PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

TREZOT 50 and 100 hard capsules

Trazodone hydrochloride

Contains sugar.

Each TREZOT 50 capsule contains 81,2 mg lactose monohydrate.

Each TREZOT 100 capsule contains 162,4 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking TREZOT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist nurse or other health care provider.
- TREZOT 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 TREZOT is and what it is used for

2. What you need to know before you take TREZOT

3. How to take TREZOT

4. Possible side effects

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1. What TREZOT is and what it is used for

TREZOT contains the active ingredient trazodone hydrochloride which belongs to a group of medicines called antidepressants. It is used to treat depression and depression associated with anxiety.

2. What you need to know before you take TREZOT

Do not take TREZOT

- If you are hypersensitive (allergic) to trazodone hydrochloride, or any of the other ingredients of TREZOT listed in section 6 of this leaflet.
- If you have recently had a heart attack.
- If you are a heavy drinker or are taking sleeping tablets or other medicines which cause drowsiness, such as benzodiazepines (used for anxiety, seizures or as muscle relaxants) or antihistamines (used for allergies or to sleep).
- Monoamine oxidase inhibitors (used for depression).

Warnings and precautions

Take special care with TREZOT:

TREZOT should not be given to children and adolescents under 18 years of age.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting TREZOT, since TREZOT takes time to work. The beneficial effects normally start to become evident after two weeks, but this may take several weeks. You may be more likely to experience self-injurious or suicidal thoughts:

- if you have previously had thoughts about killing or harming yourself
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant such as TREZOT.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Tell your doctor or health care provider before taking TREZOT:

- If you have or have ever had seizures (fits), since gradual changes to your TREZOT dose may be required.
- If you have liver or kidney problems.
- If you have heart disease, recently had a heart attack or are taking any medicine for irregular heartbeats (see Other medicines and TREZOT).
- If you notice any of the following symptoms: nausea (feeling sick), vomiting (being sick), stomach pain, yellowing of your skin and the white areas of your eyes. These may be signs of liver disorder that may require discontinuing use of TREZOT.
- If you have flu-like symptoms, such as a sore throat and fever or any blood disorder. These are symptoms that may require discontinuing use of TREZOT.
- If you have schizophrenia or any other type of mental disorder and your symptoms worsen.
- If you take other medicines for depression or anxiety and experience high fever, a rapid heart rate and muscle stiffness (see Other medicines and TREZOT).
- If you are taking medicine for high blood pressure, as the dose may need to be adjusted.
- If you are elderly, since you may be more prone to side effects (such as feeling faint when standing up quickly or feeling tired).
- If you develop inappropriate or prolonged penile erections see possible side effects). Stop taking TREZOT immediately and go to your doctor for treatment.

Tell your doctor or health care provider before taking TREZOT, as your doctor may want to monitor you:

- If you have an overactive thyroid gland (hyperthyroidism).
- If you are male and have an enlarged prostate, are having difficulty passing urine or need to urinate frequently.
- If you have narrow angle angle glaucoma (an eye disorder causing increased pressure in your

eyes).

Children and adolescents

Do not give TREZOT to children and adolescents under the age of 18 years.

Other medicines and TREZOT

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

Tell your docor if you use:

- Oral contraceptive medicine.
- Cimetidine (used to treat stomach ulcers and excessive stomach acid).
- Sedative medicines (such as sleeping pills, medicine to treat anxiety or psychosis or antihistamines causing drowsiness).
- Erythromycin (used to treat bacterial infections).
- Ketoconazole or itraconazole (used to treat fungal infections)
- Ritonavir or indinavir (used to treat human immunodeficiency virus (HIV) infection).
- Carbamazepine (used to treat seizures (fits) or nerve pain) or phenytoin (used to treat seizures (fits)).
- Anaesthetics (used before surgery or hospital procedures) or muscle relaxing medicines.
- Levodopa (used to treat Parkinson's disease).
- Other antidepressant medicines (such as amitriptyline, imipramine or fluoxetine).
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression). Tell your doctor if you are

taking a MAOI or if you have taken them in the last 2 weeks.

- Phenothiazine medicines (such as chlorpromazine or fluphenazine).
- Medicines used to treat heart problems (such as amiodarone or digoxin).
- Medicines used to treat high blood pressure (such as clonidine).
- St. John's Wort (a complimentary medicine used to treat light depression).
- Apraclonidine or brimonidine (used to treat Glaucoma, a disease of increased pressure in the eye).
- Warfarin (used to prevent blood clots).
- Tryptophan (used for insomnia, depression, facial pain or mood swings).

TREZOT with food, drink and alcohol

You should avoid drinking alcohol while taking TREZOT.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TREZOT.

Driving and using machines

Your ability to drive and use machines may be affected by side effects, such as drowsiness, tiredness, dizziness, confusion and blurred vision. Do not drive a vehicle or operate machinery until you know how TREZOT affects you.

TREZOT contains sugar (lactose monohydrate)

TREZOT 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.

TREZOT 50 contains sunset yellow (colourant)

TREZOT 50 contains sunset yellow which may cause allergic reactions.

3. How to take TREZOT

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

Always take TREZOT exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Depression

The usual starting dose is 150 mg once a day.

