STRESIGEN

SCHEDULING STATUS S5

1. NAME OF THE MEDICINE
STRESIGEN 50 mg hard gelatin capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains: etifoxine hydrochloride 50 mg.
Each capsule contains sugar (lactose monohydrate 110 mg).

For the full list of excipients, see section 6.1

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

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
STRESIGEN is indicated in psychosomatic manifestations of anxiety.

4.2 Posology and method of administration
Posology
The usual dosage of STRESIGEN is 150 mg to 200 mg daily in two to three divided doses. STRESIGEN is prescribed for a few days to a few weeks. Treatment duration may not exceed 8 weeks.

Method of administration
Oral.
Capsules should be swallowed with a little water.

Missed dose:
Medical practitioners should advise patients who forget to take STRESIGEN, to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications
STRESIGEN is contraindicated in the following patients:
- hypersensitivity to etifoxine hydrochloride or to any of the ingredients of STRESIGEN (see section 6.1)
- states of shock
- severely impaired liver and/or renal function
- myasthenia gravis
- patients who have had severe cases of hepatitis or cytolytic hepatitis during previous treatment with STRESIGEN
- patients who have had severe dermatological reactions, including drug rash with eosinophilia and systemic symptoms (DRESS) syndrome, Stevens-Johnson syndrome (SJS) and dermatitis exfoliative generalized, during previous treatment with etifioxine.

4.4 Special warnings and precautions for use
Severe dermatological reactions
Severe dermatological reactions, including DRESS syndrome, SJS and dermatitis exfoliative generalised, have been reported with etifoxine, (as contained in STRESIGEN), with a very rare frequency. The onset of skin toxicity with etifoxine usually ranged from a few days to 1 month, depending on the reactions. Outcome of skin reactions is mostly favourable after STRESIGEN withdrawal. No fatal outcome due to severe cutaneous adverse reactions has been reported with STRESIGEN. Patients should be aware of this risk of skin toxicity and cutaneous signs and symptoms should be closely monitored. STRESIGEN should be immediately discontinued and never reintroduced should skin toxicity occur whilst taking this medicine.

Severe hepatic reactions
Severe cases of cytolytic hepatitis have been reported with the use of etifoxine, (as contained in STRESIGEN), with a very rare frequency. Time to onset of hepatic reactions after etifoxine introduction mainly occurred between 2 weeks and 1 month of treatment. Caution should be taken in patients with risk factors for hepatic disorders such as elderly patients, patients with medical history of previous viral hepatitis or any other conditions identified on an individual basis by the medical practitioner. Hepatic disorders can be asymptomatic and detected only through specific laboratory tests.
In patients with risk factors for hepatic disorders, liver function tests should be performed before starting STRESIGEN and around one month after treatment initiation. After the occurrence of liver toxicity with STRESIGEN, this medicine should be immediately discontinued and never reintroduced.

Lymphocytic colitis
Few cases of lymphocytic colitis have been reported with the use of etifoxine, (as contained in STRESIGEN). In cases of watery diarrhoea, appropriate examinations should be considered in those patients treated with STRESIGEN. Should the patient experience watery diarrhoea whilst taking STRESIGEN, the medicine should be immediately discontinued.

Metrorrhagia
In women on oral contraceptives, cases of metrorrhagia have been reported with the use of etifoxine, (as contained in STRESIGEN).

Central nervous system depressants
Because of the risk of reciprocal potentialisation:
- caution is advised when STRESIGEN is used in conjunction with central nervous system depressants
- simultaneous intake of alcoholic drinks is not advised.

Lactose intolerance
STRESIGEN contains lactose. Patients with the rare hereditary conditions of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take STRESIGEN (see section 4.3).

4.5 Interaction with other medicines and other forms of interaction
Concomitant use not advised
Alcohol
Alcohol increases the sedative effect of STRESIGEN, impairing alertness, which may make vehicle driving and operation of machinery dangerous.
Concomitant use of alcoholic drinks and alcohol-containing medicines should be avoided.

Combinations to be taken into account
Other central nervous system (CNS) depressants
Morphine derivatives (analgesics, antitussives and narcotic substitutes); benzodiazepines; hypnotics; neuroleptics, sedative H_1 antihistamines, sedative antidepressants, central antihypertensives, baclofen; thalidomide. The concurrent use of STRESIGEN and these medicines may lead to increased central nervous system depression. Impaired alertness may make vehicle driving or machinery operation dangerous.

4.6 Fertility, pregnancy and lactation
The administration of STRESIGEN during pregnancy and whilst breastfeeding is not recommended as there is limited data available.
STRESIGEN crosses the placenta.

Fertility
No data on male and female fertility are available.

