APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

STRESIGEN 50 mg capsule

Etifoxine hydrochloride

STRESIGEN contains sugar (lactose 110 mg)

Read all of this leaflet carefully before you start taking STRESIGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- STRESIGEN 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

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1. What STRESIGEN is and what it is used for

STRESIGEN is an anti-anxiety medicine.

STRESIGEN is used to decrease the various emotional and bodily reactions, which accompany anxiety.

2. What you need to know before you take STRESIGEN

Do not take STRESIGEN:

- if you are hypersensitive (allergic) to etifoxine hydrochloride, or to any of the ingredients of STRESIGEN (see 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 injury of the liver diagnosed by a biopsy, during previous treatment with etifoxine (the active ingredient in STRESIGEN)
- if you have had severe skin reactions during previous treatment with etifoxine (the active ingredient in STRESIGEN) like a syndrome called DRESS (Drug Rash with Eosinophilia and Systemic Symptoms – severe rash with multiple organ involvement, swollen lymph nodes and blood disorders), Stevens Johnson Syndrome (a rare, serious disorder of the skin and membranes that line the body's canals and organs) and dermatitis exfoliative (severe inflammation of the entire skin surface)

Warnings and precautions

Take special care with STRESIGEN:

Talk to your doctor or pharmacist before taking STRESIGEN:

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

Stop taking STRESIGEN and seek urgent medical attention if you experience the following events during treatment:

- 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 are taking oral contraceptives during treatment with STRESIGEN and experience bleeding from the uterus between menstrual periods (metrorrhagia).

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 STRESIGEN) or alcohol- containing medicines together with STRESIGEN (see STRESIGEN with food and drink).

Other medicines and STRESIGEN

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

STRESIGEN 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 or medicine from a medicine class called benzodiazepines (used to treat anxiety, sleeplessness or treat seizures)
- hypnotic medicines (medicines used to help you sleep) or neuroleptic medicines (medicine used to treat psychiatric conditions)
- antihistamines (medicines used to relieve allergic symptoms)
- baclofen (a muscle relaxant)
- thalidomide (a medicine used to treat a certain type of cancer).

STRESIGEN with food and drink

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

Pregnancy, breastfeeding and fertility

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 using STRESIGEN.

STRESIGEN should not be taken by pregnant or breastfeeding women.
No data on the effects of STRESIGEN on male and female fertility are available.

Driving and using machines

STRESIGEN causes drowsiness, and impaired alertness (at the beginning of treatment and especially when used in combination with central nervous system depressants or alcohol/ alcohol-containing medicines).
It is not always possible to predict to what extent STRESIGEN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which STRESIGEN affects you.

STRESIGEN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take STRESIGEN

Do not share medicines prescribed for you with any other person. Always use STRESIGEN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is: 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 STRESIGEN will last. If you have the impression that the effect of STRESIGEN is too strong or too weak, tell your doctor or pharmacist.

If you take more STRESIGEN than you should

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

Symptoms of overdose may include drowsiness or strong desire to fall asleep.

If you forget to take STRESIGEN

If you forget to take STRESIGEN, take as soon as you remember, but if it is close to your next due dose, skip the forgotten dose and take the next normal dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking STRESIGEN

Talk to your healthcare provider before you stop taking STRESIGEN.

4. Possible side effects

STRESIGEN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to STRESIGEN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- anaphylactic shock (severe flushing, itching, nausea, vomiting, swelling of the mouth and tongue and throat)
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals, skin rash), Drug reaction with eosinophilia and systemic symptoms (DRESS) (symptoms include fever, rash, facial swelling, enlarged lymph nodes and kidney or liver injury)
- jaundice (yellowing of the skin and eyes), vomiting, tiredness, abdominal (belly) pain - these could be signs of severe liver problems, hepatitis
- watery diarrhoea.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- feeling of rapidly progressing obstruction in the throat (Quincke's oedema)
- slight drowsiness at the start of treatment and disappearing spontaneously with its continuation
- skin rash or itchy skin, swelling of the face, extreme redness of the skin, scaling, crusting, thickening of the skin
- bleeding between the expected menstrual periods, in women taking oral contraceptive pill.

The following side effects have been reported but the frequency for them to occur is not known:

- inflammation of small blood vessels (symptoms include low grade fever, unexplained weight loss, muscle aches, joint pain, bloody urine or stool, abdominal pain, vomiting, coughing, weakness).

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

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

5. How to store STRESIGEN

Store all medicines out of reach of children.

Store at or below 25 °C

Keep blisters in carton until required for use.

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).

6. Contents of the pack and other information

What STRESIGEN contains

The active ingredient is etifoxine hydrochloride.

The other ingredients are:

azorubine (carmosine), fumaric acid, gelatin, lactose monohydrate, , patent blue V, stearic acid, titanium dioxide.

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What STRESIGEN looks like and contents of the pack

The hard gelatin capsule consists of a white-coloured opaque body and blue-coloured opaque cap. Capsules contain an off-white powder.

60's pack: Clear PVC/PVDC- aluminum blisters packed into a printed outer carton.

Holder of Certificate of Registration

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This leaflet was last revised in

Date of registration: 25 November 2025

Registration number

A59/2.6/0102