

APPROVED PATIENT INFORMATION LEAFLET:
PPS PHARMACEUTICALS (PTY) LTD.
ZIPDON (Ziprasidone mesylate, Powder for solution for Injection)

SCHEDULING STATUS:

S5

ZIPDON Powder for solution for injection (vials)

Ziprasidone mesylate

Sugar free.

Read all of this leaflet carefully before you start taking ZIPDON.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZIPDON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZIPDON is and what it is used for
2. What you need to know before you are given ZIPDON
3. How ZIPDON is administered
4. Possible side effects
5. How to store ZIPDON
6. Contents of the pack and other information

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1. What ZIPDON is and what it is used for.

ZIPDON belongs to a group of medicines called antipsychotics. ZIPDON injection is used in emergency situations to quickly relieve the symptoms of what is known as an acute schizophrenic episode.

2. What you need to know before you are given ZIPDON.

You may have been given ZIPDON injection in an emergency, so you may be reading this leaflet after having been given it. Your doctor would have considered the following points but check them yourself in case you need to be given ZIPDON injection again.

ZIPDON injection should not be administered to you:

- If you are hypersensitive (allergic) to ziprasidone or any of the other ingredients of ZIPDON injection (listed in section 6). An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips, or shortness of breath.
- If you have or have had any problems with your heart like a recent heart attack, severe heart failure, or certain irregularities of heart rhythm (discuss the specifics with your doctor).
- If you use other medicines that affect your heart's rhythm.
- If you are pregnant.
- If you are breastfeeding your baby.
- If you are under 18 years of age.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have ever had problems with your heart, especially if you have a history of dysrhythmia (a problem with the rate or rhythm of the heartbeat). You must inform

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your doctor if you are taking any medicines that are known to affect the heart's rhythm.

- If you have a low resting heart rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (nausea) or usage of diuretics (water tablets).

Take special care with ZIPDON:

- If you are over 65 years old, and especially if you have a condition known as “dementia-related psychosis”, ZIPDON should not be used.
- If you have ever had a reaction to ZIPDON called neuroleptic malignant syndrome (NMS), which includes symptoms such as high fever associated with muscle stiffness/pain/weakness, tiredness, confusion and sweating.
- If you develop a rash or other signs or symptoms of hypersensitivity such as fever or enlargement of lymph nodes, you should tell your doctor immediately as this may be an indication of a serious medical event.
- If you have problems with your blood pressure.
- If you are experiencing involuntary movements especially of the mouth, tongue, trunk and limbs. This may be symptoms of a neurological disorder called tardive dyskinesia.
- ZIPDON may cause sleepiness, dizziness, fall in blood pressure when standing up and gait disturbances, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.
- If you have or have had seizures (fits).
- If you have a history of blood clots.
- If you have painful and long-lasting erections.
- If you have thoughts of harming or killing yourself.
- If you have diabetes or a family history of diabetes, ZIPDON injection can cause

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episodes of high blood sugar.

Other medicines and ZIPDON

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary, over-the-counter traditional medicines).

ZIPDON sometimes affects the action of other medicines and sometimes ZIPDON is affected by other medicines.

Certain medicines can affect how ZIPDON works in the body:

Antifungal medicines like ketoconazole might slightly increase ziprasidone levels, but this is unlikely to cause major problems.

The epilepsy medicine carbamazepine can lower ziprasidone levels, potentially making it less effective.

Common antacids and the ulcer medicine cimetidine do not seem to affect ziprasidone.

It's crucial to inform your doctor about all medications you are taking.

What happens when you take ZIPDON with other medicines?

Studies have looked at how ziprasidone (active ingredient in ZIPDON) pills might interact with other medicines you might be taking. Here's what they found:

- Generally Low Interaction Risk: ziprasidone doesn't usually cause significant problems with how many other common medicines work in your body.
- Cough Medicine: It doesn't seem to affect a common ingredient in cough medicine.
- Birth Control: It's unlikely to make birth control pills less effective.
- Lithium: It doesn't seem to change how lithium works in the body.

Still Tell Your Doctor Everything: Even though the risk seems low, it's crucial to inform your doctor or pharmacist about all the medicines you take.

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Do not receive ZIPDON injection if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm such as:

- Class IA and III anti-dysrhythmic medicines, dofetilide, sotalol and quinidine.
- Mesoridazine, thioridazine, chlorpromazine (used to treat schizophrenia).
- Droperidol, dolasetron mesylate (used to treat or prevent nausea).
- Pimozide (used to treat uncontrolled movements, motor or phonic tics).
- Sparfloxacin, moxifloxacin (antibiotics used to treat bacterial infections).
- Gatifloxacin (antibiotic used to treat eye infections).
- Halofantrine, mefloquine (used to treat malaria).
- Pentamidine (used to treat pneumonia).
- Arsenic trioxide (used to treat leukaemia).
- Levomethadyl acetate (an opioid used to treat pain).
- Probucol (used to treat high cholesterol).
- Tacrolimus (used to prevent organ transplant rejection).
- Tell your doctor if you are taking any of the following:
- Other centrally acting medicines including selective serotonin reuptake inhibitors (SSRIs) (used to treat depression).
- Ketoconazole (a medicine used to treat fungal infections).
- Carbamazepine (a medicine used to control seizures).

ZIPDON with food and alcohol

You should not drink alcohol during treatment with ZIPDON injection, as this may increase the risk of side effects.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

ZIPDON injection must not be given to you if you are pregnant or think you may be pregnant.

