

Bigwin® XR

Metformin hydrochloride

ZENTIVA
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What is Bigwin® XR?

- Bigwin® XR 500 film coated extended release tablet contains metformin hydrochloride 500mg.
- Bigwin® XR 750 film coated extended release tablet contains metformin hydrochloride 750mg.
- Bigwin® XR 1000 film coated extended release tablet contains metformin hydrochloride 1000mg.

Excipients: carboxymethylcellulose sodium, povidone, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, polyethylene glycol, talc, titanium dioxide.

Why should you take Bigwin® XR?

Bigwin® XR is an oral anti diabetic medication prescribed to control type 2 diabetes (Non insulin dependent). Diabetes develops when the body is unable to utilize the sugar taken leading to an increase in sugar concentration in the blood. Bigwin® XR decreases sugar concentration in the blood by lowering sugar production by the liver, sugar absorption by the intestine, and increasing your body's sensitivity to insulin. It does not have any impact on insulin production. Bigwin® XR is not a substitute for insulin. It can be prescribed alone or in combination with insulin or other anti diabetics.

What should you know about Bigwin® XR?

Bigwin® XR is an aid to but not a substitute for good diet and exercise. Bigwin® XR is not an oral form of insulin and cannot be used in place of insulin.

What is the recommended dosage of Bigwin® XR?

Adults

The usual starting dose of Bigwin® XR is one 500mg tablet taken once daily with the evening meal. The dose may be increased by 500mg on weekly intervals up to a maximum of 2000mg of Bigwin® XR once daily with the evening meal. In case a single 2000mg dose of Bigwin® XR cannot control your blood sugar your doctor may ask you to take one Bigwin® XR 1000mg tablet twice daily. If higher doses are required your doctor may shift to Bigwin® XR 750 and Bigwin® XR 1000 are intended for patients who are already treated with Bigwin® XR or Bigwin®. The dose of Bigwin® XR 750 or Bigwin® XR 1000 should be equivalent to the daily dose of Bigwin® XR or Bigwin®, up to a maximum dose of 1500mg or 2000mg respectively, given with the evening meal.

Children

Bigwin® XR has not been tested in children below 17 years of age.

Older Adults

Lower doses are recommended for older adults and malnourished people because their kidneys may be weaker, a condition that may enhance side effects.

How is Bigwin® XR taken?

Take Bigwin® XR exactly as prescribed by your doctor. Bigwin® XR should be taken with meals to minimize the incidence of nausea or diarrhea particularly during the first weeks of therapy. Bigwin® XR tablets must be swallowed as a whole and never crushed or chewed. Occasionally, the inactive ingredients may appear in the feces as a soft hydrated mass.

What to do if you miss a dose?

Take the missed dose as soon as you remember. If it is almost time for your next dose skip the dose you missed and go back to your regular schedule. Do not take two doses at the same time.

What to do in case of overdose?

Any medication taken in excess may lead to serious consequences. If you suspect an overdose, seek medical attention immediately. Bigwin® XR overdose may lead to lactic acidosis, which is a metabolic complication.

Are there any food or drug interactions with Bigwin® XR?

Bigwin® XR can be taken with most other drugs; however you should consult your doctor before combining Bigwin® XR with any of the following drugs: Calcium channel blockers, Cimetidine, Amiloride, Digoxin, Estrogens, Furosemide, Thorazine, Glibenclamide, Isoniazide, Oral contraceptives, Morphine, Nifedipine, Quinidine, Phenytoin, Procainamide, Quinine, Vancomycin, Ranitidine, Trimethoprim, Steroids such as prednisone, Thyroid hormones, and Diuretics. You must avoid excessive alcohol consumption with Bigwin® XR since alcohol enhances

the effects of Bigwin® XR which may lead to low blood sugar levels.

What are the side effects of Bigwin® XR?

Side effects may include:

Diarrhea, abdominal discomfort, gas, headache, indigestion, nausea and vomiting. A very rare but a serious side effect is lactic acidosis. It is a metabolic problem occurring due to accumulation of lactic acid in the blood leading to symptoms of dizziness, weakness, low body temperature, difficulty in breathing or rapid breathing, sleepiness, irregular or slow heart beat, and unusual muscle pain. This complication is more likely to occur in patients with liver and/or kidney problems, congestive heart failure, or patients with multiple medical problems or taking several medications.

Precautions about Bigwin® XR

Your doctor will assess your kidney function before starting your therapy with Bigwin® XR and at least once a year thereafter for normal patients and more frequently for older adults. In case you develop kidney problems during your therapy you might have to stop the medication. Bigwin® XR must not be taken for 2 days prior to and after having an X-ray procedure that uses an injectable dye. Bigwin® XR is usually stopped prior to surgery, except for minor surgery, and is initiated after normal food and fluid intake is resumed.

Drinking excess alcohol should be avoided with Bigwin® XR as it may lead to lactic acidosis. Impaired liver function may also be a cause of lactic acidosis thus liver function must be periodically monitored by your doctor. In case you develop liver problems during your therapy you might have to stop the medication. Bigwin® XR does not cause hypoglycemia; however this may occur in elderly malnourished people and those who have kidney, liver, adrenal or pituitary gland problems. The risk of hypoglycemia is boosted by missed meals, alcohol consumption and excessive physical activity. You should inform your doctor if you lose a significant amount of fluid due to vomiting, diarrhea, or some other conditions since dehydration increases the possibility of developing lactic acidosis.

What are the cases in which you should not take Bigwin® XR?

If you have impaired kidney function, metabolic ketoacidosis, allergy to the drug or to any of its components, or if you are taking medications for congestive heart failure.

What should you do if you are pregnant or breastfeeding?

Bigwin® XR must not be taken during pregnancy, thus you must inform your doctor if you are pregnant or planning to be pregnant while on therapy with Bigwin® XR. It is not known whether Bigwin® XR is secreted in breast milk, thus you must consult your doctor on whether to discontinue the medication or to stop breastfeeding.

How to store Bigwin® XR?

Store below 25°C.

Keep in original pack in intact conditions.

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Manufactured by
Benta SAL, Dbayeh- Lebanon



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A SANOFI COMPANY

This is a medication

- A medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Medication: keep out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists