

PRYZEX and PRYZEX ODT tablets

Olanzapine film coated and orally disintegrating tablets

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What PRYZEX is used for

PRYZEX is used to treat symptoms of schizophrenia and related psychoses. PRYZEX alone, or in combination with lithium or valproate, is used for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

PRYZEX is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with Bipolar I Disorder.

Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour. Bipolar I

Disorder is a mental illness with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

PRYZEX belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain, which may cause mental illness. Your doctor may have prescribed PRYZEX for another reason.

Ask your doctor if you have any questions about why PRYZEX has been prescribed for you.

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

Before taking PRYZEX

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

Do not take PRYZEX:

- **if you have had an allergic reaction to Olanzapine or to any of the ingredients listed at the end of this leaflet (see 'Product Description').** Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- if the packaging is torn or shows signs of tampering or the tablets do not look quite right.
- if the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed it may not work as well. If you are not sure whether you should start taking PRYZEX, talk to your doctor or pharmacist

Before you start to take it

You must tell your doctor:

- **if you have had an allergic reaction to any medicine which you have taken previously to treat your current condition**
- **if you have, or have had, any medical conditions, especially the following:**
 - tumour of the pituitary gland (a small gland at the base of the brain)
 - disease of the blood with a reduced number of white or red blood cells
 - disease of the blood vessels of the brain, including stroke
 - prostate problems
 - kidney or liver disease
 - high blood sugar, diabetes or a family history of diabetes
 - breast cancer or a family history of breast cancer
 - paralytic ileus, a condition where the bowel does not work properly
 - epilepsy, seizures or fits
 - glaucoma, a condition in which there is usually a build up of fluid in the eye
 - heart disease, including irregular heart rhythm
 - neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions

- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs.
- **If you are pregnant or intend to become pregnant**
Like most antipsychotic medicines, PRYZEX is not recommended for use during pregnancy. If there is a need to consider PRYZEX during your pregnancy, your doctor will discuss with you the benefits and risks of using it. Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother uses the medicine in the last trimester of her pregnancy. PRYZEX should not be used in pregnancy only if the anticipated benefit outweighs the risk and the administered dose and duration of treatment should be as low and short as possible.
- **If you are pregnant or plan to breast feed**
It is recommended that you do not breast feed while taking PRYZEX.
- **If you suffer from lactose intolerance (because PRYZEX tablets contain lactose).**
PRYZEX is not recommended for use in children.

Taking other medicines

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

Some medicines may be affected by PRYZEX or may affect how it works. These include:

- medicines used to treat a fast or irregular heart beat (arrhythmia)
- medicines taken for anxiety or to help you sleep
- medicines taken for depression

- carbamazepine, a medicine used for mood stabilisation and to treat epilepsy
- other centrally acting medicines (eg tranquilisers)
- ciprofloxacin, a medicine used to treat bacterial infections
- medicines that lower blood pressure
- medicines used for Parkinsons disease
- medicines that can change the hearts electrical activity or make it more likely to change

Smoking may affect PRYZEX or may affect how it works. Your doctor or pharmacist has more information on medicines to be carefully with or avoid while taking PRYZEX.

Tell your doctor about these things before you take PRYZEX.

How to take PRYZEX

Follow all directions given to you by your doctor or pharmacist carefully.

These may differ from the information contained in this leaflet.

How much to take

PRYZEX film coated or orally dispersible tablets:

Your doctor will tell you how many PRYZEX tablets you should take.

The dose your doctor will prescribe for you will usually be in the range 5 mg to 20 mg per day.

Your doctor may increase or decrease your dose in order to find the appropriate dose for your condition.

A lower starting dose may be prescribed for elderly patients over the age of 65 years.

How to take it

PRYZEX:

These film coated tablets should be

swallowed whole with a glass of water.

PRYZEX ODT:

These orally disintegrating tablets will dissolve in your mouth, therefore do not require water.

