Opsumit

Generic name: macitentan [*MA-si-TEN-tan*]
Drug class: Agents for pulmonary hypertension

Medically reviewed by Philip Thornton, DipPharm. Last updated on Dec 2, 2024.

Uses   Warnings   Before taking   Dosage   Side effects   Interactions

What is Opsumit?

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

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

Opsumit 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.

Warnings

Do not use Opsumit if you are pregnant. Tell your doctor right away if you miss a menstrual period or think you may have become pregnant during treatment. You must use highly effective birth control methods to prevent pregnancy while you are using this medication and for at least 30 days after your treatment ends.

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

Before taking this medicine

You should not use Opsumit if you are allergic to macitentan, or if you are pregnant or might become pregnant during treatment.

To make sure this medicine is safe for you, tell your doctor if you have ever had:

- liver disease;

- heart disease; or

- anemia (low red blood cells).

This medication can harm an unborn baby or cause birth defects. **Do not use Opsumit 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 Opsumit 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).

Opsumit 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 medication, 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.

ⓘ [Opsumit pregnancy and breastfeeding warnings](#) (more detail)

How should I take Opsumit?

Take Opsumit exactly as prescribed by your doctor. Follow all directions on your prescription label. Do not take this medicine in larger or smaller amounts or for longer than recommended.

You may take this medicine with or without food.

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

While using Opsumit, you may need frequent blood tests.

Store at room temperature away from moisture and heat.

Dosing information

Usual Adult Dose for Pulmonary Hypertension:

Recommended dose: 10 mg orally once a day

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

ℹ️ [Detailed Opsumit dosage information](#)

What happens if I miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

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

What to avoid

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

Opsumit side effects

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

Stop using Opsumit 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 Opsumit side effects 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.

ℹ Opsumit side effects (more detail)

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What other drugs will affect Opsumit?

Other drugs may interact with 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.

ⓘ Opsumit drug interactions (more detail)

Does Opsumit interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Opsumit

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Professional resources

- Opsumit prescribing information
- Macitentan (AHFS Monograph)

Related treatment guides

- Pulmonary Arterial Hypertension

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.

Medical Disclaimer

DRUG STATUS

Rx

Availability
Prescription only

Pregnancy & Lactation
Risk data available

N/A

CSA Schedule*
Not a controlled drug ⌄

10+ years

Approval History
FDA approved 2013 ⌄

User Reviews & Ratings

8.2 / 10

10 Reviews

Images

Opsumit 10 mg (10)

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