

Stresam®

ETIFOXINE HYDROCHLORIDE

IDENTIFICATION OF MEDICINE

Name

STRESAM®, capsule

Composition

Etifoxine hydrochloride..... 50 mg

Excipients: lactose, talc, microcrystalline cellulosa, colloidal silica, magnesium stearate.

Pharmaceutic form

Box of 24 or 60 capsules.

Pharmaco-therapeutic group.

ANXIOLYTIC.

Name and address of the Marketing Authorization Holder

BIOCODEX

7 avenue Gallieni - 94250 Gentilly - FRANCE

WHEN TO USE THIS MEDICINE?

This drug is recommended to decrease the various emotional and body reactions (swell in the throat, palpitations, feeling of suffocation ...) which accompany the anxiety.

WARNING!

When not to use this medicine

This medicine must not be used in the following cases:

- state of shock
- severe hepatic insufficiency
- myasthenia
- severe renal insufficiency

WHEN IN DOUBT ASK YOUR PHYSICIAN OR YOUR PHARMACIST FOR ADVICE.

Special warning

Due to the presence of lactose, this medicine must not be used in case of galactosemia, in case of syndrome of malabsorption of glucose and galactose or of lactase deficit (rare metabolic diseases).

Precautions for use

The simultaneous absorption of alcoholic beverages is not advisable.

WHEN IN DOUBT DO NOT HESITATE TO ASK YOUR PHYSICIAN OR YOUR PHARMACIST FOR ADVICE.

Drug interactions or other interactions.

IN ORDER TO AVOID POSSIBLE DRUG INTERACTIONS YOU MUST INFORM YOUR PHYSICIAN OR YOUR PHARMACIST ABOUT ANY OTHER CURRENT TREATMENT.

Pregnancy – Lactation

It is not advisable to use this medicine during pregnancy. If you discover that you are pregnant, consult your physician as only he can consider if it is needed to continue the treatment.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR PHYSICIAN OR YOUR PHARMACIST FOR ADVICE.

Driving and using machines

The drivers and the users of machine have to be informed about the risk of somnolence linked to this medicine.

Noticeable excipient: lactose

HOW TO USE THIS MEDICINE?

Dosage

The dosage is variable from one patient to another one. It does not depend on the gravity of the disorders but of the reactions of each one. Only the doctor can define it.

Mode and way of use

Oral route

Swallow the capsules with a little amount of water.

Frequency and time to take it

The administration of the capsules will be divided into 2 or 3 intakes per day.

Duration of treatment

IN EVERY CASES RESPECT YOUR PHYSICIAN'S PRESCRIPTION.

Overdosage

In case of intoxication by accidental intake of a big dose of Stresam, it is necessary to contact immediately your physician.

If you forget to take this medicine

In that case it is not recommended to increase the next dose.

Withdrawal syndrome

The stopping of the treatment does not provoke a withdrawal syndrome (the withdrawal syndrome is a feeling of deprivation after certain medicines are stopped, with the recurrence or the worsening of the initial disorders).

POSSIBLE SIDE EFFECTS

As for every active product, this medicine can provoke more or less some side effects in certain patients:

- Slight somnolence, appearing at the beginning of the treatment and disappearing spontaneously during the rest of the treatment.
- Rare cutaneous eruptions, very rare allergic reactions such as urticaria and Quincke's oedema.

INFORM YOUR PHYSICIAN OR YOUR PHARMACIST ABOUT ANY SIDE EFFECT NOT MENTIONED IN THIS LEAFLET.

STORAGE

Do not exceed the expiry date indicated on the outer pack.

Keep away from reach and sight of children.

Date of revision of the text: January 2006.