ZYPREXA TABLET /ZYPREXA ZYDIS ORODISPERSIBLE TABLET

Olanzapine (5 mg, 10 mg)

What is in this leaflet

What Zyprexa is used for

Zyprexa is used to treat the following conditions:

- Schizophrenia, a mental 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.
- Short-term treatment of acute manic episode associated with Bipolar Disorder.

Zyprexa has been shown to prevent recurrence of manic, depressive or mixed episodes in Bipolar Disorder.

How Zyprexa works

Zyprexa is an antipsychotic, antimanic and mood stabilising agent. Zyprexa contains the active ingredient olanzapine. Zyprexa belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain which may cause mental illness.

Before you use Zyprexa

- *When you must not use it*

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (see section **Product description**). 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 Parkinson's disease.
- If you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).
- The use if Zyprexa in elderly with dementia (symptoms that may include memory loss and difficulties with thinking, problem-solving or language) is not recommended as it may have serious side effects.

- *Before you start to use it*

Talk to your doctor or pharmacist before you take Zyprexa.

- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in individuals taking Zyprexa. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Zyprexa 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 the formation of blood clots.
- If you have or are at a risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking Zyprexa and regularly during treatment.

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

- Stroke or "mini" stroke (temporary symptoms of stroke)
- Prostate enlargement
- A blocked intestine (Paralytic ileus)
- Liver or kidney disease
- Blood disorders
- Heart disease
- Diabetes
- Seizures

Pregnancy and lactation

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 taking this medicine. You should not be given this medicine when breast-feeding, as small amounts of Zyprexa can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used Zyprexa 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.

- *Taking other medicines*

Only take other medicines while you are on Zyprexa if your doctor tells you that you can.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- medicines for Parkinson's disease
- carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant), charcoal or ciprofloxacin (an antibiotic) - it may be necessary to change your Zyprexa dose.

Do not drink any alcohol if you have been given ZYPREXA as together with alcohol it may make you feel drowsy.

Other medicines not listed above may also interact with Zyprexa. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Zyprexa.

How to use Zyprexa

- *How much to use*

Your doctor will tell you how many Zyprexa tablets to take and how long you should continue to take them. The daily dose of Zyprexa is between 5 mg and 20 mg. Consult your doctor if your symptoms return but do not stop taking Zyprexa unless your doctor tells you to.

Children and adolescents: Zyprexa is not for children and adolescents under 18 years.

- *When to use it*

You should take your Zyprexa tablets normally once a day following the advice of your doctor or pharmacist. Try to take your tablets at the same time each day. It does not matter whether you take them with or without food. Zyprexa tablets and Zyprexa Zydis orodispersible tablets are for oral use.

Zyprexa Tablet:
Zyprexa tablets should be swallowed whole with a glass of water.

Zyprexa Zydis Orodispersible Tablet:
Zyprexa Zydis orodispersible tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing.
3. Gently push the tablet out.
4. Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

You can also place the tablet in a full glass or cup of water, orange juice, apple juice, milk or coffee, and stir. With some drinks, the mixture may change colour and possibly become cloudy. Drink it straight away.

- *How long to use it*

Continue taking Zyprexa for as long as your doctor recommends.

- *If you forget to use it*

Take your tablets as soon as you remember. Do not take two doses in one day.

- *If you use too much (overdose)*

Individuals who have taken more Zyprexa 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, high fever, faster breathing, sweating, muscle stiffness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart.

Contact your doctor or hospital straight away if you experience any of the above symptoms. Show the doctor your pack of tablets.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Zyprexa.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking your tablets just because you feel better. It is important that you carry on taking Zyprexa for as long as your doctor tells you.

If you suddenly stop taking Zyprexa, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment.

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

- *Things to be careful of*

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

Zyprexa tablet contains lactose
If you have been told by your doctor that you have an intolerance to some sugar, contact your doctor before taking this medicinal product.

Zyprexa Zydis orodispersible tablet contains aspartame, sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate.

This medicine contains up to 1.6 mg aspartame in each tablet.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it proper.

Zyprexa Zydis contains methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). An allergic reaction may be recognized as a rash, itching or shortness or breath. This may occur immediately or some time after you take Zyprexa Zydis.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Side effects

Weight gain
Weight gain has been seen in individuals taking Zyprexa. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.

Elderly
As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

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 (rare side effects [may affect up to 1 in 1000 people]);
- Increase in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination);

- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome);
- Trouble breathing during sleep (sleep apnoea);
- Difficulty or inability to pass urine (urinary retention).

Very common side effects (may affect more than 1 in 10 people) include weight gain; sleepiness; and increases in 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 (may affect up to 1 in 10 people) include changes in the levels of some blood cells, 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; 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 (sexual desire) in males and females or erectile dysfunction (inability to get and maintain an erection) in males.

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 (build up of acid in the blood) 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 the nose; abdominal distension; drooling; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence 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 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 with dementia may suffer from stroke, pneumonia (infection that leads to inflammation of the lungs), urinary incontinence, falls, extreme tiredness, visual hallucinations (seeing things that are not real), a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of individuals.

In people with Parkinson's disease Zyprexa may worsen the symptoms.

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my *[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*.

Storage and disposal of Zyprexa

- *Storage*

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date, which is stated on the carton.

Zyprexa Tablet
Do not store above 30°C.

Zyprexa Zydis Orodispersible Tablet
Store below 30°C in the original package in order to protect from light and moisture.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Zyprexa Tablet

Zyprexa 5 mg Tablets are round, white, coated tablets imprinted with "LILLY" and a numeric identicode “4115”.

ZYPREXA 10mg Tablets are round, white, coated tablets imprinted with "LILLY" and a numeric identicode “4117”.

Zyprexa Zydis Orodispersible Tablet

Zyprexa Zydis 5mg and 10mg Orodispersible Tablet is a yellow, round, freeze dried, rapid-dispersing preparation to be placed in the mouth or alternatively to be dispersed in water or other suitable beverages for use.

Not all formulations are marketed.

- *Ingredients*
- Active ingredient

Olanzapine

- Inactive ingredients

Zyprexa Tablet

Tablet core

- Lactose monohydrate
- Hydroxypropylcellulose
- Crospovidone
- Microcrystalline cellulose
- Magnesium stearate

Tablet coat

- Hypromellose
- Color mixture white (hypromellose, titanium dioxide)
- Carnauba wax
- Edible blue ink (shellac, macrogol, indigo carmine E132)

Zyprexa Zydis Orodispersible Tablet

- Gelatin

- Mannitol (E421)
- Aspartame (E951)
- Sodium methyl parahydroxybenzoate (E219)
- Sodium propyl parahydroxybenzoate (E217)

- *MAL number(s)*

Zyprexa Tablet 5 mg
MAL08061564AZ

Zyprexa Tablet 10 mg
MAL08061565AZ

Zyprexa Zydis 5mg Orodispersible Tablet
MAL04125490ACRZ

Zyprexa Zydis 10mg Orodispersible Tablet
MAL04125491ACRZ

Manufacturer
Zyprexa Tablet 5mg
Zyprexa Tablet 10mg
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Zyprexa Zydis 5mg Orodispersible Tablet
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Product Registration Holder
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