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	Description	Olanzapine		
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Prepared By Regulatory Affairs		Checked By Regulatory Affairs		Approved By Quality Assurance



PACKAGE LEAFLET: INFORMATION FOR THE USER

Olanzapine Accord 2.5 mg film-coated tablets
Olanzapine Accord 5 mg film-coated tablets
Olanzapine Accord 7.5 mg film-coated tablets
Olanzapine Accord 10 mg film-coated tablets
Olanzapine Accord 15 mg film-coated tablets
Olanzapine Accord 20 mg film-coated tablets
Olanzapine

Read all of this leaflet carefully before you start taking 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, please ask your doctor or your 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 or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Olanzapine Accord is and what it is used for

Olanzapine Accord belongs to a group of medicines called antipsychotics.

Olanzapine Accord is used to treat 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

Olanzapine Accord is used to treat a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It is also a mood stabilizer that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with this condition.

2. What you need to know before you take Olanzapine Accord

Do not take Olanzapine Accord

- If you are allergic to Olanzapine Accord or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may be recognized 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

- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olanzapine Accord tell 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.
- 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.
- Weight gain has been seen in patients taking olanzapine tablets. You and your doctor should check your weight regularly.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking olanzapine tablets. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking olanzapine tablets and regularly during treatment.
- The use of Olanzapine Accord in elderly patients with dementia is not recommended as it may have serious side effects.

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

- Diabetes
- Heart disease
- Liver or kidney disease
- Parkinson's disease
- Epilepsy
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Blood disorders
- Stroke or "mini" stroke (temporary symptoms of stroke)

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 blood pressure may be monitored by your doctor.

Olanzapine Accord is not for patients who are under 18 years.

Taking other medicines:

Only take other medicines while you are on Olanzapine Accord if your doctor tells you that you

can. You might feel drowsy if Olanzapine Accord is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

You should tell your doctor if you are taking fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic), as it may be necessary to change your Olanzapine Accord dose.

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.

Taking Olanzapine Accord with food and drink:
Do not drink any alcohol if you have been given Olanzapine Accord as Olanzapine Accord and alcohol together may make you feel drowsy.

Pregnancy and breast-feeding and fertility

Tell your doctor as soon as possible if you are pregnant or think you may be pregnant. You should not take this medicine when pregnant, unless you have discussed this with your doctor. You should not be given this medicine when breast-feeding, as small amounts of Olanzapine Accord 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 Olanzapine Accord. If this happens do not drive or operate any tools or machines. Tell your doctor.

Important information about some of the excipients

Olanzapine Accord contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Olanzapine Accord

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

You should take your Olanzapine Accord once a day following the advice of your doctor. Try to take your tablets at the same time each day. It does not matter whether you take them with or without food. Olanzapine Accord coated tablets are for oral use. You should swallow the Olanzapine Accord whole with water.

If you take more Olanzapine Accord than you should

Patients who have taken more Olanzapine Accord 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. Contact your doctor or hospital straight away. Show the doctor your pack of tablets.

If you forget to take Olanzapine Accord

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

If you stop taking Olanzapine Accord

Do not stop taking your tablets just because you feel better. It is important that you carry on taking Olanzapine Accord for as long as your doctor tells you. If you suddenly stop taking Olanzapine Accord, 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 or nurse.

4. Possible side effects

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

Very common side effects: affect 1 user in 10

- Weight gain
- Sleepiness.
- Increases in the levels of prolactin in the blood.

Common side effects: affect 1 to 10 users in 100

- Changes in the levels of some blood cells and circulating fats
- Increases in the level of sugars in the blood and urine
- Feeling more hungry
- Dizziness
- Restlessness
- Tremor
- Muscle stiffness or spasm (including eye movements).
- Problems with speech
- Unusual movement (especially of the face or tongue)
- Constipation
- Dry mouth
- Rash
- Loss of strength
- Extreme tiredness
- Water retention leading to swelling of the hands, ankles or feet
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate),

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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.

- Sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males

Uncommon side effects: affect 1 to 10 users in 1,000

- Slow heart rate
- Make you sensitive to sunlight
- Urinary incontinence
- Hair loss.
- Absence or decrease in menstrual periods.
- Changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.
- Blood clots in the veins 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.

Other possible side effects: frequency cannot be estimated from the available data.

- Allergic reaction (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
- Lowering of normal body temperature.
- Seizures, usually associated with a history of seizures (epilepsy).
- Combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness.
- Spasms of the muscle of the eye causing rolling movement of the eye.
- 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.
- Difficulty in passing urine.
- Prolonged and/or painful erection.

While taking Olanzapine Accord, 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 Accord may worsen the symptoms.

