

## Forms and presentation

Eliza<sup>®</sup>60: Capsules: Box of 30. Eliza<sup>®</sup>120: Capsules: Box of 30.

### Composition

Eliza®60: Each capsule contains Orlistat 60mg.

Excipients: Lactose, povidone, sodium starch glycolate, sodium lauryl sulphate, indigotine, titanium dioxide, gelatin.

Eliza<sup>®</sup>120: Each capsule contains Orlistat 120mg.

Excipients: Lactose, povidone, sodium starch glycolate, sodium lauryl sulphate, indigotine, titanium dioxide, gelatin.

# Why should you take Eliza®?

Therapeutic class: Peripherally acting antiobesity agent, ATC code A08AB01.

Eliza® is used to treat obesity. It works in your digestive system to block about one-third of the fat in the food you eat from being digested. Eliza® attaches to the enzymes in your digestive system (lipases) and blocks them from breaking down some of the fat you have eaten during your meal. The undigested fat cannot be absorbed and is eliminated by your body. Eliza® is indicated in the treatment of obesity in conjunction with a low calorie intake diet.

# What should you know about Eliza®?

Eliza® reduces the absorption of supplements of some fat soluble nutrients, particularly beta-carotene and vitamin E. You should therefore follow your doctor's advice in taking a well balanced diet rich in fruit and vegetables. Your doctor may suggest you take a multivitamin supplement.

### What is the recommended dosage of Eliza®?

### ADULTS AND CHILDREN 12 YEARS AND OLDER

The usual dose is 60 or 120mg capsule, 3 times per day, taken with each meal containing fat.

### How is Eliza® taken?

Eliza® capsule must be taken during, or within 1 hour after, each meal containing fat. The usage of Eliza® must be accompanied with a low-calorie diet, in which calories from fat do not exceed 30%. Omit the dose of Eliza® when you miss a meal, or when your meal is fat free.

### What to do if you miss a dose?

Take the forgotten dose at the next meal. Do not take two doses at the same time.

# What to do in case of overdosage?

Any medication taken in excess may lead to serious consequences. If you suspect an overdose, seek medical attention.

Symptoms of Eliza® overdosage are not known very well, although the drug seems relatively harmless.

# Are there drug interactions with Eliza®?

It is especially important to inform your physician before combining Eliza® with the following: Warfarin, Ciclosporin, Iodine salts and/or levothyroxine, Amiodarone, Medicines to treat HIV, Medicines for depression, psychiatric disorders or anxiousness

Eliza® may unbalance an anticonvulsivant treatment, by decreasing the absorption of antiepileptic drugs, thus leading to convulsions. Please contact your doctor if you think that the frequency and/or severity of the convulsions have changed when taking Eliza® together with antiepileptic drugs.

Eliza<sup>®</sup> is not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus).

### What are the side effects of Eliza®?

Eliza® side effects seem to be more common during the first year of treatment and include the following:

Anxiety, dizziness, fatigue, sleep problems, abdominal discomfort or pain, diarrhea, fatty or oily stools, fecal urgency or incontinence, flu, gas with fecal discharge, increased defecation, nausea, oily discharge, rectal discomfort or pain, vomiting, urinary tract infections, vaginal inflammation, menstrual problems, respiratory tract infections, skin rash, arthritis, back pain, earache, headache, muscle pain, tooth problems, gum problems.

After the first year of treatment, side effects that usually occur include: swollen feet, leg pain, tendonitis and depression.

### Precautions about Eliza®

Eliza® will be discontinued by your doctor after 12 weeks if you have not lost at least 5 % of your body weight as measured at the start of the treatment. The effect of using Eliza® for more than 4 years is not known yet.

High-fat meal or high-fat diet may worsen some side effects seen with Eliza® especially diarrhea and abdominal pain. Thus, you must decrease your fat intake.

If your overweight is caused by an underactive thyroid gland, a condition known as hypothyroidism, Eliza® is not an appropriate treatment to such conditions. Thus your physician may test your thyroid function before prescribing Eliza® to be sure of your problem origin.

If you have a history of kidney stones, use Eliza® with caution, since it raises the probability of having such problems.

If you are a diabetic, loosing weight seems to reduce your blood sugar levels. Thus, if you are treated with an oral diabetes medication or insulin, you might need a dosage adjustment.

Eliza® is not been established to be safe and effective in children younger than 12 years old.

# What are the cases in which you should not take Eliza®?

Eliza® is contraindicated if you are allergic to the drug or if you suffer from a "chronic malabsorption syndrome", a condition that inhibits nutrients from passing from your stomach into your bloodstream or from "cholestasis", a blockage in the supply of bile needed for digestion.

### What should you do if you are pregnant or breastfeeding?

There are no adequate studies about the effects of Eliza® during pregnancy, thus its usage is not recommended during pregnancy. If you are pregnant or planning to become pregnant, inform your physician immediately.

It is unknown whether Eliza® is secreted in breast milk. Thus, avoid Eliza® while breastfeeding.

## How to store Eliza®?

Store below 30°C.

Keep in original pack in intact conditions.

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# This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor

Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists