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

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Tel: +27 11 239 6200 (Other)

DATE OF PUBLICATION

Date of registration: 11 October 1976

Date of the most recently revised professional information as approved by Council: 28 July 2017

Namibia:
Trepiline 10: NS3 90/1.2/001241
Trepiline 25: NS3 90/1.2/001242

Botswana:
Trepiline 10: NS3 B9322960 S2
Trepiline 25: NS3 BOT0801152 S2

ZA_TREPTAB_1707_01

SUID-AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S5

EIENDOMSNAAM EN DOSEERVORM

TREPILINE 10 (tablette)

TREPILINE 25 (tablette)

SAMESTELLING

TREPILINE 10: Elke tablet bevat 10 mg amitriptilien-hidrochloried.

Eksipiënte:

Kolloïdale silikondioksied, dinatrium edetaat, indigo karmyn aluminium lak 73015, laktosemonohidraat, makrogol, magnesiumstearaat, polivinielalkohol, stysel (mielie), stysel (pregelatiniseerd), “sunset” geel FCF aluminium lak 15985, talk, titaandioksied 77891, kinoleen geel aluminium lak 47005.

Bevat suiker: Laktosemonohidraat 60 mg

TREPILINE 25: Elke tablet bevat 25 mg amitriptilien-hidrochloried.

Eksipiënte:

Kolloïdale silikondioksied, dinatrium edetaat, indigo karmyn aluminium lak 73015, ysteroksied geel 77492, laktosemonohidraat, makrogol, magnesiumstearaat, polivinielalkohol, stysel (mielie), stysel (pregelatiniseerd), “sunset” geel FCF aluminium lak 15985, talk, titaandioksied

77891, kinoleen geel aluminium lak 47005.

Bevat suiker: Laktosemonohidraat 40 mg

KATEGORIE EN KLAS

A 1.2 Psigo-analeptika (anti-depressante)

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Amitriptilien is ’n trisikliese antidepressant wat die membraan-pompmeganisme wat verantwoordelik is vir die heropname van noradrenalien in adrenergiese neurone in, inhibeer. Daar word geglo dat hierdie inmenging met die heropname van noradrenalien die antidepressiewe aktiwiteit van amitriptilien tot gevolg het. Die presiese werkingsmeganisme in mense is nie bevestig nie.

Farmakokinetiese eienskappe

Absorpsie

Piek-plasmakonsentrasies kom binne ongeveer 6 ure vanaf mondelikse toediening voor.

Verspreiding

Amitriptilien en nortriptilien word wyd deur die liggaam versprei en is hoogs gebonde aand plasma en weefselproteïen. Die geskatte halfleeftyd van amitriptilien is 9 tot 25 ure. Dit kruis die plasentale skans en word in borsmelk uitgeskei.

Metabolisme

Amitriptilien word omvattend gedemetileer in die lewer na die primêre aktiewe metaboliet daarvan, nortriptilien. Die metaboliese pad sluit N-oksidasie en konjugasie met glukuroonsuur in.

Uitskeiding

Dit word uitgeskei in die urine in die vorm van metaboliete.

INDIKASIES

TREPILINE is ’n trisikliese antidepressant wat aangedui word vir die behandeling van pasiënte 18 jaar en ouer met depressie.

KONTRA-INDIKASIES

TREPILINE word teenaangedui by:

- Pasiënte met hipersensitiwiteit teenoor amitriptilien of teenoor enige van die eksipiënte (sien SAMESTELLING).
- Miokardiale infarksie.
- Geskiedenis van miokardiale infarksie, disritmieë, veral hartblok van enige graad, kongestiewe hartversaking, koronêre arteriële ontoereikendheid.
- Meegaande gebruik met mono-amienoksidase inhibeerders of binne 14 dae vanaf staking van behandeling met MAOIs (sien INTERAKSIES).
- Meegaande gebruik met linesolied.
- Meegaande gebruik met antihipertensiewe medisyne (sien INTERAKSIES).
- Swangerskap en laktasie (sien MENSLIKE VOORTPLANTING).
- Kinders onder 18 jaar oud.
- Manie.
- Ernstige lewersiekte.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

TREPILINE moet ten alle tye buite bereik van kinders gehou word, aangesien selfs klein dosisse vir hulle noodlottig kan wees.

Lomerigheid kom dikwels aan die begin van TREPILINE behandeling voor.

