SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

STRESAM®, capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Etifoxine hydrochloride ..... 50 mg

For excipients: see 6.1

3. PHARMACEUTICAL FORM

Capsule (blue and white).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Psychosomatic manifestations of anxiety such as autonomic dystonia, notably of a cardiovascular nature.

4.2 Posology and method of administration

Posology

Usually 3 to 4 capsules a day, taken as 2 or 3 divided doses.
Treatment duration : a few days to a few weeks.

Method of administration

Swallow the capsules with a little amount of water.

4.3 Contraindications

- states of shock,
- severely impaired liver and/or renal function,
- myasthenia.

4.4 Special warnings and special precautions for use

Warning

Because of the presence of lactose, this medicine is contraindicated in patients with congenital galactosemia, glucose and galactose malabsorption syndrome or lactase deficit.

Precautions

Because of risks of reciprocal potentialisation:
- combination with central depressants must be prescribed cautiously,
- simultaneous intake of alcoholic drinks is inadvisable.

4.5 Interactions with other medicinal products and other forms of interaction

INADVISABLE COMBINATIONS

+ ALCOHOL :
Alcohol increases the sedative effect of these substances. Impaired alertness may make vehicle driving and machinery operation dangerous.
Avoid alcoholic drinks and medicines containing alcohol.

COMBINATIONS NEEDING TO BE TAKEN INTO ACCOUNT

+ Other central nervous system (CNS) depressants :
Morphine derivatives (analgesics, antitussives and narcotic substitutes); benzodiazepines; hypnotics; neuroleptics; sedative H1 antihistamines; sedative antidepressants; central antihypertensives; baclofene, thalidomide.
Increased central depression. Impaired alertness may make vehicle driving or machinery operation dangerous.

4.6 Pregnancy and lactation

Taking into account the data available, it is preferable as a safety measure to avoid using etifoxine during the pregnancy whatever is the term. Indeed the animal data are reassuring but the clinical data are insufficient.

4.7 Effects on ability to drive and use machines

Attention is drawn, of vehicle drivers and machinery operators in particular, to the risks of drowsiness associated with this medicine.

4.8 Undesirable effects

Slight drowsiness, occurring at the start of treatment and disappearing spontaneously with its continuation.
Rare skin rashes, very rare allergic reactions in the form of urticaria and angio-edema.

4.9 Overdose

If a massive amount is taken, gastric washout should be the first step, followed by symptomatic treatment if necessary. There is no specific antidote.

5. PHARMACOLOGICAL PROPERTIES

ANTIANXIETY AGENT
(N : central nervous system)

5.1 Pharmacodynamic properties

Etifoxine hydrochloride belongs to the benzoxazines chemical group.
As antianxiety agent, it has an autonomic regulatory action.
Animal and human studies have failed to establish any rebound effect, nor dependency potential (physical or psychological).

5.2 Pharmacokinetic properties

Etifoxine hydrochloride is well absorbed by oral route, it does not bind to blood cells, its plasma levels fall slowly in three phases and it is mainly eliminated in urine. Etifoxine hydrochloride crosses the placenta barrier.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, toxicity to reproduction.

PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose, talc, microcrystalline cellulose, colloidal silica, magnesium stearate

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

STRESAM should be stored under normal conditions of temperature and humidity.

6.5. Nature and contents of container

Capsules contained within heat-formed blister packs consisting of aluminium foil and polyvinyl chloride - Cardboard box containing 60 capsules.

6.6 Instructions for use and handling (and disposal)

See 4.2.

7. PRESENTATION AND MARKETING AUTHORISATION NUMBER

Box of 60 capsules.
A.M.M. 322 857.7 (France)

8. GENERAL CLASSIFICATION FOR SUPPLY

List I.
Prescription duration is restricted to 12 weeks.

9. MARKETING AUTHORISATION HOLDER

BIOCODEX
7 avenue Gallieni
94250 GENTILLY
FRANCE

10. MARKETING AUTHORIZATION NUMBER

MA239/00401

11. DATE OF FIRST AUTHORIZATION

February 28th, 2006

12. DATE OF REVISION OF THE TEXT

July 2010

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

{CARDBOARD BOX}

1. NAME OF THE MEDICINAL PRODUCT

STRESAM
Etifoxine hydrochloride 50mg
Capsules

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Etifoxine hydrochloride 50mg

3. LIST OF EXCIPIENTS

Noticeable excipient: lactose.

4. PHARMACEUTICAL FORM AND CONTENTS

Capsule – 60 capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral route

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

N/A

8. EXPIRY DATE

EXP.:

9. SPECIAL STORAGE CONDITIONS

Store below 30°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

N/A

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BIOCODEX
7 avenue Gallieni
94250 Gentilly

12. MARKETING AUTHORISATION NUMBER(S)

MA239/00401

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
Prescription duration limited to 12 weeks

15. INSTRUCTIONS ON USE

Swallow the capsules with a little amount of water.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Aluminium blister}

1. NAME OF THE MEDICINAL PRODUCT

STRESAM
Etifoxine hydrochloride 50mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOCODEX

3. EXPIRY DATE

EXP.:

4. BATCH NUMBER

Lot:

5. OTHER

N/A

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{/}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

N/A

2. METHOD OF ADMINISTRATION

N/A

3. EXPIRY DATE

N/A

4. BATCH NUMBER

N/A

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

N/A

6. OTHER

N/A

LEAFLET

STRESAM®, capsule

1. IDENTIFICATION

Name:
STRESAM®, capsule

Composition:

Etifoxine hydrochloride ..... 50 mg
Excipients: lactose, talc, microcrystalline cellulosa, colloidal silica, magnesium stearate.

Pharmaceutic form:
Box of 60 capsules in blisters.

Pharmaco-therapeutic group:

ANXIOLYTIC

Name and address of the Marketing Authorization Holder:

BIOCODEX
7 avenue Gallieni
94250 Gentilly - France

Name and address of the Manufacturer:

BIOCODEX
1 avenue Blaise Pascal
60000 Beauvais - France

2. 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.

3. WARNING !

When not to use this medicine:

This medicine must not be used in the following cases:
- state of shock
- severe hepatic insufficiency
- severe renal insufficiency
- myasthenia

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 YOUOR PHARMACIST ABOUT ANY OTHER CURRENT TREATMENT

Pregnancy – Breast-feeding:

Due to the absence of clinical data, the use of this drug is not advisable during the pregnancy and the breast-feeding.

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

4. 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 separated during the day in 2 or 3 intakes.

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.

5. 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.

6. 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: July 2010.