

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking TALZENNA?

TALZENNA contains the active ingredient talazoparib. TALZENNA is used to treat patients with certain types of breast cancer. The breast cancer type is HER2-negative and has an abnormal inherited BRCA gene. TALZENNA is also used to treat patients with a type of prostate cancer with certain abnormal inherited or acquired genes called homologous recombination repair (HRR genes) that no longer responds to hormone therapy or surgery to lower testosterone levels. TALZENNA is used when the cancer has spread to other parts of the body. For more information, see Section [1. Why am I taking TALZENNA?](#) in the full CMI.

2. What should I know before I take TALZENNA?

Do not take TALZENNA if you have ever had an allergic reaction to talazoparib or any of the ingredients listed at the end of the CMI.

Tell your doctor if you have ever had a low number of red blood cells (anaemia), white blood cells or platelets, liver problems, kidney problems, or have ever had chemotherapy or radiation therapy to treat cancer.

Also tell your doctor if you are pregnant, plan to become pregnant or plan to father a child, are breastfeeding, or taking any other medicines. For more information, see Section [2. What should I know before I take TALZENNA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TALZENNA and affect how well it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TALZENNA?

The usual dose of TALZENNA for breast cancer is 1 mg taken once a day. The usual dose of TALZENNA for prostate cancer is 0.5 mg taken once a day. Swallow the capsules whole with a glass of water. Your doctor may change your dose during treatment. More instructions can be found in Section [4. How do I take TALZENNA?](#) in the full CMI.

5. What should I know while taking TALZENNA?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">Follow your doctor's instructions. Keep all of your appointments, including any blood tests.Tell your doctor immediately if you or your partner become pregnant.Use effective birth control while taking TALZENNA and for at least 7 months after taking the last dose.Tell any doctor, dentist or pharmacist you visit that you are taking TALZENNA. |
| Things you should not do | <ul style="list-style-type: none">Do not stop taking TALZENNA or change the dose without checking with your doctor. |
| Driving or using machines | <ul style="list-style-type: none">TALZENNA may cause dizziness and tiredness. Be careful driving or using any machines or tools until you know how TALZENNA affects you. |
| Looking after your medicine | <ul style="list-style-type: none">Store TALZENNA capsules below 30°C.Keep the capsules in the pack until it is time to take a capsule. |

For more information, see Section [5. What should I know while taking TALZENNA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include tiredness, nausea (feeling sick), vomiting, headache, diarrhoea, hair loss, loss of appetite, stomach pain, feeling dizzy, dizziness, change in sense of taste, soreness or redness of mouth, lips or tongue, mouth ulcers, cold sores. Serious side effects include lack of energy, feeling very tired, pale skin, shortness of breath, fast heartbeat, infection, fever, chills, bleeding or bruising more easily than usual.

Some side effects might only be detected by blood tests or other tests.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TALZENNA[®]

Active ingredient: *talazoparib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TALZENNA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TALZENNA.**

Where to find information in this leaflet:

1. [Why am I taking TALZENNA?](#)
2. [What should I know before I take TALZENNA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take TALZENNA?](#)
5. [What should I know while taking TALZENNA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking TALZENNA?

TALZENNA contains the active ingredient talazoparib.

TALZENNA is used to treat patients with a certain type of breast cancer. The breast cancer type is HER2-negative and has an abnormal inherited BRCA gene. HER2 is short for Human Epidermal growth factor Receptor 2. BRCA is short for BReast CAncer gene.

You would have had a test that shows you have inherited an abnormal BRCA gene.

TALZENNA is also used in combination with a medicine called enzalutamide or XTANDI to treat patients with a type of prostate cancer with certain abnormal inherited or acquired genes called homologous recombination repair (HRR genes) that no longer responds to hormone therapy or surgery to lower testosterone levels.

TALZENNA is used when the cancer has spread to other parts of the body.

TALZENNA may slow or stop the growth of these types of breast cancer and prostate cancer.

Ask your doctor if you have any questions about why TALZENNA has been prescribed for you. Your doctor may have prescribed it for another reason.