Anticholinergiese effekte

Perifere anticholinergiese newe-effekte, veral droë mond, hardlywigheid, urinêre retensie en pupillêre dilatasie met dowwe visie en veranderinge in visuele akkommodasie is aangemeld. Wanneer anticholinergiese effekte ernstig is, moet TREPILINE gestaak of verminder word.

Sedatiewe effekte

Lomerigheid of oormatige sedasie kan in sekere pasiënte veroorsaak word en disoriëntasie en agitasie, slapeloosheid en rusteloosheid kan voorkom.

Hartsiekte

By pasiënte wat aan hartsiekte ly, moet spesiale sorg waargeneem word as gevolg van die geleentheidsprobleme van tagikardie, disritmieë, ortostatiese hipotensie en ander ongewenste effekte op bloeddruk, verergering van geleidingsversteurings en elektrokardiografiese abnormaliteite. Gereelde kardiologiese en elektrokardiografiese ondersoek word aanbeveel.

Endokriene effekte

Endokriene effekte sluit veranderings in libido, inmenging met seksuele funksie, ginekomastie en borsvergroting, en galaktorree in. Veranderings in bloedsuikerkonsentrasies kan ook voorkom en, minder dikwels, onvanpaste sekresie van antidiuretiese hormoon.

Manies-depressiewe psigose

Versigtigheid moet waargeneem word by pasiënte wat ly aan ’n depressiewe fase van manies-depressiewe psigose, aangesien manie ter geleentheid by sulke pasiënte ontketen kan word. TREPILINE moet onttrek word indien die depressie in ’n maniese fase ontwikkel.

Selfmoordneigings

Pasiënte met selfmoordneigings moet versigtig onder toesig gehou word gedurende behandeling. Gevalle van selfmoord-ideevorming en selfmoordgedrag is aangemeld tydens TREPILINE terapie of vroeg nadat behandeling gestaak is.

Direk-werkende simpatomimetika en narkosemiddels

Die pressor-effekte van die direk-werkende simpatomimetiese middels, epinefrien en norepinefrien, word versterk deur TREPILINE, en plaaslike verdowingsmiddels wat hierdie vasokonstriktors bevat moet vermy word, aangesien hipertensiewe reaksies kan voorkom. Wanneer moontlik, moet behandeling gestaak word vir etlike dae voor gekose sjirurgie. Die hipotensiewe effek van sekere antihipertensiewe middels kan verminder word.

Porfirie

Die gebruik van TREPILINE by pasiënte wat aan akute vorms van porfirie ly, veral gevarieerde porfirie en tot ’n mindere mate akute intermitterende porfirie en oorerflike koproporfirie, is betwisbaar, en daarom moet TREPILINE versigtig by hierdie pasiënte gebruik word.

Versigtige gebruik by sekere toestande

TREPILINE moet ook versigtig gebruik word by pasiënte met hipertiroïdisme of met ingekorte lewerfunksie, en by dié pasiënte met ’n geskiedenis van epilepsie, onbehandelde nouhoek-gloukoom, urinêre retensie, prostatiese hipertrofie of hardlywigheid. Hierdie toestande kan vererger word deur TREPILINE.

Veltoestande

TREPILINE moet onttrek word indien allergiese velreaksies verskyn.

Medetoediening van sekere medisyne

Effekte van sentrale senuweestelsel onderdrukkers (insluitende barbiturate en alkohol) en

anticholinergiese middels kan verhoog word deur TREPILINE. Medetoediening moet vermy word.

Elektrokonvulsiewe terapie

Tensy noodsaaklik, word die kombinasie van TREPILINE en elektrokonvulsiewe terapie (EKT) nie aanbeveel nie.

Hiponatremie

Hiponatremie (gewoonlik by bejaardes en moontlik as gevolg van onvoldoende sekresie van antidiuretiese hormoon) hou verband met alle tipes antidepressante soos TREPILINE en moet oorweeg word by alle pasiënte wat lomerigheid, verwarring of konvulsies ontwikkel terwyl hulle TREPILINE neem (’n antidepressant).

NOTA: Bejaarde pasiënte is meer geneig tot al hierdie effekte, en terapie moet geïnisieer word by laer as standaard dosisse by bejaardes.

Laktose waarskuwing

TREPILINE bevat laktose wat ’n uitwerking op die glisemiese beheer van pasiënte met diabetes mellitus kan hê. TREPILINE bevat laktose. Pasiënte met die seldsame oorerflike toestande van galaktose onverdraagsaamheid bv. galaktosemie, die Lapp-laktase tekort, glukose-galaktose wanabsorpsie of fruktose onverdraagsaamheid moet nie TREPILINE neem nie.

