

Package leaflet: Information for the patient

Talzenna® 0.1 mg hard capsules
Talzenna® 0.25 mg hard capsules
Talzenna® 0.35 mg hard capsules
Talzenna® 0.5 mg hard capsules
Talzenna® 1 mg hard capsules
talazoparib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Talzenna is and what it is used for
2. What you need to know before you take Talzenna
3. How to take Talzenna
4. Possible side effects
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6. Contents of the pack and other information

1. What Talzenna is and what it is used for

What Talzenna is and how it works

Talzenna contains the active substance talazoparib. It is a type of anticancer medicine known as a 'PARP (poly-ADP ribose polymerase) inhibitor'.

Talzenna works by blocking PARP, which is an enzyme that repairs damaged DNA in certain cancer cells. As a result, the cancer cells can no longer repair themselves and they die.

What Talzenna is used for

Talzenna is a medicine used

- alone to treat adults with breast cancer of a type known as HER2-negative breast cancer who have an abnormal inherited BRCA gene. Your healthcare provider will perform a test to make sure that Talzenna is right for you.
- in combination with a medicine called enzalutamide, to treat adults with prostate cancer who no longer respond to a hormone therapy or surgical treatment to lower testosterone.

Talzenna is used when the cancer has spread beyond the original tumour or to other parts of the body.

If you have any questions about how Talzenna works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Talzenna

Do not take Talzenna

- If you are allergic to talazoparib or any of the other ingredients of this medicine (listed in section 6).
- If you are breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Talzenna and during your treatment if you experience signs or symptoms described in this section.

Low blood cell counts

Talzenna 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:

- **Anaemia:** Being short of breath, feeling very tired, pale skin, or fast heartbeat – these may be signs of a low red blood cell count.
- **Neutropenia:** Infection, developing chills or shivering, or fever – these may be signs of a low white blood cell count.
- **Thrombocytopenia:** Bruising or bleeding for longer than usual if you hurt yourself – these may be signs of a low blood platelet count.

You will have regular blood tests during treatment with Talzenna to check your blood cells (white blood cells, red blood cells, and platelets).

Serious problems with the bone marrow

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.

Blood clots

Talzenna may cause blood clots in the veins. Tell your doctor, pharmacist or nurse if you experience signs or symptoms of blood clots in the veins such as pain or stiffness, swelling and redness in the affected leg (or arm), chest pain, shortness of breath or lightheadedness.

Male and female contraception

Women who can become pregnant and men with partners who are or can become pregnant should use effective contraception.

Please see section “Male and female contraception” below.

Children and adolescents

Talzenna is not to be used in children or adolescents (under 18 years of age).

Other medicines and Talzenna

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Talzenna can affect the way some other medicines work. Also some medicines can affect the way Talzenna works.

In particular, the following may increase the risk of side effects with Talzenna:

- Amiodarone, carvedilol, dronedarone, propafenone, quinidine, ranolazine and verapamil – generally used to treat heart problems.
- Clarithromycin and erythromycin antibiotics – used to treat bacterial infections.
- Itraconazole and ketoconazole – used to treat fungal infections.
- Cobicistat, darunavir, indinavir, lopinavir, ritonavir, saquinavir, telaprevir and tipranavir used to treat HIV infections/AIDS.
- Ciclosporin – used in organ transplantation to prevent rejection.
- Lapatinib – used to treat patients with certain types of breast cancer.
- Curcumin (e.g. found in turmeric root) in some medicines (see also section Talzenna with food and drink below).

The following medicines may reduce the effect of Talzenna:

- Carbamazepine and phenytoin – anti-epileptics used to treat seizures or fits.

- St. John's wort (*Hypericum perforatum*) – a herbal remedy used to treat mild depression and anxiety.

Talzenna with food and drink

Do not use curcumin in food supplements while you are taking Talzenna as it may increase Talzenna's side effects. Curcumin is found in turmeric root and you should not use large amounts of turmeric root, but using spices in food is not likely to cause a problem.

Pregnancy

Talzenna could harm an unborn baby. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will perform a pregnancy test prior to starting Talzenna.

- You should not use Talzenna if you are pregnant unless considered necessary by your doctor.
- You should not become pregnant while taking Talzenna.
- Discuss contraception with your doctor if there is any possibility that you or your partner may become pregnant.

Male and female contraception

Women who are able to become pregnant should use effective birth control (contraception) during treatment with Talzenna and for at least 7 months after the last dose of Talzenna. Since the use of hormonal contraception is not recommended if you have breast cancer, you should use two non-hormonal contraception methods.

Talk to your healthcare provider about birth control methods that may be right for you.

Men with female partners who are pregnant or able to become pregnant should use effective birth control (contraception), even after a vasectomy, during treatment with Talzenna and for at least 4 months after the last dose.

Breast-feeding

You must not breast-feed while taking Talzenna and for at least 1 month after the last dose. It is not known if Talzenna passes into breast milk.

Fertility

Talazoparib may reduce fertility in men.

Driving and using machines

Talzenna may have a minor influence on the ability to drive and use machines. If you feel dizzy, weak, or tired (these are very common side effects of Talzenna), you should not drive or use machines.

3. How to take Talzenna

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

Talzenna is taken by mouth once daily. The recommended dose is:

- for breast cancer: one 1 mg capsule of Talzenna.
- for prostate cancer: Talzenna is taken with a medicine called enzalutamide. The usual dose of Talzenna is 0.5 mg.

