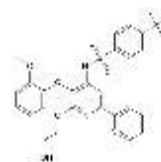


Rx BOSENTAN

(Bosentan is used to treat a condition of high blood pressure in the lungs)



GENERIC NAME: BOSENTAN - ORAL (boh-SEN-tan)

USES

Bosentan is used to treat a condition of high blood pressure in the lungs (pulmonary arterial hypertension). It works by causing the blood vessels (arteries) in the lungs to relax and expand, thus decreasing the pressure.

HOW TO USE

Before using, review the bosentan Medication Guide for information on the safe use of this medicine. Take this medication by mouth usually twice daily in the morning and evening with or without food; or as directed by your doctor. The dosage is based on your medical condition and response to therapy. Your doctor may recommend to gradually increase your dose over time so your body may better adjust to the effects of this drug. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased.

SIDE EFFECTS

Headache, nose/throat irritation, itching, flushing, or stomach upset may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: irregular heartbeat, unusual tiredness and weakness, swelling of the feet or ankles, trouble breathing, dizziness or lightheadedness. If you notice any of the following very serious side effects of liver problems, stop taking bosentan and consult your doctor immediately: vomiting, stomach pain, yellowing eyes or skin. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, dizziness, severe trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Tell your doctor your medical history, especially of: liver problems, blood disorders (e.g., anemia), any allergies. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug. This medication must not be used during pregnancy because it may cause fetal harm. If you are pregnant or think you may be pregnant, do not take this medication and consult your doctor immediately. It is recommended that you use two reliable forms of birth control while taking this medicine. It is also recommended to have a pregnancy test done before treatment and every month during treatment with this drug. It is not known whether this drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended.

DRUG INTERACTIONS

This drug is not recommended for use with: cyclosporine, glyburide. Ask your doctor or pharmacist for more details. Tell your doctor of all prescription and nonprescription medication you may use, especially: azole antifungals (e.g., itraconazole, ketoconazole), statins for high cholesterol (e.g., lovastatin, simvastatin), HIV protease inhibitors (e.g., indinavir, ritonavir), tacrolimus. This medication may decrease the effectiveness of combination-type birth control pills. This can result in pregnancy. You may need to use an additional form of reliable birth control while using this medication. Consult your doctor or pharmacist for details. Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 68 and 77 degrees F (20 and 25 degrees C) away from light and moisture. Brief storage between 59 and 86 degrees F (15 and 30 degrees C) is permitted.

WARNING

This medication may cause serious liver problems. Your doctor should monitor your liver function closely to decrease your risk of liver-related side effects. Tell your doctor immediately if you notice any of these symptoms of liver problems: nausea, vomiting, stomach pain, unusual tiredness, and yellowing eyes or skin. These effects, if they occur, may go away over time (are reversible). This medication must not be used during pregnancy because it can cause fetal harm (e.g., birth defects). See the pregnancy warning information below (in Precautions section).

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

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Taj Group of Companies INDIA

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

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