

ZYPREXA RELPREVV®

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.

1. Why am I being given ZYPREXA RELPREVV?

ZYPREXA RELPREVV contains the active ingredient olanzapine (as pamoate monohydrate). It is used to help correct chemical imbalances in the brain, which may cause mental illness.

For more information, see Section [1. Why am I being given ZYPREXA RELPREVV?](#) in the full CMI.

2. What should I know before being given ZYPREXA RELPREVV?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before being given ZYPREXA RELPREVV?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZYPREXA RELPREVV and affect how it works.

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

4. How am I being given ZYPREXA RELPREVV?

ZYPREXA RELPREVV is given as an injection into a large muscle in the buttocks where it is slowly released over 2 to 4 weeks. This injection should only be given by a doctor or nurse.

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

More instructions can be found in Section [4. How am I being given ZYPREXA RELPREVV?](#) in the full CMI.

5. What should I know while having ZYPREXA RELPREVV?

Things you should do	• Remind any doctor, nurse or pharmacist you visit that you are using ZYPREXA RELPREVV. • Tell your doctor if you become pregnant while taking ZYPREXA RELPREVV. • Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not stop taking your medicine, or change the dosage, without first checking with your doctor.
Driving or using machines	• Do NOT drive or operate heavy machinery for the remainder of the day after your injection. • ZYPREXA RELPREVV may cause drowsiness in some people. If this happens, do not drive or operate any tools or machines.
Drinking alcohol	• Be careful when drinking alcohol while using ZYPREXA RELPREVV. The effects of alcohol could be made worse while taking ZYPREXA RELPREVV.
Looking after your medicine	• ZYPREXA RELPREVV vials should be stored below 30° C. • The vials will be stored by your doctor or pharmacist. • Keep this medicine where children cannot reach it.

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

6. Are there any side effects?

Like other medicines, ZYPREXA RELPREVV may cause some unwanted side effects. These are likely to vary from patient to patient, although not everybody gets them. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need urgent medical attention.

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.

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.

ZYPREXA RELPREVV®

Active ingredient(s): Olanzapine (as pamoate monohydrate).

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZYPREXA RELPREVV. **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 ZYPREXA RELPREVV.**

Where to find information in this leaflet:

- [1. Why am being given ZYPREXA RELPREVV?](#)
- [2. What should I know before being given ZYPREXA RELPREVV?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I being given ZYPREXA RELPREVV?](#)
- [5. What should I know while having ZYPREXA RELPREVV?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am being given ZYPREXA RELPREVV?

ZYPREXA RELPREVV contains the active ingredient **olanzapine**. Olanzapine belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

ZYPREXA RELPREVV is used to treat symptoms of schizophrenia.

Schizophrenia is a mental illness with disturbances in thinking, feelings and behavior.

ZYPREXA RELPREVV is given as an injection into a large muscle in the buttocks where it is slowly released over 2 to 4 weeks. This injection should only be given by a doctor or nurse.

Your doctor may have prescribed ZYPREXA RELPREVV for another reason.

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

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

ZYPREXA RELPREVV is not recommended for use in children under the age of 18 years as there is not enough information on its effects in this age group.

2. What should I know before given ZYPREXA RELPREVV?

Warnings

Do not use ZYPREXA RELPREVV if:

- you have an allergic reaction to ZYPREXA, ZYPREXA RELPREVV or to any of the ingredients listed at the end of this leaflet.

Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

- the packaging is torn or shows signs of tampering, or the injection vials do not look quite right.
- the expiry date on the pack has passed. If you have this medicine after the expiry date has passed it may not work as well.

If you are not sure whether you should have ZYPREXA RELPREVV, talk to your doctor, pharmacist or nurse.

