

MEDICATION GUIDE

Macitentan (ma" si ten' tan) Tablets

Read this Medication Guide for macitentan tablets before you start taking macitentan tablets 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 macitentan tablets?

- **Serious birth defects.**

Macitentan tablets can cause serious birth defects if taken during pregnancy.

- **Females should not be pregnant when they start taking macitentan tablets or become pregnant during treatment with macitentan tablets.**
- Females who are able to get pregnant should have a negative pregnancy test before beginning treatment with macitentan tablets. Talk to your healthcare provider about your menstrual cycle. Your healthcare provider will decide when to do the 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 should use effective birth control before starting treatment with macitentan tablets, during treatment, and for one month after stopping macitentan tablets because the medicine may still be in the body.

- 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 macitentan 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.
- **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 macitentan 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.**

If you are a female who can get pregnant, you should talk to your healthcare provider to understand the benefits and risks of macitentan tablets.

What are macitentan tablets?

- Macitentan tablets are a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.
- Macitentan tablets can improve your ability to exercise, improve some of your symptoms, and help slow down the progression of your disease. Macitentan tablets can also lower your chance of being hospitalized for PAH.
- It is not known if macitentan tablets are safe and effective in children.

Who should not take macitentan tablets?

Do not take macitentan tablets if you are pregnant, plan to become pregnant, or become pregnant during treatment with macitentan tablets. Macitentan tablets can cause serious birth defects (see the Medication Guide section above called "What is the most important information I should know about macitentan tablets?").

Do not take macitentan tablets if you are allergic to macitentan or any of the ingredients in macitentan tablets. See the end of this Medication Guide for a complete list of ingredients in macitentan tablets.

Tell your healthcare provider about all your medical conditions and all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Macitentan tablets and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your healthcare provider.

Especially tell your healthcare provider if you take an HIV medicine.

How should I take macitentan tablets?

Macitentan tablets will be mailed to you by a specialty pharmacy. Your healthcare provider will give you complete details.

- Take macitentan tablets exactly as your healthcare provider tells you to take it. Do not stop taking macitentan tablets unless your healthcare provider tells you.
- You can take macitentan tablets with or without food.
- If you take too much macitentan tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- If you miss a dose of macitentan tablets, take it as soon as you remember that day. Take the next dose at your regular time. Do not take 2 doses at the same time to make up for a missed dose.

What should I avoid while taking macitentan tablets?

- **Do not get pregnant while taking macitentan tablets.** See the serious birth defects section of the Medication Guide above called “What is the most important information I should know about macitentan tablets?” If you miss a menstrual period, or think you might be pregnant, call your healthcare provider right away.
- **It is not known if macitentan passes into your breastmilk. You should not breastfeed if you take macitentan tablets.** Talk to your healthcare provider about the best way to feed your baby if you take macitentan tablets.

What are the possible side effects of macitentan tablets?

Macitentan tablets can cause serious side effects, including:

- **Serious birth defects.** See “What is the most important information I should know about macitentan tablets?”
- Some medicines that are like macitentan tablets can cause liver problems. Your healthcare provider should do blood tests to check your liver before you start taking macitentan tablets. Tell your healthcare provider if you have any of the following symptoms of liver problems while taking macitentan tablets.
 - 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** can happen within weeks after starting macitentan tablets. Tell your healthcare provider right away if you have any unusual weight gain or swelling of your ankles or legs. Your healthcare provider will look for the cause of any fluid retention.
- **Low red blood cell levels (anemia) can occur with macitentan tablets treatment, usually during the first weeks after starting therapy. In some cases a blood transfusion may be needed, but this is not common.** Your healthcare provider will do blood tests to check your red blood cells before starting macitentan tablets. Your healthcare provider may also need to do these tests during treatment with macitentan tablets.
- **Decreased sperm count.** Macitentan tablets, and other medicines like macitentan tablets, may cause decreased sperm counts in men who take these medicines. A decreased sperm count may affect the ability to father a child. Tell your healthcare provider if being able to have children is important to you.

The most common side effects of macitentan tablets are:

- Stuffy nose or sore throat
- Irritation of the airways (bronchitis)
- Headache
- Flu
- Urinary tract infection

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 macitentan tablets. For more information, ask your healthcare provider or pharmacist.

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

How should I store macitentan tablets?

- Store macitentan tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- Macitentan tablets comes in a child-resistant package.
- **Keep macitentan tablets and all medicines out of the reach of children.**

General information about macitentan tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use macitentan tablets for a condition for which it was not prescribed. Do not give macitentan 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 macitentan tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about macitentan tablets that is written for health professionals.

For more information, call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in macitentan tablets?

Active ingredient: macitentan

Inactive ingredients: croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, poloxamer 188, povidone, sodium stearyl fumarate. The tablets are film-coated with a coating material containing lecithin (soya), polyvinyl alcohol, talc, titanium dioxide and xanthan gum.

Manufactured by:

Alembic Pharmaceuticals Limited
(Formulation Division),
Panelav 389350, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, USA