

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

PROPRIETARY NAME AND DOSAGE FORM

TREPILINE 10

Tablets

TREPILINE 25

Tablets

Read all of this leaflet carefully before you start taking TREPILINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TREPILINE 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 TREPILINE CONTAINS

TREPILINE 10:

The active substance is amitriptyline hydrochloride.

The other ingredients are colloidal silicon dioxide, disodium edetate, indigo carmine aluminium lake 73015, lactose monohydrate, macrogol, magnesium stearate, polyvinyl alcohol, starch (maize), starch (pregelatinised), sunset yellow FCF aluminium lake 15985, talc, titanium dioxide 77891, quinolene yellow aluminium lake 47005.

Contains sugar: Lactose monohydrate 60 mg

TREPILINE 25:

The active substance is amitriptyline hydrochloride.

The other ingredients are colloidal silicon dioxide, disodium edetate, indigo carmine aluminium lake 73015, iron oxide yellow 77492, lactose monohydrate, macrogol, magnesium stearate, polyvinyl alcohol, starch (maize), starch (pregelatinised), sunset yellow FCF aluminium lake 15985, talc, titanium dioxide 77891, quinolene yellow aluminium lake 47005.

Contains sugar: Lactose monohydrate 40 mg

WHAT TREPILINE IS USED FOR

TREPILINE contains amitriptyline. Amitriptyline belongs to a group of medicines called tricyclic antidepressants. These medicines alter the levels of chemicals in the brain to relieve the symptoms of depression.

TREPILINE is used to treat the symptoms of depression in patients 18 years and older.

BEFORE YOU TAKE TREPILINE

Do not take TREPILINE:

- If you are allergic (hypersensitive) to amitriptyline, other tricyclic antidepressants or to any inactive ingredients (see WHAT TREPILINE CONTAINS).
- If you have recently had a heart attack.
- If you are taking monoamine oxidase inhibitors (MAOIs) or you have taken MAOIs within the previous 14 days for the treatment of depression.
- If you are taking certain medicines for the treatment of high blood pressure.
- If you are pregnant or breastfeeding.
- If the child is under 18 years of age.
- If you have heart disease such as irregular heart beats, heart block or failure, coronary artery disease.

- If you suffer from periods of increased and exaggerated behaviour (mania).
- If you have severe liver disease.
- If you are taking linezolid (which is an antibiotic).

Take special care with TREPILINE:

- TREPILINE should at all times be kept out of sight and reach of children, as even small doses may be fatal to them.
- TREPILINE may cause drowsiness at the start of therapy.
- If you experience dry mouth, constipation, difficulty to urinate and blurred vision or other vision disturbances, consult your doctor.
- If you have drowsiness, agitation, restlessness or insomnia (inability to sleep).
- If you have hypertension (high blood pressure) or a heart disorder.
- If you have changes in libido (sex drive), interference with sexual function, gynecomastia (enlargement of man's breasts), breast enlargement in women, galactorrhoea (flow of milk from breast not whilst breastfeeding).
- If you have diabetes (high blood sugar levels).
- If you have a psychiatric disorder (such as mania or depression).
- If you have thoughts of harming or killing yourself.
- If you are due to have any surgery that involves an anaesthetic.
- If you are taking medicines called epinephrine or norepinephrine, TREPILINE can increase these medicines' effects.
- If you have a condition called porphyria.
- If you have a thyroid gland disorder.
- If you have a liver disorder.
- If you suffer from epilepsy (seizures or fits).
- If you have an eye condition called glaucoma (increased pressure in the eye).
- If you are not able to pass water (urinate) or have an enlarged prostate gland.

- If you have constipation.
- If you develop allergic skin reactions.
- If you are taking medicines called barbiturates or alcohol- their effects can be increased.
- If you are being given electroconvulsive therapy (ECT) (procedure when electric currents are passed through the brain).
- If you develop low levels of sodium in your blood that can arise as the following symptoms:
if you feel drowsy, confused or have fits.
- If you are an elderly person (older than 65 years of age).