Check with your doctor if you:

- have had an allergic reaction to any medicine which you have taken previously to treat your current condition.**
- have any other medical conditions, especially the following:**
 - tumor of the pituitary gland (a small gland at the base of the brain)
 - disease of the blood or bone marrow 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
 - lipid alterations such as high blood fat values (cholesterol and triglycerides)
 - breast cancer or a family history of breast cancer
 - paralytic ileus, a condition where the small bowel does not work properly
 - epilepsy (seizures or fits)
 - glaucoma, a condition in which there is usually a buildup 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
- DRESS, a severe drug reaction to olanzapine, with a combination of three or more of the following: rash, eosinophilia (higher number of a group of white blood cells), fever, swollen lymph nodes or inflammation of liver, kidney, lung, or heart
- tardive dyskinesia, a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs
- Akathisia, a subjective feeling of restlessness and difficulty sitting still/sleep apnea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep

Tell your doctor if

- you will be in a hot environment or do a lot of vigorous exercise. ZYPREXA RELPREVV may make you sweat less, causing your body to overheat.
- you smoke. Smoking may affect ZYPREXA RELPREVV or may affect how it works.
- you are elderly with dementia-related psychosis.
- you have previously had a stroke or transient ischaemic attack (mini-stroke) or if you have high blood pressure

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

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

Like most antipsychotic medicines, ZYPREXA RELPREVV is not recommended for use during pregnancy.

Newborn babies of mothers taking antipsychotic drugs (including ZYPREXA RELPREVV) during the last trimester of pregnancy are at risk of experiencing extrapyramidal neurological disturbances and/or withdrawal symptoms following delivery. These may include, but are not limited to agitation, tremor, muscle stiffness or weakness, drowsiness, feeding problems, and breathing difficulty. If there is a need to consider ZYPREXA RELPREVV during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Tell your doctor if you are breastfeeding or intend to breastfeed.

It is recommended that you do not breast-feed while taking ZYPREXA RELPREVV.

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 ZYPREXA RELPREVV and affect how it works. These include:

- medicines used to treat a fast or irregular heartbeat (arrhythmia)
- medicines taken for anxiety or to help you sleep
- medicines taken for depression
- carbamazepine, a medicine used for mood stabilization and to treat epilepsy
- other centrally acting medicines (eg. Tranquilizers or strong painkillers)
- ciprofloxacin, a medicine used to treat bacterial infections
- medicines that lower blood pressure
- medicines used for Parkinson's disease

- medicines that can change the heart's electrical activity or make it more likely to change.
- activated charcoal

Your doctor, pharmacist or nurse has more information on medicines to be careful with or avoid while taking ZYPREXA RELPREVV.

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

4. How am I given ZYPREXA RELPREVV?

How often it is given

Your doctor or nurse will decide what dose you will receive and how often you will need to be given an injection.

It is recommended that ZYPREXA RELPREVV is given every 2 to 4 weeks, depending on how your body responds to the medicine.

ZYPREXA RELPREVV helps control your condition but will not cure it. Therefore, you need regular injections. Do not miss any injections, even if you feel better.

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

How it is given

ZYPREXA RELPREVV comes as a powder. Your doctor or nurse will make it up into a liquid suspension. The information your doctor or nurse needs to prepare the ZYPREXA RELPREVV suspension is included in the package.

After it has been made up, ZYPREXA RELPREVV is given as a deep injection into a large muscle in your buttock. ZYPREXA RELPREVV should never be injected directly into the blood (intravenously or under the skin (subcutaneously)).

Do not massage or rub the area where the injection was given.

What happens after an injection

An uncommon but serious reaction might occur after you receive an injection of ZYPREXA RELPREVV.

ZYPREXA RELPREVV can sometimes enter the bloodstream too quickly. If this happens, you may have the symptoms listed below after your injection. In some cases, these symptoms can lead to unconsciousness.

- excessive sleepiness
- confusion
- irritability
- dizziness, disorientation
- anxiety
- aggression
- difficulty talking or walking
- weakness
- muscle stiffness or shaking
- increases in blood pressure
- convulsions

The symptoms typically resolve within 24 to 72 hours after your injection. Because of this risk, do not drive or operate

machinery for the remainder of the day after each injection.