If you are able to become pregnant, you should use an appropriate method of contraception when receiving this medicine.

ZIPDON injection must not be given to you if you are breastfeeding.

Driving and using machines

ZIPDON injection can cause sleepiness. Be advised not to drive a car or operate potentially dangerous machinery until it is known that this medicine does not affect your ability to engage in these activities.

It is not always possible to predict to what extent ZIPDON injection may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZIPDON injection affects them.

ZIPDON injection contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per mL of reconstituted solution for injection and therefore is essentially sodium-free.

3. How ZIPDON is administered

Do not share medicines prescribed for you with any other person.

ZIPDON injection is given by injection into a muscle. Your doctor will decide how much ZIPDON injection you should receive.

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You will not be expected to give yourself ZIPDON injection. It will be given to you by a person who is qualified to do so.

Adults

The usual dose is 10 mg, but some patients may need 20 mg as their first dose. After a 10 mg injection, you may be given another dose 2 hours later. If your first dose is 20 mg, you may be given another injection 4 hours later.

Your doctor may adjust the amount of ZIPDON injection you are given so you get the right amount to control your symptoms.

ZIPDON injection may be given for up to 3 days in a row. After receiving ZIPDON injection, your doctor may prescribe ZIPDON capsules which you swallow.

If you take more ZIPDON than you should

Since a health care provider will administer ZIPDON injection, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take ZIPDON:

Since a health care provider will administer ZIPDON injection, it is unlikely that the dose will be missed.

4. Possible side effects:

ZIPDON can have side effects.

Not all side effects reported for ZIPDON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZIPDON, please consult your health care provider for advice.

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If any of the following happens, stop taking ZIPDON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZIPDON injection. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fast, irregular heartbeat and fainting. These could be symptoms of a life-threatening condition known as Torsades de Pointes.
- Loss of consciousness.
- High blood pressure.
- Fever, faster breathing, sweating, muscle stiffness, shaking, difficulty swallowing and reduced consciousness. These could be symptoms of a condition known as neuroleptic malignant syndrome.
- Skin reactions, in particular rash, fever and swollen lymph nodes which could be symptoms of a condition called drug reaction with eosinophilia and systemic symptoms (DRESS). These reactions could be life-threatening.
- If you develop a skin rash that causes blistering (this can affect the mouth, tongue and eyes). This potentially life-threatening skin rash is often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. These may be signs of a condition known as Stevens-Johnson syndrome.

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling agitated or anxious;
- Unusual movements;
- Restlessness;
- Shaking;
- Sleepiness;
- Headache;
- Dizziness;
- Nausea;
- Constipation;
- Dry mouth;
- Muscle rigidity;
- Feeling weak and loss of strength;
- Pain and/or burning at the injection site;
- Tiredness.

Less frequent side effects:

- Decreased appetite;
- Abnormal thinking and perceptions;
- Antisocial behaviour;
- Tic;
- Personality disorder;
- Psychosis;
- Difficulty controlling movements or making involuntary noises such as throat clearing;

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- Unintended, involuntary and uncontrollable movements;
- Abnormal or rigid movements;
- Speech disorder;
- Feeling dizzy when you stand up;
- Inability to sleep;
- Loss of balance, light-headedness (vertigo);
- Slow heart rate;
- Feeling flushed;
- Diarrhoea;
- Loose stools;
- Increased sweating;
- Painful urination;
- Medicine withdrawal syndrome;
- Flu-like symptoms;
- Discomfort and/or irritation at the injection site;
- Lower blood pressure;
- Increase in liver enzymes;
- Skin rash;
- A long-lasting and painful erection (of the penis).

Frequency unknown side effects:

- Difficulty sleeping;
- Mania (extremely high mood energy, strange thinking patterns and hyperactivity);
- Movement disorder;
- Fainting;

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- Confusion, agitation, high temperature, sweating, difficulty coordinating muscles, muscle twitching. These could be symptoms of a condition known as serotonin syndrome;
- Involuntary twitching or movements of the face and tongue, as well as of the arms and legs. These could be symptoms of a condition known as tardive dyskinesia;
- Facial droop;
- Low blood pressure;
- Blood clots in the veins;
- Vomiting;
- Difficulty swallowing;
- Swelling of the tongue;
- Loss of bladder control;
- Involuntary urination (bed wetting);
- Persistent abnormal and painful erection of the penis;
- Abnormal breast milk production.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ZIPDON.

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5. How to store ZIPDON

Store at or below 25 °C and protected from light.

The storage of ZIPDON will not be your responsibility.

6. Contents of the pack and other information

What ZIPDON contains:

- The active ingredient of ZIPDON injection is ziprasidone mesylate.
- The other ingredient is sulphobutyl ether beta cyclodextrin sodium (see section 2 – ZIPDON injection contains sodium).

The ZIPDON powder is mixed with water for injection. After mixing, each mL contains 20 mg ziprasidone.

What ZIPDON looks like and contents of the pack:

Off white to Pale pink lyophilized powder/cake in a clear tubular glass vial with 20 mm grey rubber stopper and sealed with 20 mm aluminium seal having blue colour polypropylene disc.

Pack size: 10 single vials in a box.

REGISTRATION NUMBER

59/2.6.5/0507

Holder of Certificate of Registration

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For access to the Professional Information leaflet, please send an email to

info@ppspharmaceuticals.com