If you get certain side effects while you are taking Talzenna alone or in combination with enzalutamide (see section 4), your doctor may lower your dose or stop treatment, either temporarily or permanently. Take Talzenna and enzalutamide exactly as your doctor has told you.

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.

If you take more Talzenna than you should

If you have taken more Talzenna than your normal dose, contact your doctor or nearest hospital right away. Urgent treatment may be necessary.

Take the carton and this leaflet so that the doctor knows what you have been taking.

If you forget to take Talzenna

If you miss a dose or vomit, take your next dose as scheduled. Do not take a double dose to make up for the forgotten or vomited capsules.

If you stop taking Talzenna

Do not stop taking Talzenna unless your doctor tells you to.

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

4. Possible side effects

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

Tell your doctor straight away if you notice any of the following symptoms which could be a sign of serious blood disorder:

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

- 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).
- Infection, developing chills or shivering, or fever or feeling hot – these may be signs of a low white blood cell count (neutropenia).
- Bruising or bleeding for longer than usual if you hurt yourself – these may be signs of a low blood platelet count (thrombocytopenia).

Talk to your doctor if you get any other side effects. These can include:

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

- Low counts of white blood cells, red blood cells, and blood platelets
- Decreased appetite
- Feeling dizzy
- Headache
- Feeling sick (nausea)
- Being sick (vomiting)
- Diarrhoea
- Pain in the abdomen
- Hair loss

Common (may affect up to 1 in 10 people)

- Alteration in taste (dysgeusia)
- Painful swollen leg, chest pain, shortness of breath, rapid breathing or rapid heart rate as these can be signs of blood clots in the vein
- Indigestion
- Mouth inflammation

Uncommon (may affect up to 1 in 100 people)

- Abnormal blood cell counts due to serious problems with bone marrow (myelodysplastic syndrome or acute myeloid leukaemia). See Warnings and precautions in Section 2

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Talzenna

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 the bottle or blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if the pack is damaged or shows signs of tampering.

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. Contents of the pack and other information

What Talzenna contains

The active substance is talazoparib. Talzenna hard capsules come in different strengths.

- Talzenna 0.1 mg hard capsules: each capsule contains talazoparib tosylate equivalent to 0.1 mg talazoparib.
- Talzenna 0.25 mg hard capsules: each capsule contains talazoparib tosylate equivalent to 0.25 mg talazoparib.
- Talzenna 0.35 mg hard capsules: each capsule contains talazoparib tosylate equivalent to 0.35 mg talazoparib.
- Talzenna 0.5 mg hard capsules: each capsule contains talazoparib tosylate equivalent to 0.5 mg talazoparib.
- Talzenna 1 mg hard capsules: each capsule contains talazoparib tosylate equivalent to 1 mg talazoparib.

The other ingredients are:

- Capsule content: silicified microcrystalline cellulose (microcrystalline cellulose and silicone dioxide).
- 0.1 mg capsule shell: hypromellose and titanium dioxide (E171).
- 0.25 mg capsule shell: hypromellose, yellow iron oxide (E172) and titanium dioxide (E171).
- 0.35 mg capsule shell: hypromellose, yellow iron oxide (E172) and titanium dioxide (E171).
- 0.5 mg capsule shell: hypromellose, red iron oxide (E172) and titanium dioxide (E171).
- 1 mg capsule shell: hypromellose, yellow iron oxide (E172), titanium dioxide (E171) and red iron oxide (E172).
- Printing ink: shellac (E904), propylene glycol (E1520), ammonium hydroxide (E527), black iron oxide (E172) and potassium hydroxide (E525).

What Talzenna looks like and contents of the pack

Talzenna 0.1 mg is supplied as opaque, approximately 14 mm x 5 mm hard capsule with a white cap (printed with "Pfizer" in black) and a white body (printed with "TLZ 0.1" in black).

Talzenna 0.25 mg is supplied as opaque, approximately 14 mm x 5 mm hard capsule with an ivory cap (printed with "Pfizer" in black) and a white body (printed with "TLZ 0.25" in black).

Talzenna 0.35 mg is supplied as opaque, approximately 14 mm × 5 mm hard capsule with an ivory cap (printed with “Pfizer” in black) and ivory body (printed with “TLZ 0.35” in black).

Talzenna 0.5 mg is supplied as opaque, approximately 14 mm × 5 mm hard capsule with a light pink cap (printed with “Pfizer” in black) and white body (printed with “TLZ 0.5” in black).

Talzenna 1 mg is supplied as opaque, approximately 14 mm x 5 mm hard capsule with a light red cap (printed with “Pfizer” in black) and a white body (printed with “TLZ 1” in black).

Talzenna 0.1 mg is available in plastic bottles of 30 hard capsules.

Talzenna 0.25 mg is available in perforated unit dose blister packs of 30 × 1, or 60 × 1, or 90 × 1 hard capsules and in plastic bottles of 30 hard capsules.

Talzenna 0.35 mg is available in plastic bottles of 30 hard capsules.

Talzenna 0.5 mg is available in plastic bottles of 30 hard capsules.

Talzenna 1 mg is available in perforated unit dose blister packs of 30 x 1 hard capsules and in plastic bottles of 30 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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