



# **Pertensio (Bosentan)** Medication Guide

Version: 1

Date: 09/2018

## **Pertensio (Bosentan)**

### **Medication Guide**

Read the Medication Guide that comes with Pertensio 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 Pertensio?**

**Pertensio 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 Pertensio 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 Pertensio:
  - nausea
  - vomiting
  - fever
  - unusual tiredness
  - stomach area (abdominal) pain
  - yellowing of the skin or the whites of your eyes (jaundice)

#### **Serious birth defects.**

**Pertensio can cause serious birth defects if taken during pregnancy. You must not be pregnant when you start taking Pertensio or during Pertensio treatment. Serious birth defects from Pertensio can happen early in pregnancy. Females who are able to get pregnant must have a negative pregnancy test before starting treatment with Pertensio, each month during treatment with Pertensio, and 1 month after stopping treatment with Pertensio.**

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 Pertensio, and for one month after stopping Pertensio because the medicine may still be in the body.**

- o 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.
- o 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 Pertensio.
- o 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 Pertensio.**

- o **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.**
- o **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 Pertensio 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**

<b>options 1</b>	<b>options 2</b>	<b>options 3</b>	<b>options 4</b>
<p><b>One method from this list:</b> Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Tubal steriliza</p>	<p><b>One method from this list:</b> Estrogen &amp; Progesterone oral contraceptives (“the pill”) Estrogen &amp; progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant</p> <p><b>PLUS</b> <b>One method from this list</b> Male condom Diaphragm with permicide Cervical cap with spermicide</p>	<p><b>One method from this list:</b> Diaphragm with spermicide Cervical cap with spermicide</p> <p><b>PLUS</b> <b>One method from this list</b> Male condom</p>	<p><b>One method from this list:</b> Partner’s vasectomy</p> <p><b>PLUS</b> <b>One method from this list</b> Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen &amp; progesterone oral contraceptives (“the pill”) Estrogen &amp; progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant</p>

## What is Pertensio ?

Pertensio is 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.

Pertensio can improve your ability to exercise and can slow the worsening of your physical condition and symptoms.

Pertensio lowers high blood pressure in your lungs and lets your heart pump blood more efficiently.

## Who should not take Pertensio?

### Do not take Pertensio if you:

- are pregnant, plan to become pregnant, or become pregnant during Pertensio treatment. Pertensio can cause serious birth defects. All females should read the birth defects section of “What is the most important information I should know about Pertensio?”
- 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 Pertensio. If you have a rash, hives or your lips swell after taking Pertensio, it may be a sign of allergy. You should stop taking your Pertensio and talk to your healthcare provider.

## What should I tell my healthcare provider before taking Pertensio?

Pertensio 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 Pertensio passes into your milk. You and your healthcare provider should decide if you will take Pertensio 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. Pertensio and other medicines may affect how each other works and cause side effects. Especially tell your healthcare provider if you take:

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

## What are the possible side effects of Pertensio?

Pertensio can cause serious side effects, including:

- See “What is the most important information I should know about Pertensio?”
- **Fluid retention and swelling of your ankles and legs.** Pertensio 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 Pertensio 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 Pertensio.

The most common side effects of Pertensio 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 Pertensio. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

For further information please read the patient leaflet. If you have any further questions on the use of this medicine, ask your doctor, health care provider or pharmacist.

### Call of reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmaco-vigilance and Drug Safety Centre or Pharmacovigilance department in SPIMACO, according to the following

Calling: 19999

By e-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)

Or by fax: +966 11 2057662

Or by online: <https://ade.sfda.gov.sa>

Pharmacovigilance department in Spimaco:

QPPV: Arwa Alsayil

E-mail : [Arwa.alsayil@spimaco.sa](mailto:Arwa.alsayil@spimaco.sa)

Fax no. : +966 11 252 3300

Phone: +966 11 252 3393