

Package leaflet: Information for the user

Ceyxa 10 mg powder for solution for injection

olanzapine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effect, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ceyxa 10 mg powder for solution for injection is and what it is used for
2. What you need to know before you use Ceyxa 10 mg powder for solution for injection
3. How to use Ceyxa 10 mg powder for solution for injection
4. Possible side effects
5. How to store Ceyxa 10 mg powder for solution for injection
6. Contents of the pack and other information

1. What Ceyxa 10 mg powder for solution for injection is and what it is used for

Ceyxa 10 mg powder for solution for injection contains olanzapine, which belongs to a group of medicines called antipsychotics and is used to treat quickly symptoms of agitation and distressing behaviour that may occur in diseases with symptoms such as:

- Schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense. .
- Mania, a condition with symptoms of excitement or euphoria.

Ceyxa 10 mg powder for solution for injection is given when rapid control of agitation and distressing behaviour is needed and treatment with olanzapine tablets is not appropriate. Your doctor will change your treatment to olanzapine tablets, as soon as appropriate.

2. What you need to know before you take Ceyxa 10 mg powder for solution for injection

Do not take Ceyxa

- if you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.
- if you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).

Warnings and precautions

Talk to your doctor before you take Ceyxa.

- Tell the 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 may also want to measure your blood pressure and pulse.
- The use of Ceyxa in elderly patients with dementia (confusion and memory loss) is not recommended as it may have serious side effects.
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Ceyxa, talk to your doctor.

- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once. No more injections will be given to you.
- Weight gain has been seen in patients taking olanzapine. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking olanzapine. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking olanzapine and regularly during treatment.
- Tell the doctor if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

If you suffer from any of the following illnesses tell your doctor as soon as possible:

- Stroke or “mini” stroke (temporary symptoms of stroke) .
- Parkinson’s disease
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Liver or kidney disease
- Blood disorders
- If you have had a recent heart attack, or have heart disease, including sick sinus syndrome, unstable angina or suffer from low blood pressure.
- Diabetes
- Seizures
- If you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)

If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or “mini” stroke.

As a routine precaution, if you are over 65 years your doctor may monitor your blood pressure.

Children and adolescents

Ceyxa is not for patients who are under 18 years.

Other medicines and Ceyxa

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking medicines for Parkinson’s disease.

A combination of Ceyxa with the following medicines might make you feel drowsy: medicines taken for anxiety or to help you sleep (tranquillisers, including benzodiazepines), and antidepressants. Only take other medicines while you are on Ceyxa if your doctor tells you that you can.

If you receive Ceyxa, a benzodiazepine injection is not recommended at the same time as this may result in excessive sleepiness, may have serious effects on your heart rate or your breathing, and, in very rare cases, may result in death. If your doctor has to give a benzodiazepine injection to treat your condition, there should be at least a one-hour time period after the Ceyxa and you are to be monitored closely after the benzodiazepine injection is given.

Ceyxa with alcohol

Do not drink any alcohol if you have been given Ceyxa as Ceyxa and alcohol together may make you feel drowsy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine. You should not be given this medicine when breast-feeding, as small amounts of Ceyxa can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used olanzapine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

There is a risk of feeling drowsy when you are given Ceyxa. If this happens do not drive or operate any tools or machines. Tell your doctor.

3. How to use Ceyxa 10 mg powder for solution for injection

Information on reconstitution and administration is provided in a detachable section at the end of this leaflet.

Your doctor will decide how much Ceyxa you need and how long you need it for. The recommended dose is usually 10 mg in for the first injection, but it may be less than this. Up to 20 mg in 24 hours may be given. The dose for patients aged over 65 years is 2.5 or 5 mg.

Ceyxa comes as a powder. Your doctor or nurse will make it up into a solution. Ceyxa powder for solution for injection is for intramuscular use. The correct amount of solution will be injected into your muscle.

If you are given more Ceyxa than you think you should be

Patients who have been given more Ceyxa than they should have experienced the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness. Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart. Tell your doctor or nurse of your concern.

Only a few doses of Ceyxa are needed. Your doctor will decide when you need a dose of Ceyxa.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have:

- Unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue;
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately;

- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (the frequency of this side effect cannot be estimated from the available data).