If these symptoms are going to occur, they will usually first appear within 2 hours after your injection. After each injection you will be observed in your healthcare facility for at least 2 hours for the symptoms listed above. If you have any of the symptoms listed above your doctor or nurse may need to observe you for longer than 2 hours. Your doctor or nurse will check you to confirm that you do not have any of these symptoms before you leave the healthcare facility.

Contact your doctor or nurse immediately if you get these symptoms more than 2 hours after your injection.

You will be given details of how to contact your doctor or nurse if you have any of these symptoms, as you will need their assistance until they have resolved.

If you are given too much ZYPREXA RELPREVV

As ZYPREXA RELPREVV is given under medical supervision, it is very unlikely that you will receive too much. However, if you experience any side effects after being given ZYPREXA RELPREVV, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

The most common signs of too much ZYPREXA RELPREVV are fast heartbeat, agitation/aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

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 having ZYPREXA RELPREVV?

Things you should do

It is important that you remember to attend appointments to receive your ZYPREXA RELPREVV injections.

Tell all doctors, dentists, pharmacists and nurses who are treating you that you are having ZYPREXA RELPREVV.

If you are about to start on any new medicine, remind your doctor, nurse or pharmacist that you are having ZYPREXA RELPREVV.

Tell your doctor if you become pregnant while having ZYPREXA RELPREVV.

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

- Your doctor should monitor your weight while you are taking ZYPREXA RELPREVV.

- Patients with diabetes or who have a higher chance of developing diabetes should have their blood sugar checked often.
- Your doctor may request you have a blood test from time to time to monitor your cholesterol levels.
- If you are over 65, your doctor may measure your blood pressure from time to time.

Tell your doctor or nurse if you are female and your monthly periods are absent for six months or more.

All thoughts of suicide or violence must be taken seriously. Talk to your doctor or mental health professional if you have thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others.

These may be signs of changes or worsening in your mental illness.

Things you should not do

Do not stop taking ZYPREXA RELPREVV even if you are feeling better, without checking with your doctor.

It is important that you carry on receiving ZYPREXA RELPREVV for as long as your doctor has told you to.

Things you should be careful of

If ZYPREXA RELPREVV makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Getting up slowly may help.

ZYPREXA RELPREVV may cause drowsiness in some people.. Tell your doctor or nurse.

If outdoors, wear protective clothing and use at least a 30+ sunscreen.

ZYPREXA RELPREVV 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 or nurse.

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

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

Antipsychotics have the potential to cause cardiac complications and sudden cardiac death.

Driving or using machines

Do NOT drive or operate heavy machinery for the remainder of the day after your injection.

ZYPREXA RELPREVV may cause drowsiness in some people. If this happens, do not drive or operate any tools or machines. Tell your doctor or nurse.

Drinking alcohol

Be careful when drinking alcohol while using ZYPREXA RELPREVV.

The effects of alcohol could be made worse while taking ZYPREXA RELPREVV.

Your doctor may suggest you avoid alcohol while you are being treated with ZYPREXA RELPREVV.

Looking after your medicine

ZYPREXA RELPREVV will be stored by your doctor or pharmacist. The injection is kept in a cool dry place, protected from light, where the temperature stays below 30°C.

Keep it where young children cannot reach it.

There will be an expiry date (month, year) on your ZYPREXA RELPREVV package and on each glass vial.

The medicine should not be taken after this date because it may have lost some of its strength.

Getting rid of any unwanted medicine

ZYPREXA RELPREVV is normally administered by your doctor or nurse.

If however you have some ZYPREXA RELPREVV injection that has passed its expiry date, please return any leftover portion to your pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Like other medicines, ZYPREXA RELPREVV 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 ZYPREXA RELPREVV. 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 ZYPREXA RELPREVV you are taking.

