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Medication Guide Bosentan (boe-SEN-tan) Tablets

Read the Medication Guide that comes with bosentan tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about bosentan tablets?

Bosentan tablets are only available through the Bosentan REMS Program. Before you begin taking bosentan tablets, you must read and agree to all of the instructions in the Bosentan REMS Program.

Bosentan tablets can cause serious side effects including:

- **Liver damage.**
 Liver damage may not cause symptoms at first. Only a blood test can show if you have early liver damage. You must have your blood tested to check your liver function before you start bosentan tablets and each month after that. Your healthcare provider will order these tests. Regular blood tests are important because they will help your healthcare provider adjust or stop your treatment before there is permanent damage.
- Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines. Call your healthcare provider right away if you have any of these symptoms of liver problems while taking bosentan tablets:
 - nausea
 - vomiting
 - fever
 - unusual tiredness
 - stomach area (abdominal) pain
 - yellowing of the skin or the whites of your eyes (jaundice)

Serious birth defects.

- **Bosentan tablets can cause serious birth defects if taken during pregnancy. You must not be pregnant when you start taking bosentan tablets or during bosentan tablets treatment. Serious birth defects from bosentan tablets can happen early in pregnancy. Females who are able to get pregnant must have a negative pregnancy test before starting treatment with bosentan tablets, each month during treatment with bosentan tablets, and 1 month after stopping treatment with bosentan tablets.**
 - Talk to your healthcare provider about your menstrual cycle. Your healthcare provider will decide when to do a pregnancy test and will order a pregnancy test for you depending on your menstrual cycle.
 - Females who **are able** to get pregnant are females who:
 - have entered puberty, even if they have not started their menstrual period, **and**
 - have a uterus, **and**
 - have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.

- Females who **are not able** to get pregnant are females who:
 - have not yet entered puberty, **or**
 - do not have a uterus, **or**
 - have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed **or**
 - are infertile for other medical reasons and this infertility is permanent and cannot be reversed.

- **Females who are able to get pregnant must use two acceptable forms of birth control during treatment with bosentan tablets, and for one month after stopping bosentan tablets because the medicine may still be in the body.**
 - If you have had a tubal sterilization or have an IUD (intrauterine device), these methods can be used alone and no other form of birth control is needed.
 - Talk with your healthcare provider or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with bosentan tablets.
 - If you decide that you want to change the form of birth control that you use, talk with your healthcare provider or gynecologist to be sure that you choose another acceptable form of birth control.

See the chart below for Acceptable Birth Control Options during treatment with bosentan tablets.

- **Do not have unprotected sex. Talk to your healthcare provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your healthcare provider may talk with you about using emergency birth control.**
- **Tell your healthcare provider right away if you miss a menstrual period or think you may be pregnant.**

If you are the parent or caregiver of a female child who started taking bosentan tablets before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your healthcare provider right away if you notice that she is developing breast buds or any pubic hair. Your healthcare provider should decide if your child has reached puberty. **Your child may reach puberty before having her first menstrual period.**

Acceptable birth control options

| Option 1 | Option 2 | Option 3 | Option 4 |
|--|---|---|---|
| One method from this list: | One method from this list: | One method from this list: | One method from this list: |
| Standard intrauterine device (Copper T 380A IUD) | Estrogen and progesterone oral contraceptives (“the pill”) Estrogen and progesterone transdermal patch Vaginal ring | Diaphragm with spermicide Cervical cap with spermicide | Partner's vasectomy PLUS One method from this list: Male condom Diaphragm with spermicide |

| | | | | | | |
|--|----|--|----|--|----|---|
| Intrauterine system (LNg 20 IUS: progesterone IUS) | or | Progesterone injection | or | PLUS One method from this list: | or | Cervical cap with spermicide |
| Tubal sterilization | | Progesterone implant | | Male condom | | Estrogen and progesterone oral contraceptives (“the pill”) Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant |
| | | PLUS One method from this list: | | | | |
| | | Male condom | | | | |
| | | Diaphragm with spermicide | | | | |
| | | Cervical cap with spermicide | | | | |

See “What are the possible side effects of bosentan tablets?” for more information about side effects.

What are bosentan tablets?

Bosentan tablets are a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the vessels of the lungs.

Bosentan tablets can improve your ability to exercise and can slow the worsening of your physical condition and symptoms. Bosentan tablets lowers high blood pressure in your lungs and lets your heart pump blood more efficiently.

Bosentan tablets are only:

Prescribed by healthcare providers who are enrolled in the Bosentan REMS Program. Available to people who understand and agree to enroll in the Bosentan REMS Program.

Who should not take bosentan tablets?