Common side effects (may affect up to 1 in 10 people) with Ceyxa include slower or faster heart rate; sleepiness; low blood pressure, discomfort at the site of injection.

Some people may feel dizzy or faint (with a slow heart rate) after injection, 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 or a nurse as soon as possible.

Uncommon side effects (may affect up to 1 in 1,000 people include breathing more slowly, and abnormal rhythms of the heart, which can be serious.

In addition, the following side effects have been seen after patients have taken Olanzapine orally.

Other very common side effects (may affect more than 1 in 10 people) include weight gain and 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.

Other common side effects (may affect up to 1 in 10 people) include changes in the levels of some blood cells and circulating fats and early in treatment, temporary increases in liver enzymes; increases in the level of sugars in the blood and urine; increases in levels of uric acid and creatine phosphokinase in the blood; feeling more hungry; dizziness; restlessness; tremor; unusual movements (dyskinesias); constipation; dry mouth; rash; loss of strength; extreme tiredness; water retention leading to swelling of the hands, ankles or feet; fever; joint pain; and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Other uncommon side effects (may affect up to 1 in 100 people) include hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms (including eye movements); restless legs syndrome; problems with speech; stuttering; slow heart rate; sensitivity to sunlight; bleeding from nose; abdominal distension; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease in menstrual periods; and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects (may affect up to 1 in 1000 people) include lowering of normal body temperature; abnormal rhythms of the heart; sudden unexplained death; inflammation of the pancreas causing severe stomach pain, fever and sickness; liver disease appearing as yellowing of the skin and white parts of the eyes; muscle disease presenting as unexplained aches and pains; and prolonged and/or painful erection.

Very rare side effects include serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen on blood tests and an increase in a type of white blood cells (eosinophilia).

While taking olanzapine, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body

temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

In patients with Parkinson's disease olanzapine may worsen the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor (pharmacist or nurse). This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ceyxa 10 mg powder for solution for injection

Keep out of the reach and sight of children.

Do not use Ceyxa 10 mg powder for solution for injection after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

After Ceyxa 10 mg powder for solution for injection is made into a solution, use within one hour. Do not freeze after reconstitution.

Discard any unused contents.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ceyxa 10 mg powder for solution for injection contains

- The active substance is olanzapine. Each vial contains 10 mg of the active substance.
- The other ingredients are maltose, citric acid monohydrate and hydrochloric acid.

What Ceyxa looks like and contents of the pack

Ceyxa comes as a yellow spongy powder in a vial. A vial of Ceyxa can provide you with 10 mg of olanzapine. Your doctor or nurse will make it up into a solution that will be given as an injection.

Ceyxa is available in a pack containing 1 or 10 vial(s).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Nordic Pharma Limited

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Manufacturer

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Alternative batch release site:

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Ceyxa

The following information is intended for healthcare professionals only

INSTRUCTIONS FOR HEALTH CARE PROFESSIONALS

Reconstitution and administration of Ceyxa

Reconstitute Ceyxa 10 mg powder for solution for injection only with water for injections.

Ceyxa 10 mg powder for solution for injection must not be combined in the syringe with any commercially available medicinal products. See examples of incompatibilities below.

Olanzapine for injection should not be combined in a syringe with haloperidol injection because the resulting low pH has been shown to degrade olanzapine over time.

Olanzapine for injection may not be combined in a syringe nor should it be used concomitantly with benzodiazepines.

Powder for solution for injection

Reconstitute Ceyxa 10 mg powder for solution for injection using standard aseptic techniques for reconstitution of parenteral products.

1. Withdraw 2.0 ml of Water for Injections into a sterile syringe. Inject into a vial of Ceyxa 10 mg powder for solution for injection.
2. Rotate the vial until the contents have completely dissolved, giving a yellow-coloured solution. The vial contains 10.0mg olanzapine as a solution of 5mg/ml.
3. The following table provides injection volumes for delivering various doses of olanzapine:

Dose (mg)	Volume of injection (ml)
10	2.0
7.5	1.5
5	1.0
2.5	0.5

4. Administer the solution intramuscularly. Do not administer intravenously or subcutaneously.
5. Discard the syringe and any unused solution in accordance with appropriate clinical procedures.
6. Use the solution immediately within 1 hour of reconstitution. Do not freeze.

Parenteral medicines should be inspected visually for particulate matter prior to administration.