Pregnancy and breastfeeding

You should not take TREPILINE if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking TREPILINE.

Driving and using machinery

Since adverse reactions such as drowsiness, dizziness and blurred vision have been reported in patients taking TREPILINE, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that TREPILINE does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients of TREPILINE

TREPILINE contain lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (you have an intolerance to some sugars), talk to your doctor before taking TREPILINE.

Using other medicines with TREPILINE

Always tell your healthcare professional if you are taking any other medicines (this includes

complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- *Monoamine oxidase inhibitors*: medicines used to treat depression such as selegiline.
- Medicines used to treat depression (serotonin reuptake inhibitors such as fluoxetine, norepinephrine reuptake inhibitors such as reboxetine).
- *Apraclonidine and brimonidine*: medicines used to treat an eye disorder called glaucoma.
- *Tramadol*: medicine used to treat moderate to severe pain.
- *Anaesthetics*: medicines used to in surgery to reduce your sensitivity to pain.
- *Amiodarone, disopyramide, procainamide, propafenone, quinidine, sotalol, isoprenaline*: medicines used to treat heart disorders.
- *Rifampicin*: medicine used to treat tuberculosis.
- *Linezolid*: medicine used to treat certain types of bacterial infections.
- *Calcium-channel blockers (diltiazem and verapamil), guanethidine, dibrisoquine, bethanidine or clonidine*: medicines used to treat high blood pressure.
- *Sympathomimetic medicines such as adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (norepinephrine), phenylephrine and phenylpropanolamine*: these may be present in many cough and cold remedies.
- *Methylphenidate*: medicine used to treat attention-deficit disorder.
- *Barbiturates*: medicines that cause central nervous system depression, including medicines used to treat anxiety or sleeping disorders.
- *Carbamazepine*: medicines used to treat epilepsy.
- *Disulfiram*: medicine used to treat alcohol abuse, as part of a treatment plan.
- *Fluconazole*: medicine used to treat fungal infections.
- *Antihistamines*: medicines used to treat allergies.
- *Ritonavir*: medicine used to treat HIV infection.
- *Pimozide and thioridazine*: medicines used to treat psychiatric disorders.

- *Diuretics (water tablets)*: medicine used to treat high blood pressure.
- *Entacapone*: medicine used to treat Parkinson's disease.
- *Baclofen*: medicine used to treat muscle cramps.
- *Nitrates*: medicine used to treat angina.
- *Oral contraceptives*: medicines used to prevent pregnancies.
- *Anticholinergic medicines (e.g. atropine)*: medicines that block a neurotransmitter called acetylcholine.
- *Cimetidine*: medicine used to treat heartburn or stomach ulcers.
- *St. John's Wort*: herbal medicine used to treat depression.
- *Thyroid hormones*: medicines used to treat a thyroid gland disorder.

HOW TO TAKE TREPILINE

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

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

The usual dose is:

Adults:

The usual dose is 75 mg to 150 mg daily in divided doses.

The maintenance dose is 50 mg to 100 mg daily in divided doses.

Your doctor will tell you how long your treatment with TREPILINE will last.

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

If you take more TREPILINE 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.

If you forget to take TREPILINE

If you miss a dose take it as soon as possible. Then continue with your regular dosing schedule.

If it is almost time for your next dose, do not take the missed dose at all and do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

POSSIBLE SIDE EFFECTS

TREPILINE can have side effects.

