

ZypAdhera is also known as olanzapine powder and solvent for prolonged release suspension for injection.



ZYPADHERA

Like all medicines, ZypAdhera™ can cause side effects, although not everybody gets them.

Common side effects: affect 1 to 10 users in 100

- ZypAdhera 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, dizziness, confusion, disorientation, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure, or convulsions
- Sleepiness
- Injection site pain

The side effects listed below have been observed when oral olanzapine has been given but may occur following administration of ZypAdhera.

Very common side effects: affect 1 user in 10

- Weight gain
- Sleepiness

- Increases in the levels of prolactin in the blood
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor

Common side effects: affect 1 to 10 users in 100

- Changes in the levels of some blood cells and circulating fats and in early treatment, temporary increases in liver enzymes
- Increases in the levels of uric acid and creatine phosphokinase in the blood
- Increases in the level of sugars in the blood and urine
- Feeling more hungry
- Dizziness
- Restlessness
- Tremor
- Unusual movement (dyskinesias)
- Constipation
- Dry mouth
- Rash

- Loss of strength
- Extreme tiredness
- Water retention leading to swelling of the hands, ankles, or feet
- Fever
- Joint pain
- Sexual dysfunction such as decreased libido in males and females or erectile dysfunction in males

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Additional information on ZypAdhera can be found in the Patient Information Leaflet.

IMPORTANT INFORMATION FOR PATIENTS

ZypAdhera can sometimes enter the bloodstream too quickly. This is also referred to as Post-Injection Syndrome and may lead to the following side effects: excessive sleepiness, dizziness, confusion, disorientation, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression, anxiety, increase in blood pressure, or convulsions and can lead to unconsciousness.

For this reason:

- Each time you get your injection you will be observed by your doctor or nurse for at least 3 hours for the symptoms listed above
- Your doctor or nurse need to make sure you don't have any of these symptoms before you leave
- **Although unlikely, you may get symptoms of Post-Injection Syndrome more than 3 hours after the injection. If this happens, contact your doctor or nurse immediately. Your doctor or nurse will need to monitor you until the symptoms go away**
- Be vigilant for signs and symptoms of a Post-Injection Syndrome event for the remainder of the day after each injection, and make sure you are able to obtain assistance if needed

- Because of this risk, do not drive or operate machinery for the remainder of the day after each injection

While still at the doctor's office or clinic, be sure to tell your doctor or nurse if you

- Feel very sleepy
- Feel dizzy
- Feel confused or disoriented
- Feel irritable or aggressive
- Feel anxious
- Have difficulty talking or walking
- Feel weak
- Have muscle stiffness or shaking

Your doctor or nurse must check on you to make sure you are alert and free of symptoms before you leave the clinic and they should explain to you what to do in case this happens once you have left. Additional information on ZypAdhera can be found in the Patient Information Leaflet.

Adverse events and product complaints should be reported:

- Reporting forms and further information can be found at: www.hpra.ie.
- Adverse events and product complaints should also be reported to CHEPLAPHARM Registration GmbH via E-Mail to cheplapharm@redlinepv.co.uk or by phone +44 (0) 330 1359 437.

MANAGING YOUR INJECTION

Name: _____

Address: _____

Phone: _____

Emergency Contact information: _____