2. What should I know before I take TALZENNA?

Do not take TALZENNA if:

- you are allergic to talazoparib or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - o anaemia or low red blood cell count
 - o low white blood cell count
 - o low platelet count
 - o kidney problems
 - o liver problems.
- have ever had any of the following cancer treatments:
 - o chemotherapy
 - o radiotherapy
- are taking any other medicines.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, plan to become pregnant or plan to father a child.

Do not take TALZENNA if you are pregnant or attempting to become pregnant.

Women who could become pregnant or men who could father a child must use a reliable method of contraception (birth control) during treatment with TALZENNA and for at least 7 months after taking the last dose.

Tell your doctor immediately if you or your partner become pregnant while taking TALZENNA. TALZENNA may affect the developing baby.

Tell your doctor if you are breastfeeding.

Do not breastfeed if you are taking TALZENNA.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TALZENNA and affect how it works.

You may need different amounts of your medicines or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- amiodarone, carvedilol, dronedarone, propafenone, quinidine, ranolazine or verapamil, medicines to treat irregular heartbeat, high blood pressure or other heart problems
- itraconazole, ketoconazole or voriconazole, medicines to treat fungal infections
- cobicistat, darunavir, indinavir, lopinavir, ritonavir, saquinavir or tipranavir, medicines to treat HIV infection/AIDS
- telaprevir, a medicine to treat hepatitis C
- clarithromycin or erythromycin, medicines to treat bacterial infections
- lapatinib, a medicine to treat some types of breast cancer
- ciclosporin, a medicine used to prevent rejection in organ transplants
- curcumin, a substance in turmeric used as a spice.

Some other medicines not on this list might also interfere with TALZENNA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TALZENNA.

4. How do I take TALZENNA?

How much to take

Your doctor will tell you how many TALZENNA capsules you need to take each day. This may depend on your medical condition and whether you are taking any other medicines.

TALZENNA capsules come in five different strengths: 0.1 mg, 0.25 mg, 0.35 mg, 0.5 mg and 1 mg.

- The usual dose of TALZENNA for breast cancer is 1 mg taken once a day.
- The usual dose of TALZENNA for prostate cancer is 0.5 mg taken once a day.

TALZENNA for prostate cancer is taken with a medicine called enzalutamide. The usual dose of enzalutamide is 160 mg (four 40 mg capsules) once daily.

- The number of TALZENNA capsules to be taken each day depends on which strength capsule your doctor has prescribed for you.
- Your doctor may change your dose during treatment.

This may depend on results of blood tests and other tests.

When to take TALZENNA

- Take TALZENNA capsules at about the same time each day.

Taking the capsules at the same time each day will help you to remember when to take them.

- It does not matter if you take TALZENNA before food, after food or with food.

- If you vomit after taking TALZENNA, do not take an extra dose, just take your next dose at the usual time.

How to take TALZENNA

- Swallow the capsule whole with a glass of water.
- You can take TALZENNA with or without food.
- Do not open, crush or chew the capsules.

How long to take TALZENNA

- Continue taking TALZENNA for as long as your doctor tells you.

If you forget to take TALZENNA

If you miss a dose, skip the dose you missed and take your next dose at the usual time.

Do not take a double dose to make up for a dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much TALZENNA

If you think you have taken too much TALZENNA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking TALZENNA?

Things you should do

- keep all your appointments so your progress can be checked.
 - keep your appointments for blood tests and other tests
- These tests might check for side effects or see if TALZENNA is working.
- if you are about to be started on a new medicine, tell your doctor and pharmacist you are taking TALZENNA.
 - tell any doctor, dentist or pharmacist you visit that you are taking TALZENNA.
 - use effective birth control while taking TALZENNA and for at least 7 months after taking the last dose.
 - tell your doctor immediately if you or your partner become pregnant while taking TALZENNA

Call your doctor straight away or go to the Emergency Department at your nearest hospital if:

- you have any serious side effects, see Section [6. Are there any side effects?](#)

Things you should not do

- do not stop taking TALZENNA or change the dose, without checking with your doctor.
- do not give TALZENNA to anyone else, even if their condition seems similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TALZENNA affects you.

