

ZYPREXA RELPREVV®

Olanzapine pamoate monohydrate

Consumer Medicine Information

WARNING:

ZYPREXA RELPREVV should be administered by appropriately qualified health professionals in a healthcare facility with access to emergency services for management of olanzapine overdose. Your healthcare professional who prescribes or administers ZYPREXA RELPREVV will need to monitor you for at least two hours after each injection for signs and symptoms of sedation and/or confusion (post injection syndrome). The two hour period should be extended if you show any potential signs or symptoms of post injection syndrome event.

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 with your doctor.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about ZYPREXA RELPREVV and its use that you should be aware of.

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 this medicine.

You may need to read it again.

What ZYPREXA RELPREVV is used for

ZYPREXA RELPREVV 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 behaviour.

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 or nurse 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.

Before you are given ZYPREXA RELPREVV

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

When you must not be given it

Do not have ZYPREXA RELPREVV:

- **if you have had an allergic reaction to ZYPREXA®, ZYPREXA RELPREVV 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**

injection vials do not look quite right.

- **if 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 start having ZYPREXA RELPREVV, talk to your doctor, pharmacist or nurse.

Before you are given it

Tell your doctor if you have had an allergic reaction to any medicine which you have taken previously to treat your current condition.

Tell your doctor 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 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
- 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 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.

- sleep apnoea, a sleep disorder where a person has pauses in breathing or periods of shallow breathing during sleep.

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 or nurse will discuss with you the benefits and risks of using it.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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

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.

Tell your doctor if you smoke.

Smoking may affect ZYPREXA RELPREVV or may affect how it works.

If you are elderly with dementia-related psychosis, tell your doctor if you have previously had a stroke or transient ischaemic attack (mini-stroke) or if you have high blood pressure.

Taking other medicines

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

Some medicines may be affected by ZYPREXA RELPREVV 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. Tranquillisers or strong painkillers)
- ciprofloxacin, a medicine used to treat bacterial infections
- medicines that lower blood pressure
- medicines used for Parkinson's disease
- medicines that change the heart's electrical activity or make it more likely to change.

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

Tell your doctor or nurse about these things before you are given ZYPREXA RELPREVV.

How ZYPREXA RELPREVV is given

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

These may differ from the information contained in this leaflet.

How much is given

Your doctor or nurse will decide what dose you will receive and how

often you will need to be given an injection.

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.

Do NOT drive a motor vehicle after the injection.

Tell your doctor or nurse if you feel dizzy or faint after the injection.

You will probably need to lie down until you feel better. The doctor or nurse may also want to measure your blood pressure and pulse.

How often is it given

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

How many injections will you need

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.

Overdose

As ZYPREXA RELPREVV is given to you under medical supervision, it

is very unlikely that you will receive too much.

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or the New Zealand National Poisons Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has received too much ZYPREXA RELPREVV. Do this even if there are no signs of discomfort or poisoning.

If you have received too much ZYPREXA RELPREVV, the most common signs are fast heart beat, agitation/aggression, difficulty speaking, uncontrollable movements and sleepiness (sedation).

While you are having ZYPREXA RELPREVV

Things you must do

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

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

While you are having ZYPREXA RELPREVV, tell your doctor, pharmacist or nurse before you start any new medicine.

If you become pregnant while having ZYPREXA RELPREVV, 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 having 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 must not do

Do not stop having 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 to be careful of

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.

Be careful when drinking alcohol while using ZYPREXA RELPREVV.

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

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

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.

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

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

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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.

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

- 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 heart beat
- fast heart beat.
- speech disorder
- sleepwalking
- sleep eating

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.

These are the more common side effects of ZYPREXA.

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

- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occur more quickly than normal
- rash or allergic reaction
- slow heart beat

- 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
- 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.

These side effects are uncommon but may require medical attention.

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

- 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, yellowing of the skin and/or eyes

- 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 heart beat, 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 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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Most of these side effects are very rare.

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

Elderly patients with dementia-related psychosis

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

- 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.

Zyprexa 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.

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.

Also, 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.

You may not experience any of them.

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

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

After using ZYPREXA RELPREVV

Storage

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.

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

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.

Disposal

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 left over portion to your pharmacist.

®= Registered Trademark

Australian Registration Numbers

ZYPREXA RELPREVV 210 mg -
AUST R 143658

ZYPREXA RELPREVV 300 mg -
AUST R 143657

ZYPREXA RELPREVV 405 mg -
AUST R 143636

This leaflet was revised in January 2024.

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Product Description

What it looks like

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.

Ingredients

Active Ingredient - 210 mg, 300 mg or 405 mg olanzapine pamoate monohydrate.

Diluent Inactive Ingredients -
carmellose sodium, mannitol,
polysorbate 80 and water for
injections.

Supplier

ZYPREXA RELPREVV is a product of:

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street, Sydney,

NSW 2000

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