

APEMIN®

15 mg Capsules

Information about APEMIN

Each APEMIN capsule for oral administration contains 15 mg sibutramine hydrochloride monohydrate.

Sibutramine is an anti-obesity agent which produces its therapeutic effects by norepinephrine, serotonin and dopamine reuptake inhibition.

Sibutramine helps to lose weight by increasing the amount in the brain of free norepinephrine and serotonin which control hunger. This enhances the feeling of fulfillment from eating, and so makes you feel satisfied after eating less food.

APEMIN helps obese people, as determined by their doctor, lose weight and keep weight off.

APEMIN is indicated for the management of obesity, including weight loss and maintenance of weight loss.

APEMIN is also recommended for obese patients with other risk factors such as diabetes and dyslipidemia.

It is recommended to use APEMIN in conjunction with a reduced calorie diet.

The use of sibutramine is associated with improvements in lipid profile, serum uric acid and glycemic control.

The way to take APEMIN

Take APEMIN as directed by your physician.

The usual recommended dose is one capsule of 15 mg, once daily, in the morning, with liquid. The capsule can be taken with or without food.

Duration of treatment

Treatment must be discontinued in patients who have not responded adequately.

Safety and effectiveness of sibutramine have been determined for periods up to 2 years.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss a dose, just skip it. Do not take an extra dose to make up for missed doses.

Contraindications

This drug is contraindicated in the following cases:

- known hypersensitivity to any of the components
- in patients taking monoamine oxidase inhibitors (MAOIs)
- in patients who have a major eating disorder (anorexia nervosa or bulimia nervosa)
- in patients taking other centrally acting weight loss drugs
- organic causes of obesity (e.g. untreated hypothyroidism)

Precautions

- It is recommended to monitor your blood pressure and pulse at regular intervals during treatment with this drug. Contact your doctor if you experience an increase in blood pressure.
- This drug should not be used in patients with a history of coronary artery disease, congestive heart failure, arrhythmias, stroke, uncontrolled hypertension, hyperthyroidism, Gilles de la Tourette's syndrome, benign prostatic hyperplasia with urine retention, pheochromocytoma, severe renal impairment or severe hepatic

dysfunction.

- This drug should be used with caution in patients predisposed to bleeding events, in patients with epilepsy, mild to moderate hepatic or renal impairment, narrow angle glaucoma, history of hypertension or psychiatric disorders.
- You should change your lifestyle in terms of eating habits and physical activity while taking this medicine, so that you are able to maintain your new weight after you have stopped treatment. Your doctor will advise you on the changes you need to make and continue to monitor your weight after you stop treatment. If you don't change your lifestyle you may regain the weight you have lost.
- Certain weight loss medicines have been associated with a rare condition that affects the blood pressure in lungs (pulmonary hypertension). Because the condition is so rare, it is not known if sibutramine may cause this disease. Inform your doctor if you experience new or worsening shortness of breath.
- Caution should be taken when driving a car or operating dangerous machinery until you are reasonably certain that your performance is not affected.
- This drug should not be used during pregnancy. Women of childbearing potential should employ adequate contraception while taking this medication. This drug is not recommended for use in nursing mothers.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug should not be used concomitantly with a MAOI or within 2 weeks of discontinuing treatment with a MAOI. At least 2 weeks should elapse between discontinuation of sibutramine and initiation of treatment with a MAOI.

Caution is advised in case of concomitant administration with centrally-acting drugs and medications known to affect hemostasis or platelet function.

Inform your doctor before using this medication if you are taking any prescription or over-the-counter drugs, especially weight reducing agents, decongestants, antidepressants, cough suppressants, lithium, dihydroergotamine, sumatriptan, triptophan, dextromethorphan, meperidine, pentazocine, fentanyl, ketoconazole, itraconazole, erythromycin, clarithromycin, troleandomycin, or cyclosporine since there is a potential for interactions.

The concomitant use of this drug and excess alcohol is not recommended.

Adverse reactions

The most reported adverse effects include increases in blood pressure and pulse; dry mouth; headache; insomnia and constipation.

Other reported adverse reactions include: nausea, abdominal pain, allergic reactions, dyspepsia, nervousness, anxiety, depression, dizziness, taste perversion, vasodilation and sweating.

Isolated cases of interstitial nephritis, convulsions and reversible increases in liver enzymes have been reported.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

APEMIN, sibutramine HCl monohydrate 15 mg, pack of 30 capsules

Issue date: 03/2008

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