Effekte op die vermoë om te bestuur en masjinerie te gebruik

Ten tye van aanvang van terapie, moet pasiënte aangeraai word om nie ’n motorvoertuig te bestuur, gevaarlike hoogtes te klim of gevaarlike masjinerie te bedryf nie, ten minste vir verskeie dae. In hierdie situasies kan ingeperkte besluitneming tot ongelukke lei.

Aangesien ongunstige reaksies soos lomerigheid, duiseligheid en dowwe visie aangemeld is by pasiënte wat TREPILINE ontvang, moet pasiënte nie bestuur, masjinerie gebruik of enige take verrig wat konsentrasie verg nie, totdat hulle seker is dat TREPILINE nie hulle vermoë om dit te doen ongunstig affekteer nie (sien NEWE-EFFEKTE).

INTERAKSIES

Mono-amienoksidase inhibeerders (MAOIs) kan die effekte van trisikliese antidepressante soos TREPILINE potensieer en hiperpiretiese krisis, ernstige konvulsies en sterftes het al voorgekom. ’n Minimum van 14 dae moet verloop tussen die staking van ’n MAOI en die aanvang van TREPILINE, wat versigtig bekendgestel moet word en die dosis moet geleidelik verhoog word (sien KONTRA-INDIKASIES).

TREPILINE kan die antihipertensiewe werking van debrisokien, betanidien en klonidien blokkeer (sien KONTRA-INDIKASIES). Daar is ’n verhoogde risiko van hipertensie met klonidien onttrekking. Alle antihipertensiewe terapie moet hersien word gedurende behandeling met TREPILINE.

Meegaande gebruik van TREPILINE en reboksetien moet versigtig gebruik word. Die plasma konsentrasies van amitriptilien in TREPILINE kan verhoog word deur selektiewe serotonien-heropname inhibeerders (SSRIs). Fluoksetien inhibeer sitochroom P450 II D6, wat betrokke is by die metabolisme van ’n aantal trisikliese antidepressante soos TREPILINE, merkbaar. Pasiënte moet gemoniteer word vir verhoogde antidepressant plasmavlakke en toksisiteit wanneer fluoksetien saam met TREPILINE gebruik word. Aanpassing van die dosis van TREPILINE en/of fluoksetien mag nodig wees.

Alfa$_2$-adrenoseptor stimulante: Meegaande gebruik van apraklonidien en brimonidien saam met TREPILINE moet vermy word.

Pynstillers: Die risiko van sentrale senuweestelsel (SSS) toksisiteit van TREPILINE word verhoog met tramadol. Daar is ’n moontlikheid van verhoogde sedasie met opioïed pynstillers.

Narkosemiddels: Meegaande terapie met TREPILINE en narkosemiddels kan die risiko van disritmieë en hipotensie verhoog. Indien sjirurgie benodig word, moet die narkotiseur ingelig word dat die pasiënt met TREPILINE behandel word.

Antidisritmiese middels: Daar is ’n vehoogde risiko van ventrikulêre disritmieë wanneer TREPILINE gebruik word saam met medisyne wat die QT interval verleng, insluitend amiodaroon, disopiramied, prokaïenamied, propafenoon en kinidien. Meegaande gebruik moet vermy word.

Antibakteriële middels: Plasmakonsentrasies van amitriptilien in TREPILINE, kan verlaag word deur rifampisien wat die antidepressiewe effek verlaag. Meegaande gebruik van TREPILINE en linesolied kan SSS-opwekking en hipertensie tot gevolg hê (sien KONTRA-INDIKASIES). TREPILINE moet nie saam met simpatomimetiese middels soos epinefrien (adrenalien), isoprenalien, norepinefrien (noradrenalien), fenielefrien en fenielpropanolamien gegee word nie, as gevolg van hipertensie en disritmieë.

Metielfenidaat kan die metabolisme van amitriptilien, soos bevat in TREPILINE, inhibeer, en daardeur die antidepressiewe werking van TREPILINE vermeerder.

TREPILINE kan die respons teenoor alkohol, barbiturate en ander SSS-onderdrukkers verhoog. Meegaande gebruik van disulfiram kan die metabolisme van amitriptilien inhibeer. Delirium is aangemeld by pasiënte wat TREPILINE saam met disulfiram neem.

Meegaande gebruik van TREPILINE en stuipwerende middels kan die konvulsiewe drempel verlaag. Barbiturate en karbamasepien kan die antidepressiewe werking van TREPILINE verlaag.