Do not take bosentan tablets if you:

- **are pregnant, plan to become pregnant, or become pregnant during bosentan tablets treatment. Bosentan tablets can cause serious birth defects.** All females should read the **birth defects** section of “What is the most important information I should know about bosentan tablets?”
- take any of these medicines:
 - cyclosporine A used to treat psoriasis and rheumatoid arthritis, and to prevent rejection of heart, liver, and kidney transplants
 - glyburide used to treat diabetes
- are allergic to bosentan or any of the ingredients in bosentan tablets. See the end of this Medication Guide for a complete list of the ingredients in bosentan tablets. If you have a rash, hives or your lips swell after taking bosentan tablets, it may be a sign of allergy. You should stop taking your bosentan tablets and talk to your healthcare provider.

What should I tell my healthcare provider before taking bosentan tablets?

Bosentan tablets may not be right for you. **Tell your healthcare provider about all your medical conditions, including if you:**

- **have liver problems.**
- **are breast-feeding or plan to breast feed.** It is not known if bosentan passes into your milk. You and your healthcare provider should decide if you will take bosentan tablets or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Bosentan tablets and other medicines may affect how each other works and cause side effects. Especially tell your healthcare provider if you take:

- o hormone-based birth control, such as pills, shots, patches, and implants. These birth control methods may not work as well when taken with bosentan tablets.
- o simvastatin or other “-statin” medicines used to lower cholesterol
- o rifampin used for tuberculosis
- o ketoconazole, fluconazole, itraconazole, or voriconazole used for fungal infections
- o warfarin sodium used to prevent blood clots
- o ritonavir used to treat HIV

There may be more than one brand name medicine. Ask your healthcare provider if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your healthcare provider or pharmacist when you get a new medicine.

How should I take bosentan tablets?

Your healthcare provider will give you detailed information about the Bosentan REMS Program.

- Bosentan tablets are only available through certified pharmacies. You will only receive a 30-day supply of bosentan tablets at one time.
- Take bosentan tablets exactly as prescribed.
- Your healthcare provider will tell you how much bosentan tablets to take and when to take it.
- In most cases, you will take 1 tablet in the morning and 1 in the evening.
- You can take bosentan tablets orally with or without food.
- If you take more than the prescribed dose of bosentan tablets, call your healthcare provider right away.
- If you miss a dose of bosentan tablets, take your tablet as soon as you remember. Do not take 2 doses at the same time. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time.
- Do not stop taking bosentan tablets unless your healthcare provider tells you to. Suddenly stopping your treatment may cause your symptoms to get worse. If you need to stop taking bosentan tablets, speak with your healthcare provider about the right way to stop.

What are the possible side effects of bosentan tablets?

Bosentan tablets can cause serious side effects, including:

- **See “What is the most important information I should know about bosentan tablets?”**
- **Fluid retention and swelling of your ankles and legs. Bosentan tablets can cause your body to hold too much water, and you may get swelling of your ankles and legs. Tell your healthcare provider if you have swelling of your ankles and legs that happens either with or without weight gain, or if you have more trouble with your breathing than normal. Your healthcare provider will look for the cause of this.**

- **Lower Sperm Count. Some men who take bosentan tablets may have lower sperm counts. This may affect your ability to father a child. Tell your healthcare provider if fertility is a concern for you.**
- **Low red blood cell levels (anemia). Your healthcare provider will do blood tests to check your red blood cells during treatment with bosentan tablets.**

The most common side effects of bosentan tablets include:

- respiratory tract infection
- headache
- fainting
- flushing
- low blood pressure
- inflamed nose passages (sinusitis)
- joint pain
- irregular heart beats

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of bosentan tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store bosentan tablets?

- Store bosentan tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature].
- Bosentan tablets come in a child-resistant package.

Keep bosentan tablets and all medicines out of the reach of children.

General information about bosentan tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use bosentan tablets for a condition for which it was not prescribed. Do not give bosentan tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about bosentan tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about bosentan tablets that is written for health professionals. For more information, call 1-800-818-4555.

What are the ingredients in bosentan tablets?

Active ingredient: bosentan

Inactive ingredients: corn starch, pregelatinized maize starch, sodium starch glycolate, povidone, glyceryl behenate, magnesium stearate, hydroxypropylmethylcellulose, triacetin, talc, titanium dioxide, iron oxide yellow, iron oxide red, ethylcellulose.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Distributed by:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512



Manufactured by:

Sun Pharmaceutical Industries Ltd.

Survey No. 1012, Dadra-396 193,

U.T. of D & NH and Daman & Diu, India.

5245906
ISS.10/2023