A serious side effect can occur if ZYPREXA RELPREVV enters the blood stream too quickly. There is more information about this in the section named "What happens after an injection".

A common side effect seen with ZYPREXA RELPREVV was sleepiness/drowsiness.

A rare side effect seen with ZYPREXA RELPREVV is an abscess (infection) at the place the injection was given.

The information below concerns side effects seen with other forms of ZYPREXA. They may also occur in people who use ZYPREXA RELPREVV.

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 ZYPREXA for a few days.

Less serious side effects

Less serious side effects	What to do
• drowsiness • unusual tiredness or weakness • fever • restlessness or difficulty sitting still • increased appetite, weight gain • dizziness, confusion, forgetfulness • constipation, bloating • dry mouth • swelling of your hands, feet and ankles • aching joints • nose bleeds • low blood pressure • slow heartbeat • fast heartbeat • speech disorder • sleepwalking • sleep eating	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occur more quickly than normal • rash or allergic reaction • slow heartbeat • changes in sexual functioning or sex drive in men or women • prolonged and/or painful erection • unusual secretion of breast milk • breast enlargement in men or women • 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 • lipid alterations, such as high blood fat values (cholesterol and triglycerides) • 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 • excessive saliva in the mouth	Tell your doctor as soon as possible if you notice any of these serious side effects. You may need medical attention.

Very serious side effects

Very serious side effects	What to do
• Sudden signs of an allergic reaction such as a skin rash, itching, shortness of breath or swelling of the face, lips or tongue • Drowsiness, confusion or excessive sleepiness • frequent infections such as fever, severe chills, sore throat or mouth ulcers • bleeding or bruising more easily than normal • painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the lungs or legs • seizures, fits or convulsions • yellowing of the skin and/or eyes • nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching • severe upper stomach pain often with nausea and vomiting (inflammation of the pancreas) • 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 • sudden decrease in body temperature, intense trembling, lethargy, confusion, slow heartbeat and slow breathing • 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 attack • heart palpitations and dizziness, which may lead to collapse • fast breathing, shortness of breath, fever with chills, feeling tired or weak, chest pain while coughing, fast heartbeat. You may have pneumonia • fever or swollen glands, especially if they occur together with or shortly after a skin rash	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. You may need urgent medical attention or hospitalization.

The following additional side effects may occur in some groups of people taking ZYPREXA:

Elderly patients with dementia-related psychosis

- unusual manner of walking
- falls
- pneumonia
- involuntary passing of urine
- Stroke
- transient ischemic attack – symptoms maybe, but not limited to, paralysis in face, arm or leg

Parkinson's disease psychosis

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.

In combination with lithium or valproate

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

- tremors
- speech disorder
- dry mouth
- increased appetite
- weight gain

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.

Some side effects, such as changes to liver function, blood cell counts, 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. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

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

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.

What ZYPREXA RELPREVV contains

Active ingredient (main ingredient)	210 mg, 300 mg or 405 mg olanzapine (as pamoate monohydrate).
Other ingredients (diluent inactive ingredients)	carmellose sodium, mannitol, polysorbate 80 and water for injections.
Potential allergens	None

ZYPREXA RELPREVV comes as a yellow powder in a clear glass vial. A vial of diluent is provided to prepare the injection, which will be olanzapine 150mg/mL. A syringe with attached safety needle and three additional safety needles to prepare the injection are supplied in the kit containing ZYPREXA RELPREVV.

ZYPREXA RELPREVV 210 mg - AUST R 143658

ZYPREXA RELPREVV 300 mg - AUST R 143657

ZYPREXA RELPREVV 405 mg - AUST R 143636

Who distributes ZYPREXA RELPREVV

Pharmaco (Australia) Ltd
Level 9, Tower A
Zenith Towers
821 Pacific Highway
Chatswood, NSW 2067
Australia

Under license of CHEPLAPHARM Schweiz GmbH, Switzerland.

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