

MEDICATION GUIDE

MERIDIA® (mer-ID-dee-uh) (CIV)

(sibutramine hydrochloride monohydrate)

Capsules

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

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

MERIDIA can cause serious side effects including a large increase in your blood pressure or heart rate (pulse). Do not take MERIDIA if your blood pressure is not well controlled. Call your doctor right away if you check your blood pressure and it is higher than normal for you, or if you have symptoms of high blood pressure such as headache, dizziness or blurred vision.

Before you start taking MERIDIA, your doctor should check your blood pressure and heart rate. Your doctor should continue checking your blood pressure regularly while you are taking MERIDIA. It is important that you have regular check-ups while you are taking MERIDIA.

What is MERIDIA?

MERIDIA is a prescription medicine used to help overweight or obese people lose weight and keep the weight off. MERIDIA should be used together with a low calorie diet.

MERIDIA contains **sibutramine**, a substance that people can become addicted to. Keep your MERIDIA in a safe place to protect it from theft. Never give your MERIDIA to anyone else, because it may cause death or harm them. Selling or giving away this medicine is against the law.

The use of MERIDIA for more than 2 years has not been studied.

It is not known if MERIDIA is safe and effective in children younger than 16 years old.

Who should not take MERIDIA?

Do not take MERIDIA if you:

- have or have had, heart problems, including:
 - heart attack
 - chest pain
 - heart failure

- fast or irregular heart beat
- hardening of your arteries or other blood vessels
- poor circulation in your legs
- have or have ever had, a stroke or symptoms of a stroke
- uncontrolled high blood pressure (above 145/90)
- are over age 65
- are taking or have taken a type of medicine used to treat depression called a monoamine oxidase inhibitor (MAOI) in the past 2 weeks. Do not take MAOIs for at least 2 weeks before using MERIDIA. Do not take MAOIs for at least 2 weeks after stopping MERIDIA. Ask your doctor or pharmacist if you are not sure if any of your medicines are MAOIs.
- have an eating problem called anorexia nervosa or bulimia nervosa.
- are taking certain other weight loss medicines.
- are allergic to sibutramine hydrochloride monohydrate or any other ingredients in MERIDIA. See the end of this Medication Guide for a complete list of ingredients in MERIDIA.

Talk to your doctor before taking this medicine if you have any of these conditions.

What should I tell my doctor before taking MERIDIA?

Before you take MERIDIA, tell your doctor if you:

- have liver or kidney problems
- have glaucoma
- have or had seizures (convulsions, fits)
- have bleeding problems
- have or had gallstones
- are pregnant or plan to become pregnant. It is not known if MERIDIA will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant. If you can become pregnant, you should use birth control while taking MERIDIA. Tell your doctor right away if you become pregnant while taking MERIDIA.
- are breastfeeding or plan to breastfeed. It is not known if MERIDIA passes into your breast milk. You and your doctor should decide if you will take MERIDIA or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using MERIDIA with certain other medicines may affect how MERIDIA or the other medicines work. Using MERIDIA with other medicines can cause serious side effects.

Especially tell your doctor if you take:

- a **monoamine oxidase inhibitors (MAOIs)** medicine. See "**Who should not take MERIDIA?**"
- other weight loss medicines
- cough and cold medicines
- migraine headache medicines like sumatriptan (Imitrex, Imitrex Statdose) or dihydroergotamine (D.H.E 45, Migranal)
- medicines to treat depression
- narcotic pain medicines
- lithium (Lithobid)
- tryptophan
- medicines that thin the blood

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get new medicine.

How should I take MERIDIA?

- Take MERIDIA exactly as your doctor tells you to.
- Take MERIDIA 1 time a day.
- If you miss a dose of MERIDIA, just skip it. Do not take an extra dose to make up for missed doses.
- If you take too much MERIDIA, call your doctor or Poison Control Center right away, or go to the emergency room.
- Your doctor may change your dose if needed.
- Take MERIDIA with or without food.
- You should see your doctor regularly for check-ups.

What should I avoid while taking MERIDIA?

- Do not drive, operate heavy machinery or do other dangerous activities until you know how MERIDIA affects you.
- Do not have more than two standard alcoholic drinks per day while you take MERIDIA.

What are the possible side effects of MERIDIA?

MERIDIA may cause serious side effects, including:

- See “What is the most important information I should know about MERIDIA?”
- serotonin syndrome. Serotonin syndrome may happen when people take MERIDIA with certain other medicines that affect a brain chemical called serotonin. Do not take other medicines with MERIDIA unless your doctor has told you to. Get medical help right away if you have any of the following symptoms:
 - feel weak, restless, confused, or anxious
 - lose consciousness (faint)
 - have a fever, vomiting, sweating, shivering or shaking
 - have a fast heartbeat
- seizures (convulsions, fits)
- bleeding. Bleeding may happen if you have a condition that causes bleeding or if you take a blood thinning medicine.

Certain weight loss medicines have a rare but life-threatening problem that affects blood pressure in the lungs (pulmonary hypertension). It is not known if MERIDIA may cause this problem because pulmonary hypertension is so rare. Call your doctor right away if you have new or worsening shortness of breath.

The most common side effects of MERIDIA include:

- dry mouth
- loss of appetite
- trouble sleeping
- constipation
- headache

Tell your doctor if you get a rash or hives while taking MERIDIA. You may be having an allergic reaction.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the side effects of MERIDIA. For more information, ask your doctor or pharmacist.

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 MERIDIA?

- Store MERIDIA between 59°F to 86° F (15°C to 30° C).
- Keep MERIDIA capsules dry and away from heat.
- Keep MERIDIA in a tightly closed container, and keep MERIDIA out of the light.
- Safely throw away medicine that is out of date or no longer needed.

Keep MERIDIA and all medicines out of reach of children.

General information about MERIDIA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MERIDIA for a condition for which it was not prescribed. Do not give MERIDIA to other people, even if they have the same symptoms you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about MERIDIA. If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information about MERIDIA that is written for health professionals.

For more information, go to www.Meridia.net, or call 1-800-633-9110.

What are the ingredients in MERIDIA?

Active ingredient: sibutramine hydrochloride monohydrate

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate.

Hard-gelatin capsule: titanium dioxide, gelatin, FD&C Blue No. 2 (5 mg and 10 mg capsules only), D&C Yellow No. 10 (5 mg and 15 mg capsules only), and other inactive ingredients.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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