4.7 Effects on ability to drive and use machines
Slight drowsiness, occurring at the start of STRESIGEN therapy, disappearing spontaneously with its continuation, has been reported.
Patients, particularly vehicle drivers and machine operators, should be advised of the risks of drowsiness associated with the intake of STRESIGEN.

4.8 Undesirable effects
The frequencies of adverse events are ranked according to the following:
Frequent = (≥ 1/100 to < 1/10).
Less frequent = Infrequent (≥ 1/1 000 to < 1/100); Rare (≥ 1/10 000 to < 1/1 000);
Very rare (<1/10 000).
Frequency not known = cannot be estimated from the available data.

Tabulated summary of adverse reactions

System organ class	Frequency	Side effects
Immune system disorders	*Less frequent*	Allergic reactions (urticaria, Quincke's oedema)
	Frequency unknown	Anaphylactic shock
Nervous system disorders	*Less frequent*	Slight drowsiness, occurring at the start of therapy and disappearing spontaneously with STRESIGEN continuation
Gastrointestinal disorders	*Less frequent*	Lymphocytic colitis
Hepatobiliary disorders	*Less frequent*	Hepatitis, cytolytic hepatitis
Skin and subcutaneous tissue disorders	*Less frequent*	Skin reactions (rash, maculo-papular, polymorph erythema, pruritus, face oedema), DRESS syndrome, Stevens-Johnson syndrome, generalised exfoliative dermatitis
	Frequency unknown	Leukocytoclastic vasculitis
Reproductive system and breast disorders	*Less frequent*	Metrorrhagia in women taking oral contraceptives

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions 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.

4.9 Overdose
Signs and symptoms:
Risk of somnolence.

Management of overdose:
Symptomatic treatment will be implemented if necessary. There is no specific antidote.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
ATC code: N05BX03
Pharmacotherapeutic group: N, Nervous system
Pharmacological classification: A2.6 Tranquillisers

Mechanism of action
Etifoxine hydrochloride belongs to the class of benzoxazine chemicals.
As anti-anxiety medicine, it has an autonomic regulatory action.

In vitro and *in vivo* studies carried out in the rat and the mouse showed that the anxiolytic activity of etifoxine is due to a double mechanism of action (direct and indirect) on the $GABA_A$ receptor enhancing the GABAergic transmission:
- a direct action on the $GABA_A$ receptor by an allosteric modulation, etifoxine binds preferentially to sub-units β2 and β3; studies show that etifoxine binds to a $GABA_A$ receptor site distinct from that of benzodiazepines
- an indirect action by the increase of the neuronal production of neurosteroids (via activation of the mitochondrial translocator protein) such as allopregnanolone, those neurosteroids being positive allosteric modulators of the $GABA_A$ receptor.

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 placental barrier.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Capsule content
Fumaric acid
Lactose monohydrate
Stearic acid

Capsule shell
Azorubine (Carmoisine) (E122)
Gelatin
Patent blue V (E131)
Titanium dioxide.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at or below 25 °C.
Do not remove the blister from the outer carton until required for use.

6.5 Nature and contents of container
60's and 90's pack: Clear PVC/PVDC aluminum blisters, packed into a printed outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
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8. REGISTRATION NUMBER
A59/2.6/0102

9. DATE OF FIRST AUTHORISATION
August 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

STRESIGEN 50 mg hard gelatin capsules
Etifoxine hydrochloride
STRESIGEN contains sugar
(lactose monohydrate 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

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 tranquilisers (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 medicine.

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 50 mg.

The other ingredients are:
Azorubine (carmoisine), fumaric acid, gelatin, lactose monohydrate, patent blue V, stearic acid, titanium dioxide.

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 and 90's pack size: Clear PVC/PVDC aluminum blisters, packed into a printed outer carton.
Not all pack sizes may be marketed.

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pharma dynamics

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S5

STRESIGEN 50 mg harde gelatienkapsules
Etifoksienhidrochloried
STRESIGEN bevat suiker
(laktosemonohidraat 110 mg)

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om STRESIGEN te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- STRESIGEN is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad

1. Wat STRESIGEN is en waarvoor dit gebruik word
STRESIGEN is 'n angswerende medisyne.
STRESIGEN word gebruik om die verskeie emosionele en liggaamsreaksies wat met angstigheid gepaardgaan, te verminder.