You can also place these tablets in a full glass of water, orange juice, apple juice, milk or coffee and stir.

Drink it straight away. With some drinks, the mixture may change colour and possibly become cloudy.

The orally disintegrating tablets should not be placed in cola drinks.

When to take it

PRYZEX film coated or orally disintegrating tablets should be taken once a day as advised by your doctor.

Take your prescribed dose at the same time each day.

PRYZEX tablets can be taken with or without food.

How long to take it

Do not stop taking PRYZEX just because you feel better. It is important that you do NOT stop taking PRYZEX unless your doctor tells you.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember then go back to taking your medicine as you would normally.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26), or go to Accident and

Emergency at your nearest hospital, if you think that you or anyone else has taken too much PRYZEX.

Do this even if there are no signs of discomfort or poisoning.

If you have taken too much PRYZEX, the most common signs are fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sedation.

While you are taking PRYZEX

Things you must do

It is important that you remember to take PRYZEX daily and at the dose prescribed by your doctor.

Tell all doctors, dentists and pharmacists who are treating you that you are taking PRYZEX.

While you are taking PRYZEX, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while taking PRYZEX, tell your doctor.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor should monitor your weight while you are taking PRYZEX.

Patients with diabetes or who have a higher chance of developing diabetes should have their blood sugar checked often.

If you are over 65, your doctor may measure your blood pressure from time to time.

Things you must not do

Do not stop taking PRYZEX, or lower the dosage, even if you are feeling better, without checking with your doctor.

Do not give PRYZEX to anyone else, even if their symptoms seem

similar or they have the same condition as you.

Your doctor has prescribed PRYZEX for you and your condition.

Things to be careful of

PRYZEX may cause drowsiness in some people. **Be careful driving or operating machinery until you know how PRYZEX affects you.**

Be careful drinking alcohol while taking PRYZEX.

The effects of alcohol could be made worse while taking PRYZEX. Your doctor may suggest you avoid alcohol while you are being treated with PRYZEX.

If PRYZEX makes you feel lightheaded, dizzy or faint, be careful getting up from a sitting or lying position.

Getting up slowly may help.

If outdoors, wear protective clothing and use at least a 15+ sunscreen.

PRYZEX may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn. If your skin does appear to be burning, tell your doctor.

Make sure you keep cool in hot weather and keep warm in cool weather.

PRYZEX may affect the way your body reacts to temperature changes.

Side Effects

Tell your doctor or pharmacist as soon as possible if you experience any undesirable effect or feel unwell while you are taking PRYZEX.

Like other medicines, PRYZEX may cause some unwanted side effects. These are likely to vary from patient to patient. Some side effects may be related to the dose of PRYZEX. Accordingly, it is important that you tell your doctor

as soon as possible about any unwanted effects. Your doctor may then decide to adjust the dose of PRYZEX you are taking.

Tell your doctor if you notice any of the following side effects and they worry you:

- drowsiness
- restlessness or difficulty sitting still
- weight gain
- dizziness
- increased appetite
- constipation
- dry mouth
- swelling of your hands, feet and ankles
- unusual tiredness or weakness.

Some people may feel dizzy in the early stages of treatment, especially when getting up from a lying or sitting position. This side effect usually passes after taking PRYZEX for a few days.

Elderly patients with dementia-related psychosis may notice the following side effects:

- unusual manner of walking
- falls
- pneumonia
- involuntary passing of urine

Some patients with Parkinson's disease may hallucinate (see, feel or hear things that are not there) or develop worsening symptoms of Parkinson's disease.

Patients with bipolar mania taking PRYZEX in combination with lithium or valproate may notice the following additional side effects:

- tremors
- speech disorder

Tell your doctor if you notice any of the above side effects and they worry you.

These are the more common side effects of PRYZEX.