Antiswammiddels: Verhoogde serumkonsentrasies van amitriptilien, soos bevat in TREPILINE, het voorgekom by pasiënte wat ook flukonasool neem. Ernstige ongunstige effekte is aangemeld as gevolg van verhoogde amitriptilien plasmakonsentrasie.

Antihistamiene: Verhoogde anticholinergiese en sederende effekte kan voorkom wanneer antihistamiene saam met TREPILINE gebruik word.

Gebaseer op die bekende metabolisme van amitriptilien, soos bevat in TREPILINE, kan die protease inhibeerder, ritonavir, die serumvlakke van amitriptilien, soos bevat in TREPILINE, verhoog. Daarom word versigtige monitering van terapeutiese en ongewenste effekte aanbeveel wanneer hierdie medisyne saam toegedien word.

Antipsigotiese middels: Verhoogde risiko van ventrikulêre disritmieë. Vermy gebruik saam met pimosied of tioridasien. Meegaande gebruik met antipsigotiese middels kan plasmakonsentrasies van amitriptilien, soos bevat in TREPILINE, verhoog, en verhoog die anticholinergiese newe-effekte van fenotiasiene en moontlik klosapien.

Beta-blokkeerders: Daar is ’n verhoogde risiko van ventrikulêre disritmieë wat verband hou met die gesamentlike gebruik van TREPILINE en sotalol.

Kalsium-kanaal blokkeerders: Diltiasem en verapamil kan die plasmakonsentrasie van amitriptilien verhoog.

Diuretika: Daar is ’n verhoogde risiko van posturale hipotensie.

Dopaminergiese middels: Gesamentlike gebruik van TREPILINE en entakapoon moet vermy word. SSS toksisiteit is ook aangemeld met selegilien.

Spierverslappers: Gesamentlike gebruik van baklofen verhoog die spierverslappingseffek.

Nitrate: Verminderde effek van sublinguale nitrate (as gevolg van droë mond).

Estrogene en progestogene: Mondelikse voorbehoedmiddels antagoniseer die antidepressiewe effek van TREPILINE, maar newe-effekte kan vermeerder word as gevolg van verhoogde plasmakonsentrasies van trisikliese antidepressante soos TREPILINE.

Oormatige anticholinergiese effekte kan voorkom wanneer TREPILINE in kombinasie met anticholinergiese medisyne gebruik word. Paralitiese ileus, urinêre retensie of akute gloukoom kan ontketen word, veral by bejaarde pasiënte.

Simetidien is aangemeld om hepatiese metabolisme van TREPILINE te verminder. Gesamentlike gebruik versterk die sederende effek.

St. John’s Wort kan plasmavlakke van amitriptilien verminder.

TREPILINE kan tioridasien-vlakke verhoog, wat kan lei tot kardiale newe-effekte.

Pasiënte wat skildklierpreparate neem kan ’n versnelde reaksie teenoor TREPILINE toon. Die gebruik van TREPILINE saam met skildklierhormone kan hartdisritmieë ontketen.

MENSLIKE VOORTPLANTING

Veiligheid en doeltreffendheid gedurende swangerskap en laktasie is nie vasgestel nie (sien KONTRA-INDIKASIES).

Laktasie

Moeders op TREPILINE moet nie hulle babas borsvoed nie.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes:

Aanvanklik 75 mg tot 150 mg daagliks in verdeelde dosisse.

Instandhoudingsdosis is 50 mg tot 100 mg daagliks in verdeelde dosisse.

NEWE-EFFEKTE

Bloed- en limfstelsel afwykings

Minder dikwels: Beenmurgonderdrukking insluitende agranulositose, eosinofilie, leukopenie, trombositopenie en purpura

Immuunstelsel afwykings

Minder dikwels: Hipersensitiwiteitsreaksies insluitende veluitslag, urtikarie, fotosensitisering, edeem van gesig en tong, angio-edeem

Endokriene afwykings

Minder dikwels: Sindroom van onvanpaste ADH sekresie (SIADH), hiperglisemie, hipoglisemie, hiponatremie

Metabolisme- en voedingsafwykings

Minder dikwels: Verhoogde eetlus, gewigstoename, gewigsverlies, anoreksie

Psigiatriese afwykings

Minder dikwels: Verwarringstoestande, disoriëntasie, agitasie, slapeloosheid, nagmerries, drogbeelde, hallusinasies, manie of hipomanie, opgewondenheid, angstigheid, rusteloosheid, versteurde konsentrasie, gedragsveranderinge, selfmoordneigings, selfmoordgedrag

