SCHEDULING STATUS: **S5**

STRESAM 50 mg capsules

Etifoxine hydrochloride

Contains sugar: lactose monohydrate 119 mg

Read all of this leaflet carefully before you start taking STRESAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **STRESAM** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What STRESAM is and what it is used for

STRESAM is a tranquillizer used to oppose various emotional and bodily reactions, which accompany anxiety.

2. What you need to know before you take STRESAM

Do not take STRESAM

- If you are hypersensitive (allergic) to etifoxine hydrochloride or any of the other ingredients of **STRESAM** (listed in section 6).
- if you are in a state of shock
- if you have severely impaired liver and/or kidney function
- if you suffer from myasthenia gravis (a disease which causes weak muscles)
- if you have had severe liver problems, such as inflammation of the liver (hepatitis) or cytolytic hepatitis, during previous treatment with STRESAM
- if you have had severe skin reactions during previous treatment with STRESAM
- if you suffer from galactosaemia (a disorder of milk sugar digestion), glucose-galactose malabsorption (a rare condition which prevents the proper digestion of the sugars glucose and galactose) or lactase deficit (unable to digest lactose).

Warnings and precautions

Talk to your doctor or pharmacist **before taking STRESAM:**

- If you are at risk of developing liver problems, your doctor will do some tests to check your liver function before starting **STRESAM** and around one month after you start treatment.

You should stop taking the medicine and seek urgent medical attention if you experience the following events **during treatment with STRESAM**:

- severe skin or allergic reactions (see section 4);

- jaundice (yellowing of the skin and eyes), vomiting, tiredness, abdominal (belly) pain or swelling, swelling in the legs and ankles, dark urine colour, pale stool colour, or bloody or tar-coloured stool – these could be signs of severe liver problems (see section 4);
- watery diarrhoea (see section 4).

Talk to your doctor or pharmacist if you experience bleeding from the uterus between menstrual periods (metrorrhagia) when on oral contraceptives during treatment with **STRESAM**.

Caution is advised if you are using central nervous system depressants (medicines that slow down brain activity) such as sedatives and tranquilizers (see **Other medicines and STRESAM**) or alcohol-containing medicines together with **STRESAM** (see **STRESAM with food and drink and alcohol)**.

If you are taking STRESAM and have any questions or concerns, speak to your doctor or pharmacist.

Other medicines and STRESAM

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

STRESAM should not be used together with other central nervous system depressants as the depressant effect may be increased. Examples of other central nervous system depressants are:

- medicines related to morphine (painkillers, cough mixtures)
- antidepressants
- hypnotic medicines (medicines used to help you sleep)
- antihistamines (medicines used to relieve allergic symptoms)
- medicines used in the treatment of high blood pressure
- baclofen (a muscle relaxant)

- thalidomide (a medicine used to treat a certain type of cancer).

STRESAM with food and drink and alcohol

Do not use alcohol or alcohol-containing medications together with **STRESAM** as alcohol increases the sedating effect of **STRESAM**. This may lead to decreased alertness and may make vehicle driving and machine operations dangerous.

Pregnancy and breastfeeding and fertility

STRESAM should not be used by pregnant or breastfeeding women.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **STRESAM.**

No data on male and female fertility are available.

Driving and using machines

Do not drive or operate any tools or machinery as **STRESAM** causes drowsiness, and impaired alertness (when used in combination with central nervous system depressants or alcohol/ alcohol-containing medications), and it may hamper your ability to carry out these tasks.

STRESAM contains lactose

Do not take **STRESAM** if you have been told by your doctor that you cannot digest some sugar (galactosaemia) or have intolerance to some sugars (glucose-galactose malabsorption or lactase deficiency) (see **Do not take STRESAM**).

3. How to take STRESAM

Do not share medicines prescribed for you with any other person.

Always take **STRESAM** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is: 3 to 4 capsules (150 mg - 200 mg) daily in two to three divided doses. The duration of treatment is usually from a few days to not more than 8 weeks, depending on your doctor's recommendations.

The capsules should be swallowed with a little water.

Your doctor will tell you how long your treatment with **STRESAM** will last. If you have the impression that the effect of **STRESAM** is too strong or too weak, tell your doctor or pharmacist.

If you take more STRESAM than you should

Taking too many **STRESAM** capsules may increase the risk of somnolence (drowsiness).

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take STRESAM

Do not take a double dose to make up for forgotten individual doses.

If you stop taking STRESAM

Stopping the treatment does not lead to withdrawal (withdrawal is a state of deprivation or lack felt after stopping certain medicines with a reappearance or worsening of the disorders).

4. Possible side effects

STRESAM can have side effects.

Not all side effects reported for **STRESAM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **STRESAM**, please consult your healthcare provider for advice.

If any of the following happens, stop taking STRESAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- anaphylactic shock (severe flushing, itching, nausea, vomiting, swelling of the mouth and tongue and throat)
- severe allergic reactions of the skin and face (flushing, rashes, itching, swelling)
- allergic manifestations such as urticaria (nettle rash, hives) and angioedema (weals, swelling of lips, eyes and tongue)
- allergic reactions with fever, rash, conjunctivitis (red, swollen eyes)
- jaundice (yellowing of the skin and eyes), vomiting, tiredness, abdominal (belly) pain - these could be signs of severe liver problems
- watery diarrhoea

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- bleeding between the expected menstrual periods, in women taking oral contraceptive pill,
- slight drowsiness at the start of treatment and disappearing spontaneously with its continuation,
- skin rash or itchy skin,

- swelling of the face,
- intestinal disorder with watery diarrhoea,
- hepatitis (yellowing of the skin and eyes, belly pain, fever)
- feeling of rapidly progressing obstruction in the throat (Quincke's oedema)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **STRESAM**.

5. How to store STRESAM

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

Store in the original package and do not store in bathrooms.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What STRESAM contains

- The active substance is Etifoxine hydrochloride

- The other ingredients are colloidal silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose and purified talc.
- The Capsule: gelatine, titanium dioxide (E171), indigotin blue (E132),

What STRESAM looks like and contents of the pack

Hard gelatine capsules with blue caps and opaque white bodies. The capsules are filled with a white powder.

The capsules are packed into blister packs of 60 or 100 capsules (i.e. each blister strip contains twenty capsules and three (3) or five (5) blister strips are packed into a cardboard outer carton). The blister strips are heat-sealed and consist of a clear polyvinyl chloride film sealed by aluminium metallized film.

Holder of Certificate of Registration

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