Rarely women taking medicines of this type for a long time have started to secrete milk and have missed periods or had irregular periods. If this persists tell your doctor.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any side effects not listed in this leaflet.

5. How to store Olanzapine Accord

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blister as well as carton after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 30°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 protect the environment.

6. Contents of the pack and other information

What Olanzapine Accord contains:

The active substance is Olanzapine.

Each film-coated tablet contains either 2.5 mg ; 5 mg ; 7.5 mg ; 10 mg ; 15 mg or 20 mg Olanzapine.

The tablet also contains:

Lactose monohydrate, Cellulose microcrystalline, Crospovidone, Hydroxypropylcellulose, Magnesium stearate

Film coating contains:

Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Polysorbate 80 (E433). In addition film coat of 15 mg tablets also contains Indigo carmine aluminium lake (E132) and 20 mg tablets contains iron oxide red (E172)

What Olanzapine Accord looks like and content of the pack:

Olanzapine Accord 2.5 mg: White to off white round, biconvex, film-coated tablets plain on both sides

Olanzapine Accord 5 mg: White to off white round biconvex, film coated tablets, debossed with 'O1' on one side and plain on other side.

Olanzapine Accord 7.5 mg: White to off white round biconvex, film coated tablets, debossed with 'O2' on one side and plain on other side.

Olanzapine Accord 10 mg: White to off white round biconvex, film coated tablets, debossed with 'O3' on one side and plain on other side.

Olanzapine Accord 15 mg Tablets: Light blue coloured, round, biconvex, film coated tablets plain on both sides

Olanzapine Accord 20 mg Tablets: Light pink coloured, round, biconvex, film coated tablets plain on both sides

The tablets are available in the pack size of 28, 30, 35, 56 or 70 tablets per carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Accord Healthcare Limited,
Sage house,
319, Pinner Road,
North Harrow,
Middlesex, HA1 4HF,
UK.

Manufacturer:

CEMELOG- BRS,
2040 Budaors, Vasut u.13., Hungary

Accord Healthcare Limited,
Sage house,
319, Pinner Road,
North Harrow,
Middlesex, HA1 4HF,
UK.

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

Country	Proposed Name
Bulgaria	Olanzapine Accord 2.5/5/7.5/10/15/20 mg филмирани таблетки
Denmark	Olanzapine Accord 2.5/5/7.5/10/15/20 mg filmovertrukne tabletter
Estonia	Olanzapine Accord 2.5/5/7.5/10/15/20 mg õhukese polümeerikattega tabletid
Finland	Olanzapine Accord 2.5/5/7.5/10/15/20 mg Kalvopäävysteinien Tabletti
Hungary	Olanzapin Accord 2.5/5/7.5/10/15/20 mg Filmtabletta
Latvia	Olanzapine Accord 2.5/5/7.5/10/15/20 mg apvalkotās tabletes
Lithuania	Olanzapine Accord 2.5/5/7.5/10/15/20 mg plėvele dengtos tabletės
Norway	Olanzapine Accord 2.5/5/7.5/10/15/20 mg filmdrasjerte tabletter
Poland	Olanzapine Accord 2.5/5/7.5/10/15/20 mg tabletki powlekane
Portugal	Olanzapina Accord 2.5/5/7.5/10/15/20 mg comprimidos revestidos por película
Romania	Olanzapină Accord 2.5/5/7.5/10/15/20 mg, comprimate filmate
Spain	Olanzapine Accord 2.5/5/7.5/10/15/20 mg comprimidos recubiertos con película EFG
Sweden	Olanzapine Accord 2.5/5/7.5/10/15/20 mg Filmdragerad Tabletter
The Netherlands	Olanzapine Accord 2.5/5/7.5/10/15/20 mg Filmomhulde Tabletten
UK	Olanzapine 2.5/5/7.5/10/15/20 mg Film-coated Tablets
Austria	Olanzapine Accord 2.5/5/7.5/10/15/20 mg Filmtabletten
Belgium	Olanzapine Accord 2.5/5/7.5/10/15/20mg comprimés pelliculés
Cyprus	Olanzapine Accord 2.5/5/7.5/10/15/20 mg επικαλυμμένα με λεπτό υμένιοx δισκία
Czech republic	Olanzapine Accord 2.5/5/7.5/10/15/20 mg potahované tablety
Germany	Olanzapine Accord 2.5/5/7.5/10/15/20 mg Filmtabletten
Ireland	Olanzapine Accord 2.5/5/7.5/10/15/20 mg film-coated Tablets
Italy	Olanzapina Accord
Malta	Olanzapine Accord 2.5/5/7.5/10/15/20 mg film-coated Tablets
Slovakia	Olanzapine Accord 2.5/5/7.5/10/15/20 mg filmom obalené tablety

The leaflet was last approved in 09/2012.