E171)

Printing ink

Shellac (NF)

Dehydrated Alcohol (USP)

Isopropyl Alcohol (USP)

Butyl Alcohol (NF)

Propylene Glycol (USP)

Strong Ammonia Solution (NF)

Black iron oxide (NF)

Potassium Hydroxide (NF)

Purified Water (USP)

- MAL number:

Talzenna 0.25 mg hard capsules:

MAL21086003ACZ

Talzenna 1 mg hard capsules:

MAL21086004ACZ

Manufacturer

Excella GmbH & Co. KG,

Nurnburger Strasse 12,

90537 Feucht, Germany.

Product Registration Holder

Pfizer Malaysia Sdn. Bhd.

Level 10 & 11,

Wisma Averis, Tower 2,

Avenue 5, Bangsar South,

No. 8 Jalan Kerinchi,

59200 Kuala Lumpur, Malaysia.

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