2. Wat u nodig het om te weet, voordat u STRESIGEN neem
Moet nie STRESIGEN neem:
- indien u hipersensitief (allergies) is vir etifoksienhidrochloried, of vir enige van die ander bestanddele van STRESIGEN nie (sien afdeling 6)
- indien u in 'n skoktoestand is nie
- indien u erg belemmerde lewer- en/of nierfunksie het nie
- indien u aan myasthenia gravis ly nie ('n siekte wat swak spiere veroorsaak)
- indien u erge lewerprobleme, soos lewerinflammasie (hepatitis), gehad het, of lewerbeskadiging met 'n biopsie, tydens vorige behandeling met etifoksien (die aktiewe bestanddeel in STRESIGEN), gediagnoseer is nie
- indien u erge velreaksies tydens die vorige behandeling met etifoksien (die aktiewe bestanddeel in STRESIGEN), soos 'n sindroom wat GRESS genoem word (geneesmiddel uitslag met eosinofilie en sistemiese simptome – erge uitslag met veelvoudige orgaan betrokkenheid, geswelde limfnode en bloedversteurings), Stevens-Johnson-sindroom ('n ernstige versteuring van die vel en membrane wat die liggaamskanale en organe uitvoer) en dermatitis exfoliative (erge inflammasie van die algehele veloppervlakte), ervaar nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met STRESIGEN:
Praat met u dokter of apteker, voordat u STRESIGEN neem:
- indien u 'n risiko vir die ontwikkeling van lewerprobleme toon. U dokter sal sekere toetse uitvoer om u lewerfunksie te ondersoek, voordat u STRESIGEN begin gebruik en ongeveer 'n maand nadat u behandeling begin is.

Staak die gebruik van STRESIGEN en bekom dringende mediese aandag, indien u die volgende gevalle tydens behandeling ervaar:
- erge vel- of allergiese reaksies (sien afdeling 4)
- geelsug (vergeling van die vel en oë), braking, moegheid, abdominale (buik) pyn of swelling, swelling in die bene en enkels, donker urienkleur, bleek stoelgang, of bloederige of teer-kleurige stoelgang. Hierdie mag tekens van erge lewerprobleme wees (sien afdeling 4)
- waterige diarree (sien afdeling 4).

Praat met u dokter of apteker, indien u mondelikse voorbehoedmiddels tydens die behandeling met STRESIGEN neem en bloeding vanuit die baarmoeder, tussen menstruele siklusse, ervaar (metrorragie).

Omsigtigheid word aanbeveel, indien u sentrale senuweestelselonderdrukkers (medisyne wat die breinaktiwiteit vertraag), soos sedeermiddels en kalmeermiddels, (sien Ander medisyne en STRESIGEN), of alkohol-bevattende medisyne saam met STRESIGEN, neem (sien STRESIGEN saam met kos en drinkgoed).

Ander medisyne en STRESIGEN
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem (dit sluit aanvullende, of tradisionele medisyne in).

STRESIGEN moet nie saam met ander sentrale senuweestelselonderdrukkers gebruik word nie, aangesien dit die werking mag versterk. Voorbeelde van ander sentrale senuweestelselonderdrukkers is:
- medisyne verwant aan morfien (pynstillers, hoesmengsels)
- antidepressante, of medisyne vanuit 'n klas wat bensodiasepiene genoem word (gebruik om angstigheid, slaapkoorsheid, of aanvalle, te behandel)
- hipnotiese medisyne (medisyne wat u help om te slaap), of neuroleptiese medisyne (medisyne wat psigiatriese toestande behandel)
- antihistamiene (medisyne wat gebruik word om allergiese simptome te verlig)
- baklofen ('n spierverslapper)
- talidomied ('n medisyne wat gebruik word om 'n sekere tipe kanker te behandel).

STRESIGEN saam met kos en drinkgoed
Moet nie alkohol, of alkohol-bevattende medikasie saam met STRESIGEN gebruik nie, aangesien alkohol die kalmerende uitwerking van hierdie medisyne, mag versterk. Dit mag lei tot 'n vermindering in waaksaamheid en mag motorbestuur en die hantering van masjiene, gevaarlik maak.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of u baba borsvoed, vermoed dat swanger mag wees, of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies, voordat u STRESIGEN gebruik.

STRESIGEN moet nie deur swanger, of vroue wie borsvoed, geneem word nie.
Geen data omtrent die effek van STRESIGEN op manlike en vroulike vrugbaarheid, is beskikbaar nie.

Bestuur en die hantering van masjiene
STRESIGEN veroorsaak lomerigheid en 'n vermindering in waaksaamheid (aan die begin van behandeling en veral wanneer dit in kombinasie met sentrale senuweestelselonderdrukkers of alkohol/alkohol-bevattende medisyne), geneem word.
Dit is nie altyd moontlik om te voorspel tot watter mate STRESIGEN met u daaglikse aktiwiteite sal inmeng nie.
U moet verseker dat u nie by bogenoemde aktiwiteite betrokke raak, totdat u bewus is tot watter mate STRESIGEN u beïnvloed nie.

