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Macitentan

pronounced as (ma" si ten' tan)

IMPORTANT WARNING:

For female patients:

Do not take macitentan if you are pregnant or plan to become pregnant. There is a high risk that macitentan will cause harm to the fetus.

Because of the risk of fetal harm, a program called OPSUMIT Risk Evaluation and Mitigation Strategy (OPSUMIT REMS) has been set up to make sure that pregnant woman do not take macitentan, and that woman do not become pregnant while taking macitentan. All females, including females who are not able to get pregnant, can only receive macitentan if they are registered with OPSUMIT REMS, have a prescription from a doctor who is registered with OPSUMIT REMS, and fill the prescription at a pharmacy that is registered with OPSUMIT REMS.

Your doctor will register you in OPSUMIT REMS. Your doctor will tell you about the risks of macitentan, especially the risks of serious birth defects if taken while pregnant. You must sign an informed consent sheet stating that you understand this information in order for your doctor to register you.

Your doctor will also determine if you are able to become pregnant. If you have reached puberty (when child's body becomes physically mature and capable of having a child), have a uterus, and have not yet gone through menopause ('change in life' end of monthly menstrual periods) you are considered to be a female who is able to become pregnant, and you will have to follow certain additional rules in order to receive macitentan.

For females who are able to become pregnant:

You must use reliable birth control throughout your treatment with macitentan, and for 1 month after your final dose. Your doctor will tell you which forms of birth control are acceptable, and will give your written information about birth control. In most cases you will be required to use two forms of birth control in order to prevent pregnancy while taking macitentan.

You will have to take a pregnancy test before starting treatment, every month during treatment, and 1 month after your final dose in order to be able to receive macitentan. Your doctor will order the

pregnancy tests for you. The pharmacy will not dispense macitentan to you until they have confirmed that you have taken your required pregnancy tests.

You must not have unprotected sex while taking macitentan.

Call your doctor right away if you have had unprotected sex, think your birth control failed, missed your period, or think you may be pregnant for any reason. He will discuss your medical options with you. Do not wait until your next appointment to discuss this with your doctor.

Tell your doctor if you do not understand everything you were told about birth control, or if you do not think you will be able to use acceptable forms of birth control at all times during your treatment.

If you are a parent or guardian of a female who had not yet reached puberty, check your child regularly to see if she is developing any signs of puberty (breast buds, pubic hair)and let her doctor know about any changes.

For all patients:

Macitentan is not available at retail pharmacies. Your medication will be mailed to you from a specialty pharmacy that is registered with OPSUMIT REMS. If you are a female who has not reached puberty or a female who is able to become pregnant you will only receive a 30 day supply at a time. Ask your doctor if you have any questions about how you will receive your medication.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with macitentan and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Macitentan is used to manage the symptoms of pulmonary arterial hypertension (PAH; high blood pressure in the vessels that carry blood to the lungs). Macitentan is in a class of medications called endothelin receptor antagonists. It works by stopping the action of endothelin, a natural substance that causes blood vessels to narrow and prevents normal blood flow in people who have PAH.

How should this medicine be used?

Macitentan comes as a tablet to take by mouth. It is usually taken with or without food once a day. Take macitentan at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take macitentan exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole; do not split, chew, or crush them.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking macitentan,

- tell your doctor and pharmacist if you are allergic to macitentan, any other medications, or any of the ingredients in macitentan tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: carbamazepine (Carbatrol, Epitol, Equetro, Tegretol), clarithromycin (Biaxin, in Prevpac); efavirenz (Sustiva); certain HIV protease inhibitors such as nelfinavir (Viracept), indinavir (Crixivan), and ritonavir (Norvir, in Kaletra); itraconazole (Onmel, Sporanox); ketoconazole; nefazodone; nevirapine (Viramune); phenobarbital; phenytoin (Dilantin, Phenytek); rifabutin (Mycobutin); and rifampin (Rifadin, Rifamate, Rifater, Rimactane). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with macitentan, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had anemia (condition in which red blood cells do not bring enough oxygen to the organs) or liver disease.
- do not breastfeed while taking this medication.
- you should know that this medication may decrease fertility in men. Talk to your doctor about the risks of taking macitentan.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Macitentan may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- stuffy nose
- sore throat
- cough

- flu like symptoms
- headache
- urgent, frequent, or painful urination
- rash

Some side effects can be serious. If you experience any of these symptoms, stop taking macitentan and call your doctor immediately or get emergency medical treatment:

- itchy skin
- dark urine
- yellowing of your skin or eyes
- pain in the upper right part of your stomach
- unexplained nausea or vomiting
- loss of appetite
- extreme tiredness
- fever
- swelling of the face, throat, tongue, lips, and eyes
- difficulty swallowing or breathing
- hoarseness
- shortness of breath, especially when lying down
- coughing up pink, frothy sputum or blood
- unusual weight increase
- swelling of the ankles or legs

Macitentan may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and

young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- headache
- nausea
- vomiting

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order tests to see how well your liver is working, and to check for anemia before starting treatment and from time to time during your treatment with macitentan.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Opsumit®

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