Senuweestelsel afwykings

Dikwels: Lomerigheid of oormatige sedasie

Minder dikwels: Duiseligheid, hoofpyn, perifere neuropatie, gevoelloosheid, tinteling en parestesie van die ledemate, gebrek aan koördinasie, ataksie, bewing, koma, epileptiform toevalle, veranderde EEG, ekstrapiramidale simptome insluitende abnormale onwillekeurige beweging en tardiewe diskinesie, disartrie

Oogafwykings

Dikwels: Dowwe visie, akkommodasie versteuring, verhoogde intra-okulêre druk

Minder dikwels: Midriase

Oor- en labirint afwykings

Minder dikwels: Tinnitus

Hartafwykings

Minder dikwels: Palpitasies, tagikardie, miokardiale infarksie, hartblok, nie-spesifieke EKG veranderings en veranderings in AV-geleiding, disritmieë

Vaskulêre afwykings

Minder dikwels: Hipotensie, floute, posturale hipotensie, hipertensie, beroerte

Gastroïntestinale afwykings

Dikwels: Droë mond, hardlywigheid

Minder dikwels: Naarheid, braking, diarree, paralitiese ileus, epigastriese nood, disgeusie, stomatitis, metaalsmaak, parotis swelling, swart tong

Hepatobiliêre afwykings

Minder dikwels: Hepatitis (insluitende veranderde lewerfunksie en cholestatiese geelsug)

Vel- en onderhuidse weefsel afwyking

Minder dikwels: Veluitslag, alopesie

Muskuloskeletale-, bindweefsel- en beenafwykings

Frekwensie onbekend: Verhoogde risiko van beenfrakture (klaseffek)

Renale en urinêre afwykings

Dikwels: Urinêre retensie

Minder dikwels: Urinêre frekwensie, urienweg dilatasie

Afwykings van die voortplantingstelsel en borste

Minder dikwels: Ginekomastie, borsvergroting, galaktoree, testikulêre swelling, veranderings in libido, impotensie, seksuele disfunksie

Algemene afwykings en toedieningsplek toestande

Dikwels: Hipertermie

Minder dikwels: Swakheid, moegheid, verhoogde sweet

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien NEWE-EFFEKTE.

Simptome

Oordosering en vergiftiging word gekenmerk deur sentrale senuweestelsel onderdrukking of opwekking, ernstige anticholinergiese effekte en kardiotoksisiteit. Die volgende simptome en tekens is kenmerkend van akute oordosering: lomerigheid, rusteloosheid, ataksie, bedwelming, koma, pireksie, palpitasies, tagikardie, hartdisritmieë, hipotensie en in ernstige gevalle, respiratoriese onderdrukking. Epileptiform toevalle kan voorkom. Gemengde vergiftiging saam met ander sentrale senuweestelsel onderdrukkers is nie ongewoon nie.

Behandeling

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

TREPILINE 10: Ligblou, ronde, vlak, bikonvekse, filmbedekte tablette, gewoon aan beide kante.

TREPILINE 25: Geel, ronde, vlak, bikonvekse, filmbedekte tablette, gewoon aan beide kante.

AANBIEDING

TREPILINE 10: Verpakkings van 100 en 500 tablette in wit polipropileen “securitainers” saam met ’n skuiminsetsel/rayon en professionele inligting wat verseël is met ’n wit, lae-digtheidspoliëtileen “securitainer” dop.

Verpakkings van 28 tablette in ’n gemetalliseerde pasiënt-gereed verpakking wat verseël word met plat-lê ritssluiters na dit gevul is en in poliëtileen sakkies verpak word.

TREPILINE 25: Verpakkings van 100 en 500 tablette in wit polipropileen “securitainers” saam

met ‘n skuiminsetsel/rayon en professionele inligting wat verseël is met ’n wit, laedigtheidspoliëtileen “securitainer” dop.

Verpakkings van 28 en 84 tablette in ’n gemetalliseerde pasiënt-gereed verpakking wat verseël word met plat-lê ritssluiters na dit gevul is en word verpak in poliëtileen sakkies.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen lig en vog.

HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMERS

TREPILINE 10: J/1.2/219

TREPILINE 25: J/1.2/220

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead, 2191

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MENSLIKE GEBRUIK

Datum van registrasie: 11 Oktober 1976

Datum van mees onlangs hersiene professionele inligting soos goedgekeur deur Beheerraad: 28 Julie 2017