Not all side effects reported for TREPILINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TREPILINE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking TREPILINE 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 TREPILINE. 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:

- Heart attack (symptoms may include pain or pressure in the chest, discomfort spreading to the back, jaw, throat or arm, nausea, indigestion or heartburn, weakness, anxiety or shortness of breath and rapid or irregular heartbeats).
- Stroke (symptoms may include sudden numbness or weakness of the face, arm or leg, especially on one side of the body, sudden confusion, trouble speaking or understanding speech, sudden trouble seeing in one or both eyes, sudden trouble walking, dizziness, loss of balance or coordination and sudden severe headache with no known cause).
- Yellowing of the skin and eyes, also known as jaundice.
- Feeling faint when getting up (postural hypotension), increased blood pressure, fast/racing heart, palpitations, irregular or slow heart beats and very low blood pressure.
- Bone marrow depression or reduction in some blood cells (you may experience mouth ulcers and recurring infections, bleeding or bruising easily).
- Difficulty passing water (urine).
- Coma (state of unconsciousness).

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Drowsiness, sleepiness.
- Blurred vision, accommodation disturbance (difficulty to focus when looking at an object), increased pressure within the eye ball.
- Dry mouth, constipation.
- Hyperthermia (body temperature above the normal value).

The following side effects have been reported less frequently:

- Urticaria (skin rash characterised by pale red itchy bumps), photosensitisation (reaction of skin to sunlight).

- Inappropriate secretion of ADH (antidiuretic hormone) which may make you urinate more frequently, changes in blood sugar levels, changes blood sodium levels.
- Increased appetite, weight gain, weight loss, anorexia (loss of appetite).
- Confusion, disorientation (not knowing where you are), agitation (state of anxiety), insomnia (difficulty sleeping), nightmares, anxiety (feeling of worry), restlessness, disturbed concentration, dysarthria (condition where the muscles used for speech is weak), change in behaviour, suicidal thoughts or behaviour.
- Dizziness, headache, peripheral neuropathy (weakness, numbness or pain in hands and feet), pins and needles, lack of coordination, ataxia (loss of full control of body movements), tremors, fits, tardive dyskinesia (involuntary movements of the face and jaw).
- Mydriasis (enlargement of the pupil of the eyes).
- Tinnitus (ringing in the ears).
- Nausea (feeling sick), vomiting (being sick), diarrhoea, paralysis of the intestine, epigastric distress (characterised by slow bowel movements), inflammation in the mouth, dysgeusia (distortion of taste), swelling of the parotid gland (which produces saliva or spit), black tongue.
- Hepatitis (inflammation of the liver).
- Skin rash, alopecia (temporary hair loss).
- Increased passing of urine, urinary tract dilation (can be caused by infection).
- Breast swelling in men and women, galactorrhoea (milky nipple discharge unrelated to the normal milk production of breastfeeding), swelling of testicles, disturbances in sexual function or sex drive.
- Weakness, feeling tired, increased sweating.

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

- Increased risk of bone fractures.

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

STORING AND DISPOSING OF TREPILINE

Store at or below 25 °C.

Protect from light and moisture.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

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

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF TREPILINE

TREPILINE 10 : Packs of 100 and 500 tablets in white polypropylene securitainers together with a foam insert / rayon and professional information which is sealed with white low density polyethylene securitainer caps.

Packs of 28 tablets into metallised patient ready packs which are sealed with lay-flat zips after filling and packed into polyethylene bags.

TREPILINE 25 : Packs of 100 and 500 tablets in white polypropylene securitainers together with a foam insert/rayon and professional information which is sealed with white low density polyethylene securitainer caps.

Packs of 28 and 84 tablets into metallised patient ready packs which are sealed with lay-flat zips after filling and packed into polyethylene bags.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF TREPILINE

TREPILINE 10 : Pale blue, round, shallow, biconvex, film-coated tablets plain on both sides.

TREPILINE 25 : Yellow, round, shallow, biconvex, film-coated tablet plain on both sides.

REGISTRATION NUMBERS

TREPILINE 10: J/1.2/219

TREPILINE 25: J/1.2/220

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

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<p>Namibia: Trepiline 10: NS3 90/1.2/001241 Trepiline 25: NS3 90/1.2/001242</p>
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Botswana:

Trepiline 10: NS3 B9322960 S2

Trepiline 25: NS3 BOT0801152 S2

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