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SLIMEX INSTRUCTIONS

PATIENT INFORMATION

Read the Patient Information that comes with SLIMEX before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

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

Some people taking SLIMEX can have a large increase in blood pressure or heart rate (pulse). Do not take SLIMEX if your blood pressure is not well controlled. Contact your doctor if you experience an increase in blood pressure while taking SLIMEX.

Your doctor should check your blood pressure and heart rate before you start SLIMEX and continue checking it regularly while you are using SLIMEX. It is important to have regular check-ups while taking SLIMEX.

What is SLIMEX?

SLIMEX is a medicine that may help obese people, as determined by their doctor, lose weight and keep weight off. SLIMEX may help with weight loss because it affects areas of the brain that control hunger. You should use SLIMEX with a low calorie diet.

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

SLIMEX has not been studied in children under 16 years of age.

Who should not take SLIMEX?

Do not take SLIMEX if you:

- have uncontrolled or poorly controlled high blood pressure.
- are taking or have taken a medicine called a monoamine oxidase inhibitor (MAOI). Ask your doctor or pharmacist if you are not sure if any of your medicines are MAOIs. Do not take MAOIs for at least 2 weeks before using SLIMEX. Do not take MAOIs for at least 2 weeks after stopping SLIMEX.
- have an eating disorder called anorexia nervosa or bulimia nervosa.
- are taking weight loss medicines to control your appetite.
- are allergic to SLIMEX. The active ingredient is sibutramine hydrochloride monohydrate. See the end of this leaflet for a complete list of ingredients in SLIMEX.

How should I take SLIMEX?

- Take SLIMEX exactly as prescribed. Your doctor may adjust your dose. Do not change your dose unless your doctor tells you to do so.
- You can take SLIMEX with or without food.
- If you miss a dose of SLIMEX, just skip it. Do not take an extra dose to make up for missed doses.
- If you take too much SLIMEX, call your doctor or Poison Control Center right away, or go to the emergency room.
- Tell your doctor if you do not lose at least 4 pounds in the first 4 weeks of taking SLIMEX and eating a low calorie diet. Your doctor may change your dose or stop SLIMEX. SLIMEX does not work for everyone.

What should I avoid while taking SLIMEX?

SLIMEX may not be the right medicine for you if you have certain medical conditions. Tell your doctor about all of your

medical conditions, especially if you:

- have high blood pressure.
- have or had heart problems such as a heart attack, heart failure, chest pain or an irregular heartbeat.
- had a stroke or stroke symptoms.
- have liver or kidney problems.
- have an eye problem called glaucoma.
- have a thyroid problem (hypothyroidism).
- have or had seizures (convulsions, fits).
- have bleeding problems.
- have or had gallstones.
- have depression.
- are over age 65.
- are under age 16.
- are pregnant or planning to become pregnant. The effects of SLIMEX on your unborn baby are not known. If you can become pregnant, you should use birth control while taking SLIMEX. Tell your doctor right away if you get pregnant while taking SLIMEX.
- are breastfeeding. It is not known if SLIMEX passes into your milk. The effects of SLIMEX on your baby are not known. You should not breastfeed while taking SLIMEX.

Do not drive, operate heavy machinery or do other dangerous activities until you know how SLIMEX affects you.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking SLIMEX and certain other medicines may affect each other and may cause serious and in some cases lifethreatening side effects. Make sure you tell your doctor if you take:

- medicines called MAOIs, see "Who should not take SLIMEX?"
- other weight loss medicines
- cough and cold medicines
- migraine medicines
- depression medicines
- narcotic pain-killers
- lithium
- tryptophan
- medicines that increase bleeding
- antibiotic medicines

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get new medicine. They can tell you if it is okay to take SLIMEX with other medicines.

What are the possible side effects of SLIMEX?

Common side effects of SLIMEX include: dry mouth, headache, loss of appetite, trouble sleeping, and constipation.

The following serious side effects have been reported with SLIMEX:

- a large increase in blood pressure or heart rate in some people. See "What is the most important information I should know about SLIMEX?"
- seizures
- bleeding
- rare, but life-threatening problem called "serotonin syndrome." It may occur when people take drugs that affect a brain chemical called serotonin along with SLIMEX. Do not take other medicines with SLIMEX unless your doctor has told

you it is okay to do so. Get medical help right away if you have any of the following symptoms especially when taking other medicines with SLIMEX:

- feel weak, restless, confused, or anxious
- lose consciousness
- have a fever, vomiting, sweating, shivering or shaking
- have a fast heartbeat

Certain weight loss medicines have been associated with a rare, but life-threatening condition that affects the blood pressure in lungs (pulmonary hypertension). Because the condition is so rare it is not known if SLIMEX may cause this disease. If you experience new or worsening shortness of breath notify your doctor immediately.

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

Tell your doctor if you get effects that bother you or that do not go away.

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

SLIMEX is a controlled substance (CIV). This means that SLIMEX can be a target for people who abuse prescription medicines.

Keep your SLIMEX in a safe place. Selling or giving away SLIMEX is against the law.

How should I store SLIMEX?

- Store SLIMEX at room temperature between 59° to 86° F (15° to 30° C). Never leave it in a hot or moist place.
- Safely throw away SLIMEX that is out of date or no longer needed.
- Keep SLIMEX and all medicines out of reach of children. If your child accidentally takes SLIMEX, call their doctor or Poison Control Center right away, or take your child to the emergency room.

General information about SLIMEX.

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use SLIMEX for a condition for which it was not prescribed. Do not give SLIMEX to other people, even if they have the same symptoms you have. It may harm them and it is against the law.

This leaflet summarizes the most important information about SLIMEX. If you would like more information, talk to your doctor.

You can also ask your doctor or pharmacist for information that is written for health professionals.

What are the ingredients in SLIMEX?

Active Ingredient: sibutramine hydrochloride monohydrate Inactive Ingredients: lactose monohydrate, NF; microcrystalline cellulose,

NF; colloidal silicon dioxide, NF; and magnesium stearate, NF in a hard-gelatin capsule [which contains titanium dioxide, USP;

gelatin; FD&C Blue No. 2 (5- and 10-mg capsules only); D&C Yellow No. 10 (5- and 15-mg capsules only), and other inactive

ingredients].