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2. Macitentan

Macitentan

Generic name: macitentan [*MA-si-TEN-tan*]

Brand name: [Opsumit](#)

Dosage form: oral tablet (10 mg)

Drug class: [Agents for pulmonary hypertension](#)



[Medically reviewed](#) by Drugs.com on Oct 28, 2024. Written by [Cerner Multum](#).

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What is macitentan?

Macitentan lowers blood pressure in your lungs, helping your heart pump blood more efficiently.

Macitentan is used to treat pulmonary arterial hypertension (PAH). It improves your ability to exercise and prevents your condition from getting worse.

Macitentan is available **to women** only under a special program from a certified pharmacy. You must be registered in the program and understand the risks and benefits of taking this medication.

Macitentan may also be used for purposes not listed in this medication guide.

Macitentan side effects

Get emergency medical help if you have **signs of an allergic reaction:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Macitentan may cause serious side effects. Stop using macitentan and call your doctor at once if you have:

- pain or burning when you urinate;
- swelling, rapid weight gain;
- **liver problems**--nausea, upper stomach pain, [itching](#), tired feeling, loss of appetite, dark urine, clay-colored stools, [jaundice](#) (yellowing of the skin or eyes); or
- **new lung problems**--[anxiety](#), [sweating](#), pale skin, severe [shortness of breath](#), [wheezing](#), gasping for breath, cough with foamy mucus, chest pain, fast or uneven heart rate.

Common side effects of macitentan may include:

- stuffy nose, sinus pain, [sore throat](#);
- a [bladder infection](#);

- [headache](#); or
- flu symptoms (fever, chills, body aches).

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Macitentan side effects](#) (more detail)

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Warnings

Do not use macitentan if you are pregnant or think you might be pregnant. Use highly effective [birth control](#) to prevent pregnancy while using macitentan and for at least 30 days after your treatment ends.

You will need to take a pregnancy test before, during, and after treatment with macitentan.

Before taking this medicine

You should not use macitentan if you are allergic to it.

Tell your doctor if you have ever had:

- [liver disease](#);
- [heart disease](#); or
- anemia (low red blood cells).

This medicine can harm an unborn baby or cause birth defects. **Do not use macitentan if you are pregnant or think you might be pregnant.** Tell your doctor right away if you miss a menstrual period or think you may have become pregnant during treatment.

You will need to have a negative pregnancy test before starting this treatment. You will be re-tested every month during your treatment, and 1 month after you stop taking this medicine.

Even if you are not planning a pregnancy, **you are considered able to become pregnant if:**

- you have entered puberty (even if you have not yet started having periods);
- you have never had a [hysterectomy](#) or had your ovaries removed; or
- you have not gone through [menopause](#) (you have never gone 12 months in a row without a menstrual period).

While taking macitentan and for 30 days after your last dose, you must use a highly effective form of birth control, or two methods together.

- A tubal ligation alone is an effective birth control method.
- An intrauterine device (IUD) or birth control implant alone are also effective birth control methods.
- If you use [birth control pills](#), injections, skin patches, or vaginal rings, you must use a back-up barrier form of birth control, such as a condom or diaphragm or cervical cap. Always use a spermicide gel or insert together with a barrier form of birth control.
- If you use only a barrier method, you must use a second barrier method as a back-up. For example, use a diaphragm or cervical cap in addition to a condom, plus a spermicide gel or insert.
- If your sexual partner has had a vasectomy, you must still use a second method of birth control--either a barrier method or a hormonal form (birth control pills, injections, skin patch, or [vaginal ring](#)).

Macitentan comes with patient instructions about acceptable forms of birth control to use while taking this medicine. Follow these directions carefully. Ask your doctor or pharmacist if you have any questions.

If you are the parent or caregiver of a female child taking this medicine, talk to the child's doctor once you notice any signs of puberty (breast development or pubic hair), even if menstrual periods have not yet begun.

Macitentan can decrease sperm count and may affect fertility in men (your ability to have children).

You should not breast-feed while using this medicine.

How should I take macitentan?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

You may take macitentan with or without food.

Swallow the tablet whole and do not crush, chew, or break it.

While using macitentan, you may need frequent blood tests.

Store at room temperature away from moisture and heat.

Macitentan dosing information

Usual Adult Dose for Pulmonary Hypertension:

10 mg orally once a day

Uses: For the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression

 [Detailed Macitentan dosage information](#)

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. **Do not** take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking macitentan?

Do not have unprotected sex while taking macitentan. You must use birth control to prevent pregnancy during treatment and for at least 30 days after you stop taking macitentan.

What other drugs will affect macitentan?

Other drugs may affect macitentan, including prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Tell each of your health care providers about all medicines you use now and any medicine you start or stop using.

 [Macitentan drug interactions](#) (more detail)

Does macitentan interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

macitentan

+

Enter a drug name

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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only


Pregnancy & Lactation

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



User Reviews & Ratings

7.5 / 10

[11 Reviews](#)

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