TALZENNA may cause dizziness, tiredness and weakness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store TALZENNA capsules in a cool dry place where the temperature stays below 30°C.
- Keep the capsules in the pack until it is time to take them.

Do not store TALZENNA:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take TALZENNA or it is out of date, take it to any pharmacy for safe disposal.

Do not take TALZENNA after the expiry date on the pack.

6. Are there any side effects?

All medicines can have side effects. Most are minor. However, some side effects may need medical attention.

Read the information below and ask your doctor or pharmacist if you have any questions about side effects.

Do not be alarmed by this list of side effects. You might not experience them.

Common side effects

| Common side effects | What to do |
|--|---|
| Gastrointestinal disorders: <ul style="list-style-type: none">nausea (feeling sick), vomitingdiarrhoeastomach painheart burn or indigestionstomach painsore or red mouth, lips or tongue; mouth ulcers, cold sores | Speak to your doctor if you have any of these side effects and they worry you. |
| General disorders: <ul style="list-style-type: none">tiredness | |
| Nervous system: <ul style="list-style-type: none">dizziness | |

| Common side effects | What to do |
|---|------------|
| <ul style="list-style-type: none">headachechange in sense of taste Metabolism or nutrition disorder: <ul style="list-style-type: none">loss of appetite Skin related: <ul style="list-style-type: none">loss of hair | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| Blood disorders: <ul style="list-style-type: none">lack of energy, feeling very tired, shortness of breath, fast heartbeat These could be signs of a low number of red blood cells.infection, fever or chills These could be signs of a low number of white blood cells.bleeding or bruising more often than normal This could be a sign of a low number of platelets. | Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects can only be found when your doctor does blood tests or other tests. These tests could show a change in the liver, kidney, levels of blood cells, changes in heart rhythm or other changes.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

It is not addictive.

What TALZENNA Capsules contain

| | |
|--|---|
| Active ingredient (main ingredient) | Talazoparib tosilate |
| Other ingredients | silicified microcrystalline cellulose (all strengths) |

| | |
|-------------------------------|---|
| (inactive ingredients) | hypromellose (all strengths) titanium dioxide (E171) (all strengths) yellow iron oxide (E172) (0.25 mg, 0.35 and 1 mg strengths) red iron oxide (E172) (0.5 mg and 1 mg strengths) |
|-------------------------------|---|

Do not take TALZENNA if you are allergic to any of these ingredients.

The capsule shells are printed with black ink.

TALZENNA capsules do not contain lactose, sucrose, gluten or gelatin.

What TALZENNA looks like

TALZENNA 0.1 mg capsules have a white cap and a white body. These capsules have "Pfizer" printed on the cap and "TLZ 0.1" printed on the body in black ink. They are available in bottles containing 30 capsules (AUST R 407812).

TALZENNA 0.25 mg capsules have an ivory coloured cap and a white body. These capsules have "Pfizer" printed on the cap and "TLZ 0.25" printed on the body in black ink. They are available in blister packs containing 30, 60 or 90 capsules (AUST R 310750) or bottles containing 30 capsules (AUST R 310751).

TALZENNA 0.35 mg capsules have an ivory coloured cap and an ivory coloured body. These capsules have "Pfizer" printed on the cap and "TLZ 0.35" printed on the body in black ink. They are available in bottles containing 30 capsules (AUST R 407813).

TALZENNA 0.5 mg capsules have a light pink coloured cap and a white body. These capsules have "Pfizer" printed on the cap and "TLZ 0.5" printed on the body in black ink. They are available in bottles containing 30 capsules (AUST R 407814).

TALZENNA 1 mg capsules have a light red coloured cap and a white body. These capsules have "Pfizer" printed on the cap and "TLZ 1" printed on the body in black ink. They are available in blister packs containing 30 capsules (AUST R 310752) or bottles containing 30 capsules (AUST R 310749).

Who distributes TALZENNA

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedinfo.com.au

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