

What is TRYVIO™?

TRYVIO™ (aprocitentan) is a prescription medicine for the treatment of high blood pressure, to lower blood pressure in patients who are not adequately controlled on other drugs. TRYVIO™ is for use in combination with other blood pressure lowering medications.

What are the serious risks of TRYVIO™?

- TRYVIO™ can cause serious birth defects if taken during pregnancy, including when taken before you know you are pregnant or during the first trimester.
- You cannot take TRYVIO™ if you are pregnant.
- You must not become pregnant while taking TRYVIO™, or
- Within one month after stopping TRYVIO™.
- **Your doctor will tell you about serious birth defects (embryo-fetal toxicity) associated with taking TRYVIO™ while pregnant.**

What is the TRYVIO™ Risk Evaluation and Mitigation Strategy (REMS)?

Because of the risk of serious birth defects, the FDA has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for TRYVIO™. The purpose of the REMS is to make sure the benefits of TRYVIO™ outweigh the risks. The TRYVIO™ REMS provides patients and healthcare providers with information and requirements to manage the risk of birth defects associated with taking TRYVIO™.

Before you begin treatment with TRYVIO™

- ☐ Read this guide.
- ☐ Ask your healthcare provider any questions you have about TRYVIO™, its benefits and risks, and the TRYVIO™ REMS requirements.
- ☐ Receiving counseling about the risk of serious birth defects.

Your healthcare provider has determined that you can become pregnant using the definitions that apply to the TRYVIO REMS shown below:

Patients Who Can Become Pregnant:

- Patients with a uterus who have entered puberty and all patients with a uterus that have not passed through Menopause (as defined below).
- For the purpose of the TRYVIO™ REMS, puberty includes those patients with a uterus who have undergone noticeable bodily changes (continued breast budding and pubic hair growth) and have not yet had a menstrual period.
- For the purpose of the TRYVIO™ REMS, patients who have undergone tubal sterilization are classified as patients who can become pregnant.

Patients Who Cannot Become Pregnant:

- Patients with a uterus who have not yet undergone noticeable bodily changes and are not considered to be of reproductive potential
- Patients with a uterus who have passed through Menopause (as defined below)
- Patients with other medical reasons for permanent, irreversible infertility
- Patients without a uterus (including patients who were born male)

Definition of Menopause:

- Menopause is defined as 12 months without menstruation (not induced by a medical condition or medical therapy) or post-surgical from removal of ovaries.

If you are a patient who can become pregnant, you should:

- ☐ Have a negative pregnancy test immediately before starting TRYVIO™.
- ☐ Have a negative pregnancy test each month while taking TRYVIO™ and for one month after discontinuing treatment.
- ☐ Use acceptable birth control at all times while taking TRYVIO™ and for one month after stopping TRYVIO™ using one of the four options in the chart below.
- ☐ **Report possible pregnancy immediately.**

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:
<ul style="list-style-type: none"> Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNG-20 IUS: progesterone IUS) Progesterone implant Tubal sterilization 	<ul style="list-style-type: none"> Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection 	<ul style="list-style-type: none"> Diaphragm with spermicide Cervical cap with spermicide 	<ul style="list-style-type: none"> Partner's vasectomy
	PLUS One method from this list: <ul style="list-style-type: none"> Male condom Diaphragm with spermicide Cervical cap with spermicide 	PLUS One method from this list: <ul style="list-style-type: none"> Male condom 	PLUS One method from this list: <ul style="list-style-type: none"> Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection

Talk to your healthcare provider right away if:

- You have a positive pregnancy test.
- You think your birth control has failed. Your healthcare provider may discuss medical options with you, such as emergency contraception.
- You missed your period.
- You think you are pregnant.

How will I receive TRYVIO™?

TRYVIO™ is only available at certified pharmacies. You must receive TRYVIO™ through a certified pharmacy and will receive a **Risk of Birth Defects with TRYVIO™** with your prescription.