

MEDICATION GUIDE
TRYVIO™ (try-vee-oh)
(aprocitentan)
tablets, for oral use

Read this Medication Guide before you start taking TRYVIO and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about TRYVIO?

TRYVIO may cause serious side effects, including:

Serious birth defects.

- **TRYVIO may cause serious birth defects if taken during pregnancy.**
- **People who can become pregnant must not be pregnant when they start taking TRYVIO or become pregnant during treatment with TRYVIO or for 1 month after stopping treatment with TRYVIO.**
- **People who can become pregnant should have a negative pregnancy test** before starting treatment with TRYVIO, each month during treatment with TRYVIO, and 1 month after stopping TRYVIO.
 - People who **can become pregnant** are people 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.
 - People who **cannot become pregnant** are people 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.
- **People who can become pregnant should use acceptable birth control before starting treatment with TRYVIO, during treatment with TRYVIO, and for 1 month after stopping TRYVIO** because the medicine may still be in your body.
 - If you have had a tubal sterilization, have a progesterone implant, or have an intrauterine device (IUD), these methods can be used alone, and no other form of birth control is needed.
 - Talk with your healthcare provider or gynecologist (a healthcare provider who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with TRYVIO.
 - 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 TRYVIO.

Acceptable birth control options

Option 1	or	Option 2	or	Option 3	or	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")		Diaphragm with spermicide		Partner's vasectomy
Intrauterine system (LNG-20 IUS; progesterone IUS)		Estrogen and progesterone transdermal patch		Cervical cap with spermicide		PLUS One method from this list:
Progesterone implant		Vaginal ring		PLUS One method from this list:		Male condom
Tubal sterilization		Progesterone injection		Male condom		Diaphragm with spermicide
		PLUS One method from this list:				Cervical cap with spermicide
		Male condom				Estrogen and progesterone oral contraceptives ("the pill")
		Diaphragm with spermicide				Estrogen and progesterone transdermal patch
		Cervical cap with spermicide				Vaginal ring
						Progesterone injection

- **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 you think you might be pregnant.**

People can only receive TRYVIO through a restricted program called the TRYVIO REMS. If you are a person who can become pregnant, your healthcare provider will talk to you about pregnancy testing recommendations and the need to use acceptable birth control, the benefits and risks of TRYVIO, and the need to report suspected pregnancy right away to your healthcare provider.

TRYVIO is only available through certified pharmacies that participate in the TRYVIO REMS program. Your healthcare provider can give you information about how to find a certified pharmacy. For more information, go to www.TRYVIOREMS.com or call 1-866-429-8964.

See **"What are the possible side effects of TRYVIO?"** for more information about side effects.

What is TRYVIO?

TRYVIO is a prescription medicine used to treat high blood pressure (hypertension) in adults who are taking other high blood pressure medicines and whose blood pressure is not well controlled.

It is not known if TRYVIO is safe and effective in children.

Who should not take TRYVIO?

Do not take TRYVIO if you are:

- **pregnant or currently trying to become pregnant.** See **"What is the most important information I should know about TRYVIO?"**.
- **allergic to aprocitentan or any of the ingredients in TRYVIO.** See the end of this Medication Guide for a complete [list of ingredients](#) in TRYVIO.

Before taking TRYVIO, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have heart failure
- have anemia
- have kidney problems or get dialysis
- are pregnant or plan to become pregnant during treatment with TRYVIO. TRYVIO can cause serious birth defects. See **"What is the most important information I should know about TRYVIO?"**
- are breastfeeding or plan to breastfeed. It is not known if TRYVIO passes into your breastmilk. **Do not breastfeed** if you take TRYVIO. Talk to your healthcare provider about the best way to feed your baby if you take TRYVIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take TRYVIO?

- Take TRYVIO exactly how your healthcare provider tells you to take it and **do not** stop taking TRYVIO unless your healthcare provider tells you to.
- Swallow TRYVIO tablets whole.
- Take TRYVIO with or without food.
- If you take too much TRYVIO, contact your healthcare provider or Poison Control Center at 1-800-222-1222 or www.poison.org, or go to the nearest hospital emergency room right away.
- If you miss a dose of TRYVIO, skip the missed dose and take the next dose at your regularly scheduled time. **Do not** take 2 doses in the same day to make up for a missed dose.

What are the possible side effects of TRYVIO?

TRYVIO may cause serious side effects, including:

- **Serious birth defects.** See "[What is the most important information I should know about TRYVIO?](#)"
- **Liver problems.** TRYVIO may cause liver problems. Your healthcare provider should do blood tests to check your liver before starting treatment and as needed during treatment with TRYVIO. Tell your healthcare provider if you have any of the following symptoms of liver problems during treatment with TRYVIO:
 - nausea or vomiting
 - pain in the upper right stomach
 - tiredness
 - loss of appetite
 - yellowing of your skin or whites of your eyes
 - dark urine
 - fever
 - itching
- **Fluid retention.** Fluid retention and swelling are common during treatment with TRYVIO and can be serious. Tell your healthcare provider right away if you have any unusual weight gain, trouble breathing, or swelling of your ankles or legs. Your healthcare provider may treat you with other medicines (diuretics) if you develop fluid retention or swelling.
- **Low red blood cell levels (anemia).** Anemia is common during treatment with TRYVIO and can be serious. Your healthcare provider will do blood tests to check your red blood cells before starting and as needed during treatment with TRYVIO.
- **Decreased sperm count.** TRYVIO may cause decreased sperm counts in males and may affect the ability to father a child. Tell your healthcare provider if being able to have children is important to you.

Your healthcare provider may stop treatment with TRYVIO if you develop certain side effects. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TRYVIO. 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 TRYVIO?

- Store TRYVIO tablets at room temperature, between 68°F to 77°F (20°C and 25°C).
- Keep TRYVIO tablets in the original container.
- Tightly close the TRYVIO bottle cap each time after opening.
- The TRYVIO bottle contains a desiccant packet to help keep your tablets dry (protect them from moisture). **Do not** throw away the desiccant packet and keep it in the bottle.
- Protect TRYVIO from light and moisture.
- **Keep TRYVIO and all medicines out of the reach of children.**

General information about the safe and effective use of TRYVIO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRYVIO for a condition for which it was not prescribed. Do not give TRYVIO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TRYVIO that is written for health professionals.

What are the ingredients in TRYVIO?

Active ingredient: aprocitentan

Inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. **Film coating:** hydroxypropyl cellulose, iron oxide black, iron oxide red, iron oxide yellow, polyvinyl alcohol, silica colloidal hydrated, talc, titanium dioxide, and triethyl citrate.

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