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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet about?

1. What Olanzapine is and what it is for
2. How to take Olanzapine
3. Possible side effects
4. How to store Olanzapine
5. Contents of the pack and other information

1. WHAT OLANZAPINE IS AND WHAT IT IS USED FOR

Olanzapine tablets contain the active substance olanzapine. Olanzapine belongs to a group of medicines called antipsychotics and is used to treat the following conditions:

- Schizophrenia a disease with symptoms such as hearing voices, not being able to concentrate or remember things, unreasonable or new beliefs and becoming withdrawn.

If you suffer from any of the following illnesses tell your doctor immediately if you have:

- Any of these symptoms seek medical advice
- Very rarely, medicines of this type cause a rash, itching, a swollen face, throat (anaphylaxis) or swelling of the legs
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OLANZAPINE

- 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, throat (anaphylaxis) or swelling of the legs.

- If you have had any of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine. Olanzapine has been shown to prevent recurrence following conditions

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

Very common side effects: (may affect more than 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 creatinine,
• fever,
• muscle stiffness or spasms (including eye movements),
• joint pain and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction 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 ketoadiposis (ketones in the blood and urine) or coma.
• Abnormal blood tests, usually associated with a history of seizures (epilepsy).
• Muscle stiffness or spasms (including eye movements).
• Red blood cell syndrome.
• Problems with speech.
• Slurring.
• Slow heart rate.
• Sensitivity to sunlight.
• Bleeding from the nose.
• Abdominal distension.
• Memory loss or forgetfulness.
• Urinary incontinence, lack of ability to urinate.
• Hair loss.
• Abnormal urination.
• Loss of sensation or weakness in the limbs.
• Decrease or no reduction in appetite.
• Enlarged lymph nodes.
• Increased levels of liver enzymes seen on blood tests and an increase in a type of white blood cells (eosinophilia).
• An abnormal production of breast milk or abnormal milk growth.

Rare side effects (may affect up to 1 in 1000 people) include:
• Loss 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 whites of the eyes.
• Muscle disease presenting as unexplained aches and pains.
• Prolonged and/or painful erection.

Very rare side effects include serious allergic reactions such as Drug Reaction with Eosinophilia and Symptomatic Syndromes (DRESS). DRESS appears initially as a rash with other symptoms such as 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: 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 OLanzapine

Keep this medicine out of sight and reach of children. Store below 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What Olanzapine contains:
• The active substance is olanzapine. Each Olanzapine tablet contains either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg of the active substance. The exact amount is shown on your Olanzapine tablet pack.
• The other ingredients are - lactose monohydrate, 30 crospovidone (type B), hydroxypropyl cellulose and magnesium stearate.

What Olanzapine looks like and contents of the pack

Olanzapine 2.5 mg Tablets:
Yellow coloured, circular (6.2 mm in diameter), biconvex uncoated tablets, debossed with ‘C’ on one side and ‘45’ on the other side.
Olanzapine 5 mg Tablets:
Yellow coloured, circular (8.0 mm in diameter), biconvex uncoated tablets, debossed with ‘C’ on one side and ‘46’ on the other side.
Olanzapine 7.5 mg Tablets:
Yellow coloured, circular (7.5 mm in diameter), biconvex uncoated tablets, debossed with ‘C’ on one side and ‘47’ on the other side.
Olanzapine 10 mg Tablets:
Yellow coloured, circular (8.0 mm in diameter), biconvex uncoated tablets, debossed with ‘C’ on one side and ‘48’ on the other side.
Olanzapine 15 mg Tablets:
Yellow coloured, circular (9.0 mm in diameter), biconvex uncoated tablets, debossed with ‘C’ on one side and ‘49’ on the other side.
Olanzapine 20 mg Tablets:
Yellow coloured, circular (10.5 mm in diameter), biconvex uncoated tablets, debossed with ‘C’ on one side and ‘50’ on the other side.

Olanzapine tablets are available in:
PVC/Polyamide/Aluminium/Plastic/PVC/Aluminium blister pack:
7, 14, 30, 35, 50, 96, 98 & 100 tablets.
HDPE bottle and polyporenylene closure with silicon gel desiccant:
30 & 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mpharm Limited
Asia, Odyssey Business Park
West End Road
South Ruislip
HA4 6QD

United Kingdom

Manufacturer
Aplio Services (Malta) Limited
HP 26, Hal Far Industrial Estate, Hal Far
Brizebugia BBG 3000

Malta

or

Orion Corporation, Orion Pharma
Orioninste 1,
FI-02000 Espoo,

Finland

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium
Olanzapine A 2.5mg/ 5mg/ 7.5mg/ 10mg/ 15mg/ 20mg tablets
Cypres
Olanzapine Aurobindo 5 mg/ 10 mg tablets

Denmark
Olanzapin “Olon”

Finland
Olanzapin Orion 2.5mg/ 5mg/ 7.5mg/ 10mg/ 15mg/ 20mg tablet

France
OLANZAPINE ARROW 5mg/ 7.5mg/ 10mg,

Germany
Olanzapin Aurobindo 2.5mg/ 5mg/ 7.5mg/ 10mg/ 15mg/ 20mg Tablets

Italy
Olanzapina Aurobindo

Malta
Olanzapina Aurobindo 2.5mg/ 5mg/ 7.5mg/ 10mg/ 15mg/ 20mg Tablets

Netherlands
Olanzapina Aurobindo 2.5mg/ 5mg/ 7.5mg/ 10mg/ 15mg/ 20mg Tablets

Poland
Szoi/Olanzapina Aurobindo

Portugal
Olanzapina Aurobindo

Romania
Olanzapina Aurobindo 10mg/ 15mg

Spain
15mg/ 20mg compresse

Poland
Szoi/Olanzapina Aurobindo

United Kingdom
Olanzapina Aurobindo 2.5mg/ 5mg/ 7.5mg/ 10mg/ 15mg/ 20mg Tablets

This leaflet was last revised in 05/2019.