Package leaflet: Information for the user

Olanzapine Bexal 2.5 mg film-coated tablets
Olanzapine Bexal 5 mg film-coated tablets
Olanzapine Bexal 7.5 mg film-coated tablets
Olanzapine Bexal 10 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, 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.

What is in this leaflet

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

Olanzapine Bexal belongs to a group of medicines called antipsychotics and is used to treat the following conditions:
- 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.
- Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria

Olanzapine Bexal has been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

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

Do not take Olanzapine Bexal

- 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 or pharmacist before you take Olanzapine Bexal.
- The use of Olanzapine Bexal in elderly patients with dementia is not recommended as it may have serious side effects.
- Weight gain has been seen in patients taking Olanzapine. 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. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olanzapine Bexal and regularly during treatment.
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olanzapine Bexal 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.
- 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 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
- Heart disease
- Diabetes
- Seizures

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.

Children and adolescents
Olanzapine Bexal is not for patients who are under 18 years.

Other medicines and Olanzapine Bexal
Only take other medicines while you are on Olanzapine Bexal if your doctor tells you that you can. You might feel drowsy if Olanzapine Bexal is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

Tell your doctor or pharmacist 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 (dopamine agonists),
- carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic) - it may be necessary to change your Olanzapine Bexal dose

Olanzapine Bexal with alcohol
Do not drink any alcohol if you have been given Olanzapine Bexal as together with alcohol it 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 taking this medicine.
You should not be given this medicine when breast-feeding, as small amounts of Olanzapine Bexal can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers who have used Olanzapine Bexal 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 Bexal. If this happens do not drive or operate any tools or machines. Tell your doctor.

Olanzapine Bexal 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 Bexal

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

Your doctor will tell you how many Olanzapine Bexal tablets to take and how long you should continue to take them. The daily dose of Olanzapine Bexal is between 5 and 20 mg.

Consult your doctor if your symptoms return but do not stop taking Olanzapine Bexal unless your doctor tells you to.

You should take your Olanzapine Bexal tablets 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 Bexal film-coated tablets are for oral use. You should swallow the Olanzapine Bexal tablets with water.

If you take more Olanzapine Bexal than you should
Patients who have taken more Olanzapine Bexal 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 if you experience any of the above symptoms. Show the doctor your pack of tablets.

If you forget to take Olanzapine Bexal
Take your tablets as soon as you remember. Do not take two doses in one day.

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

If you suddenly stop taking Olanzapine Bexal, 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.

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).

Very common side effects (may affect more than 1 in 10 people):
- Weight gain
- Sleepiness
- Increases in the levels of prolactin in the blood

Common side effects (may affect up to 1 in 10 people):
- 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
- 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), 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 (may affect up to 1 in 100 people):
- Slow heart rate
- Sensitivity to sunlight
- Urinary incontinence, lack of ability to urinate
- 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

Other additional side effects for which a frequency cannot be estimated from the available data (not known):
- 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)
- 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
- Prolonged and/or painful erection

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 Bexal may worsen the symptoms.

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

5. How to store Olanzapine Bexal

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 carton and on the blister/label of the HDPE-bottle. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use Olanzapine Bexal after 6 months have elapsed from opening of the HDPE-bottle.

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 Bexal contains
The active substance is olanzapine.
Each film-coated tablet contains either 2.5 mg, 5 mg, 7.5 mg or 10 mg of olanzapine.

The other ingredients are
Tablet core: lactose monohydrate, hydroxypropylcellulose, crospovidone, microcrystalline cellulose, magnesium stearate
Tablet coat: polyvinyl alcohol, macrogol 3350, titanium dioxide (E 171), talc

What Olanzapine Bexal looks like and contents of the pack
Olanzapine Bexal 2.5 mg film-coated tablets are white and round (6.5 mm diameter).

Olanzapine Bexal 5 mg film-coated tablets are white and round (8 mm diameter) with a breaking notch on one side. The film-coated tablets can be divided into equal doses.

Olanzapine Bexal 7.5 mg film-coated tablets are white and round (9 mm diameter).

Olanzapine Bexal 10 mg film-coated tablets are white and round (10 mm diameter) with a breaking notch on one side. The film-coated tablets can be divided into equal doses.

Olanzapine Bexal is available in blisterpacks containing 7, 10, 14, 20, 28, 30, 35, 50, 56, 60, 70, 98, 100 or 500 film-coated tablets and in HDPE-bottles containing 50, 100, 250 or 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
BEXAL Farmaceutica
Centro Empresarial Osa Mayor
Avda. Osa Mayor n°4-Area B
Aravaca 28023
Madrid
Spain

Manufacturer

<To be completed nationally>

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

Spain:
Olanzapina Bexal 2.5 mg comprimidos recubiertos EFG
Olanzapina Bexal 5 mg comprimidos recubiertos EFG
Olanzapina Bexal 7.5 mg comprimidos recubiertos EFG
Olanzapina Bexal 10 mg comprimidos recubiertos EFG

Sweden:
Olanzapine Bexal

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