Tell your doctor if you notice any of the following side effects:

- symptoms of sunburn (such as redness, itching, swelling or

istering of the skin) which occur more quickly than normal

- rash
- allergic reaction
- slow heart beat
- prolonged and/or painful erection
- unusual secretion of breast milk
- breast enlargement
- symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst, having a dry mouth and skin and weakness). These may indicate the onset or worsening of diabetes reaction following abrupt discontinuation (profuse sweating, nausea or vomiting)
- absence of menstrual periods and changes in the regularity of menstrual periods
- involuntary passing of urine or difficulty in initiating urination
- unusual hair loss or thinning

Tell your doctor if your monthly periods are absent for six months or more.

These side effects are uncommon but may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- seizures, fits or convulsions
- yellowing of the skin and/or eyes
- nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes
- inflammation of the pancreas
- severe upper stomach pain often with nausea and vomiting
- worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which

may progress to the arms and legs

- sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions
- sharp chest pain, coughing of blood, or sudden shortness of breath
- pain/tenderness in the calf muscle area
- muscle pain, muscle weakness and brown urine
- heart palpitations and dizziness, which may lead to collapse.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Also, some side effects, such as changes to liver function, cholesterol or triglycerides can occur. These can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of side effects.

You may not experience any of them.

Other side effects not listed above may also occur in some patients.

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

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

After taking PRYZEX

Storage

Keep your tablets in the blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 30°C.

All medicines should be kept where young children cannot reach them.

A locked cupboard one and a half metres above the ground is a good place to store medicines.

Do not take PRYZEX after the expiry date on the pack has passed.

Disposal

If your doctor tells you to stop taking PRYZEX or you find that the tablets have passed their expiry date, please return any leftover tablets or wafers to your pharmacist.

Product description

PRYZEX

PRYZEX film coated tablets are presented in PA/Al/PVC/Al blister packs.

2.5 mg (AUST R 178975): white, round, biconvex film coated tablets

5 mg (AUST R 178991): white, round, biconvex film coated tablets

7.5mg (AUST R 178987): white, round, biconvex film coated tablets

10mg (AUST R 178996): white, round, biconvex film coated tablets

15mg* (AUST R 178979): light blue, oblong, biconvex film coated tablets

20mg* (AUST R 178995): pink, oblong, biconvex film coated tablets

PRYZEX ODT

PRYZEX Orally Disintegrating Tablets are presented in PA/Al/PVC/Al blister packs.

5 mg (AUST R 179079): yellow, round, biconvex orally disintegrating tablets

10 mg (AUST R 179076): yellow, round, flat orally disintegrating tablets

15 mg* (AUST R 179082):yellow, round, biconvex orally disintegrating tablets

20 mg* (AUST R 179071):yellow, round, flat orally disintegrating tablets

* Presentations currently not available

Name and Address of the Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Date of Preparation

February 2018

Ingredients

Active Ingredient:

PRYZEX and PRYZEX ODT tablets contain the active ingredient, Olanzapine:

- 2.5mg – 2.5mg Olanzapine per tablet
- 5mg – 5mg Olanzapine per tablet
- 7.5mg – 7.5mg Olanzapine per tablet
- 10mg – 10mg Olanzapine per tablet
- 15mg – 15mg Olanzapine per tablet
- 20mg – 20mg Olanzapine per tablet

Inactive Ingredients

PRYZEX film coated tablets:

- Lactose monohydrate
- Microcrystalline cellulose
- Crospovidone
- Hyprolose
- Purified talc
- Magnesium stearate
- Opadry AMB complete film coating system OY-B-28920
- Opadry AMB aqueous moisture barrier coating system 80W26503 Grey (**15 mg only**)
- Opadry AMB aqueous moisture barrier coating system 80W24003 Pink (**20 mg only**)

PRYZEX ODT

- Lactose monohydrate
- Crospovidone
- Hyprolose
- Colloidal anhydrous silica
- Purified talc
- Magnesium stearate
- Mint flavouring E_0613218