

Stresam®

ETIFOXINE - Capsules 50 mg

LEAFLET. INFORMATION FOR A PATIENT

Read this leaflet thoroughly, please, before first use of the drug!

Keep this leaflet. You may read it once more.

If you have any questions, consult your doctor, please.

This drug has been prescribed only for you. Don't give it to another person. It may be harmful for them, even if they have the same symptoms.

Composition of the drug

Active ingredient: etifoxine hydrochloride

Each capsule contains etifoxine hydrochloride 50 mg;

Excipients: lactose monohydrate, talc, microcrystalline cellulose, colloidal silica, magnesium stearate.

Pharmacotherapeutic group. Anxiolytic.

Pharmacological properties. Etifoxine hydrochloride in therapeutical doses possesses anxiolytic effect, Etifoxine does not influence the velocity of the psychomotor reactions, and might be used as a diurnal tranquilizer.

Indications

- Stressory neurasthenic disorders accompanied with anxiety, fear and unrest.
- Anxio-phobic disturbances.
- Vegetative disorders with moderate fear, apathy, decreased activity.

Contraindications

Hypersensitivity to any ingredient of the drug, shock condition, myasthenia, severe disorders in the liver and/or kidneys; the drug includes lactose, so it is not recommended to prescribe to the patients with congenital galactosemia, syndrome of glucose and galactose malabsorption or lactase deficiency; pregnancy and lactation period.

Precautions when using

Cessation of treatment with Stresam does not cause withdrawal syndrome. Stresam does not influence the velocity of the psychomotor reactions, but considering significant individual reactions, one could not exclude a possibility of temporal worsening in ability to drive and use machines during therapy with this drug. It is not recommended to use alcohol or other substances of central action during therapy with Stresam.

If you have ever had any allergic reactions, inform your doctor.

Interactions with other drugs

If you are taking other drugs, inform your doctor.

A reciprocal increase in effects is possible in concomitant use of Stresam with the drugs depressing action of the central nervous system (neuroleptics, tranquilizers, antidepressants, analgetics, sedative).

Dosage and administration

Duration and treatment course should be prescribed by a physician depending on the disease severity. It is prescribed 1 capsule 2-3 times a day. The maximal treatment course is 12 weeks.

Overdose. It manifests with hypertension. Gastric lavage is recommended. If necessary – systemic therapy. No specific antidote exists.

Side effects

Dizziness appears sometimes which may appear at the beginning of the treatment and disappear spontaneously during the long-term therapy. Rarely – skin rash, very rarely – allergic reactions – urticaria, angiodermatitis.

If these undesirable effects appear, stop using the drug and inform your doctor immediately!

Shelf-life

The shelf-life of the drug is 3 years. *Don't use the drug after expiring the shelf-life.*

Storage conditions

Keep out of reach of children, in a place protected from light, at temperature up to 25°C. Don't store the drug in bath-rooms and kitchen.

Package

20 capsules in a blister; 3 blisters in a package.

Delivery conditions

On prescription.

Name and address of manufacturer

BIOCODEX

7 avenue Gallieni, 94250 Gentilly-France