Your doctor may later decide to increase your daily dose. The usual dose is between 300 – 400 mg per day, depending on your condition.

For adults in hospital, the dose may be as high as 600 mg per day.

Mixed anxiety and depression

The usual starting dose is 100 mg to 150 mg a day. When depression is the predominant symptom, the dose may be 300 mg to 400 mg per day.

Elderly

Elderly or frail people may need to start on a lower dose of 100 mg once a day.

Your doctor may want you to take your capsules either in divided doses after food, or as a single dose as you go to bed.

Your doctor will decide your dose and tell you how long your treatment with TREZOT will last, depending on your condition. Do not stop your treatment without consulting your doctor.

If you have the impression that the effect of TREZOT is too strong or too weak, tell your doctor or pharmacist.

If you take more TREZOT than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You may experience the following: nausea (feeling sick) or vomiting (being sick), feeling sleepy, dizzy or faint, seizures (fits), confusion, difficulty breathing or changes in the way your heart beats.

If you forget to take TREZOT

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking TREZOT

You should take TREZOT for as long as your doctor has told you. Do not stop taking TREZOT without your doctor knowing, even if you feel better. The treatment may need to continue for a number of weeks or months. When your doctor tells you to stop taking TREZOT, he/she will help you to do so gradually.

4. Possible side effects

TREZOT can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Yellowing of the eyes or skin, abdominal pain, dark urine, fever and loss of appetite). This could be a serious liver problem (such as jaundice or liver damage).
- Inappropriate, painful or prolonged penile erections.
- Signs of recurrent infections, such as fever or sore throat.
- Easy or excessive bruising or bleeding of the skin.
- Severe abdominal pain and bloating, (vomiting (being sick) and constipation. These may be

signs that your intestine is not working properly.

These are all very serious side effects. If you have them, you may have had a serious reaction to TREZOT. 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:

- You have thoughts of harming or killing yourself.
- Neuroleptic malignant syndrome (causing high fever, sweating, stiff muscles, uncontrollable muscle twitches, shortness of breath, shaking and changes in the way your heart beats).
- Serotonin syndrome (causing fever, heavy sweating, stiff muscles, restlessness, confusion, hallucinations and a rapid heartbeat).
- Rapid, slow or irregular heartbeat.
- Convulsions (fits).
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin.
- Feeling tired, faint, dizzy, having pale skin.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Confusion, headache, dizziness, tremor (shaking) or excitement.
- Feeling drowsy.
- Nausea (feeling sick), vomiting (being sick) or dry mouth.

Less frequent side effects:

- Blurred vision.
- Feeling dizzy or light-headed when standing or sitting up quickly.
- Constipation or diarrhoea.
- Skin rashes.
- Weakness

The following side-effects have been reported with unknown frequency:

- Change in results when testing your liver function or liver enzymes.
- Uncontrollable jerking movements (mainly in the arms and legs), uncontrolled muscle movements or twitches, difficulty with speaking.
- Overactive behaviour or thoughts, believing things that are not true (delusions) or hallucinations.
- Water retention and swelling of your hands, feet, ankles or legs.
- Difficulty sleeping, feeling disorientated, anxious, nervous, agitated or less alert.
- Difficulty controlling your bladder, difficulty urinating or frequent urination.
- Feeling tired, restless, irritable, aggressive or experiencing memory disturbance.
- Blocked nose or difficulty breathing.
- Flu-like symptoms, fever or chest pain.
- Decreased sodium levels in your blood (causing tiredness, weakness, confusion, muscle aches or stiffness, headache, loss of appetite, nausea (feeling sick) or vomiting (being sick), convulsions (fits)).
- Dizziness with a sensation of spinning or feeling off balance.
- High blood pressure.

- Fainting.
- Altered taste, weight loss or increased appetite.
- Stomach cramps and pain, nausea (feeling sick) or vomtiting (being sick) and diarrhoea.
- Indigestion, increased amounts of saliva or stomach pain.
- Pain in your limbs, back, muscles or joints.
- Nightmares.
- Itching or sweating more than usual.
- Decreased sex drive.

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. This includes any possible side effects not listed in this leaflet. 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 TREZOT.

5. How to store TREZOT

- Store at or below 25 °C.
- Keep the blister strip(s) in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What TREZOT contains

The active substance in TREZOT is trazodone hydrochloride.

TREZOT 50: Each capsule contains 50 mg trazodone.

TREZOT 100: Each capsule contains 100 mg trazodone.

The other ingredients in TREZOT 50 are lactose monohydrate, magnesium stearate, gelatin, quinolone yellow (E104), sunset yellow (E110) and titanium dioxide (E171).

The other ingredients in TREZOT 100 are lactose monohydrate, magnesium stearate, gelatin, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), sodim lauryl sulphate and titanium dioxide (E171).

What TREZOT looks like and contents of the pack

TREZOT 50: White to off white powder filled in size ’3’ hard gelatine capsule
with yellow coloured cap and yellow coloured body.

TREZOT 100: White to off white powder filled in size ’2’ hard gelatine capsule with dark brown coloured cap and dark brown coloured body.

TREZOT is packed in clear PVC/PVDC and aluminium foil blister strips, packed in an outer carton.

TREZOT is available in pack sizes of 100.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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