STRESIGEN bevat laktose
Indien u dokter aangedui het, dat u 'n onverdraagsaamheid teenoor sekere suikers toon, kontak u dokter, voordat u hierdie medikasie neem.

3. Hoe om STRESIGEN te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Gebruik STRESIGEN altyd presies soos deur u dokter aanbeveel word. U moet u dokter, of apteker raadpleeg, indien u onseker is.

Die gewone dosis is: 150 mg - 200 mg daagliks in twee tot drie verdeelde doserings. Die behandelingsduur is gewoonlik vanaf 'n paar dae, tot nie meer as 8 weke nie, in ooreenstemming met u dokter se aanbeveling.
Die kapsules moet met 'n bietjie water gesluk word.

U dokter sal u vertel vir hoe lank u behandeling met STRESIGEN sal duur. Indien u onder die indruk is dat die effek van STRESIGEN te sterk, of te swak is, vertel u dokter of apteker.

Indien u meer STRESIGEN neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal of giftebeheersentrum.

Simptome van oordosering, mag lomerigheid of 'n sterk drang om aan die slaap te raak, insluit.

Indien u vergeet om STRESIGEN te neem
Indien u vergeet om STRESIGEN te neem, neem dit so gou as wat u onthou, maar as dit naby u volgende dosis is, slaan die vergete dosis oor en neem die volgende geskeduleerde dosis. Moet nie 'n dubbeldosis neem, om op te maak vir die vergete, individuele doserings nie.

Indien u die gebruik van STRESIGEN staak
Praat met gesondheidsorgverskaffer, voordat u die gebruik van STRESIGEN staak.

4. Moontlike newe-effekte
STRESIGEN kan newe-effekte hê.
Nie alle newe-effekte wat vir STRESIGEN aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige reaksies ervaar, terwyl u STRESIGEN gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van STRESIGEN en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling mag bemoeilik
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie teenoor STRESIGEN ervaar het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- anafilaktiese skok (erge blosvorming, gejeuk, naarheid, braking, swelling van die mond, tong en keel)
- Stevens-Johnson-sindroom (ernstige siekte, met blaasvorming op die vel, mond, oë en geslagsorgane, veluitslag), geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) (simptome sluit koors, uitslag, gesigswelling, vergrote limfnode en nier- of lewerbeskadiging, in)
- geelsug (vergeling van die vel en oë), braking, moegheid abdominale (buik) pyn – hierdie mag tekens van erge lewerprobleme wees, hepatitis
- waterige diarree.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Minder algemene newe-effekte:
- gevoel van 'n vinnig vorderende obstruksie in die keel (Quincke se edeem)
- effense lomerigheid aan die begin van behandeling, wat spontaan verdwyn met voortdurende gebruik
- veluitslag of jeukerige vel, swelling van die gesig, uiterste rooiheid van die vel, skubberigheid en rooiverming, verdikking van die vel
- bloeding tussen die verwagte menstruele siklusse by vroue wie mondelikse voorbehoedpille neem.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend:
- inflammasie van klein bloedvate (simptome sluit 'n lae graad koors, onverklaarbare gewigsverlies, spierpyne, gewrigspyn, bloederige urine of stoelgang, buikpyn, braking, hoes, swakheid, in).

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter of apteker. U kan ook newe-effekte by SAHPRA via die MED Safety toepassing (Medsafety X SAHPRA) en elektroniese aanmeldingsplatform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word, aanmeld.
'n E-pos kan direk aan die maatskappy gestuur word: pharmacovigilance@pharmadynamics.co.za om die veiligheid van die produk te verseker.
U kan help om meer inligting, aangaande die veiligheid van STRESIGEN in te win, deur newe-effekte aan te meld.

5. Hoe om STRESIGEN te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 25 °C
Hou stulpstroke in die kartonhouer, totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum, wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat STRESIGEN bevat:
Die aktiewe bestanddeel is etifoksienhidrochloried 50 mg.

Die ander bestanddele is:
Asorubien (karmosyn), fumariensuur, gelatien, laktosemonohidraat, patent blue V, steariensuur, titaandioksied.

Hoe STRESIGEN lyk en die verpakkingsinhoud
Die harde gelatienkapsule bestaan uit 'n wit, ondeursigtige liggaam en 'n blou gekleurde ondeursigtige doppie.
Kapsules bevat 'n naaswit poeier.

60's en 90's verpakking: Helder PVC/PVDC- aluminum stulpstroke, verpak in 'n gedrukte kartonhouer.
Alle verpakkingsgroottes word nie noodwendig bemark nie.

Eienaar van die Registrasiesertifikaat
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