SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

EMITEX TABLET

COMPOSITION

Each EMITEX TABLET contains 50 mg cyclizine hydrochloride.

Excipients:

Lactose monohydrate, magnesium stearate, pregelatinised maize starch, sodium starch glycollate, starch maize.

Contains sugar: Lactose monohydrate 19,5 mg

CATEGORY AND CLASS

A 5.7.2 Anti-emetics and antivertigo preparations

PHARMACOLOGICAL ACTION

Cyclizine is an antihistamine with anti-emetic properties.

INDICATIONS

EMITEX TABLET is indicated in the prevention and treatment of nausea and vomiting. It is indicated in prophylaxis and treatment of motion sickness, in the symptomatic management of vertigo and labyrinth disorders (Ménière's Syndrome).

CONTRAINDICATIONS

EMITEX TABLET is contraindicated in individuals who have previously reacted adversely to cylizine.

EMITEX TABLET is contraindicated in pregnancy (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS

Large doses may precipitate fits in epileptics.

EMITEX TABLET may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.

Effects on ability to drive and use machines

Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Excipients

Lactose warning:

EMITEX TABLET contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take EMITEX TABLET.

INTERACTIONS

The effects of atropine and tricyclic antidepressants may be enhanced by EMITEX TABLET. Restlessness, dizziness and tachycardia may occur if atropine and EMITEX TABLET are used together.

EMITEX TABLET may mask the warning symptoms of damage caused by ototoxic medicines and may affect the metabolism of medicines in the liver.

EMITEX TABLET may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilizers.

HUMAN REPRODUCTION

EMITEX TABLET should not be taken during pregnancy (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years: 1 tablet three times a day.

Children 6 to 12 years: Half a tablet three times a day.

For prevention of motion sickness, one tablet should be taken 20 to 30 minutes before departure. This dose may be repeated every 4 to 6 hours if necessary. The dosage for children aged 6 to 12 years is half the adult dosage.

SIDE EFFECTS

The most common side effect of EMITEX TABLET is sedation, which can vary from slight drowsiness to deep sleep and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and incoordination.

Other side-effects include gastrointestinal disturbances such as nausea, diarrhoea or constipation and epigastric pain. Headache, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands may occur.

Fixed drug eruptions, generalised chorea and hypersensitivity hepatitis have been reported after oral administration.

In children it may act as a cerebral stimulant. Symptoms of stimulation in adults include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Allergy and anaphylaxis may occur. Blood dyscrasias including agranulocytosis and hemolytic anaemia have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Symptoms of acute toxicity arise from effects of the preparation on the central nervous system and include drowsiness, dizziness, incoordination, weakness, convulsions, hyperpyrexia and respiratory depression. Agitation, ataxia and hallucinations may occur.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

White, flat bevelled edged tablet with a breakline on one side. Odourless.

PRESENTATION

10, 20, or 200 tablets are packed in a white high density polyethylene container and sealed with a white opaque polypropylene screw cap with an induction was together with a white foam plug. The container is packed into an outer cardboard carton together with a leaflet.

10, 20 or 200 tablets are packed in a white polypropylene container and sealed with a white linear low density polyethylene cap together with a white foam insert. The container is packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C and protect from moisture.

Store in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

28/5.7.2/0435

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead;2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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Namibia: NS1 04/5.7/0421

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SUID-AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S2

EIENDOMSNAAM EN DOSEERVORM

EMITEX TABLET

SAMESTELLING

Elke EMITEX TABLET bevat 50 mg siklisienhidrochloried.

Eksipiënte:

Laktosemonohidraat, magnesiumstearaat, pregelatiniseerde mieliestysel, natriumstyselglikolaat, mieliestysel.

Bevat suiker: Laktosemonohidraat 19,5 mg

KATEGORIE EN KLAS

A 5.7.2 Anti-emetika en antivertigomiddels

FARMAKOLOGIESE WERKING

Siklisien is ’n antihistamien met anti-emetiese eienskappe.

INDIKASIES

EMITEX TABLET word aangedui vir die voorkoming en behandeling van naarheid en braking. Dit word aangedui vir die voorkoming en behandeling van reissiekte, vir die simptomatiese behandeling van vertigo en labirint versteurings (Mèniére se Sindroom).

KONTRA-INDIKASIES

EMITEX TABLET word teenaangedui by individue wat voorheen ongunstig gereageer het op siklisien.

EMITEX TABLET word teenaangedui by swangerskap (sien MENSLIKE VOORPLANTING).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Groot dosisse kan stuipe by epileptiese pasiënte veroorsaak.

EMITEX TABLET kan lei tot lomerigheid en verswakte konsentrasie, wat vererger kan word deur die gelyktydige inname van alkohol en ander sentrale senuweestelsel onderdrukkers.

Effekte op die vermoë om te bestuur en masjinerie te gebruik

Pasiënte behoort gewaarsku te word om nie voertuie te bestuur of masjinerie te hanteer of moontlik gevaarlike take te onderneem waar verlies van konsentrasie tot ongelukke kan lei nie.

Eksipiënte

Laktose waarskuwing:

EMITEX TABLET bevat laktose wat ’n effek op die glisemiese beheer van pasiënte met diabetes mellitus kan hê.

Pasiënte met die seldsame oorerflike toestande van galaktose-onverdraagsaamheid bv. galaktosemie, die Lapp-laktasetekort, glukose-galaktose wanabsorpsie of fruktose-onverdraagsaamheid moenie EMITEX TABLET neem nie.

INTERAKSIES

Die effekte van atropien en trisikliese antidepressante kan versterk word deur EMITEX TABLET. Rusteloosheid, duiseligheid en tagikardie kan voorkom indien atropien en EMITEX TABLET saam gebruik word.

EMITEX TABLET kan die waarskuwingsimptome van beskadiging maskeer wat deur ototoksiese medisyne veroorsaak word en kan die metabolisme van medisyne in die lewer beïnvloed.

EMITEX TABLET kan die sedatiewe effek van sentrale senuweestelsel onderdrukkers insluitende alkohol, barbiturate, hipnotika, narkotiese analgetika, kalmeermiddels en bedaarmiddels versterk.

MENSLIKE VOORTPLANTING

EMITEX TABLET moet nie tydens swangerskap geneem word nie (sien KONTRA-INDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes en kinders ouer as 12 jaar: 1 tablet drie keer per dag.

Kinders 6 tot 12 jaar: ’n Halwe tablet drie keer per dag.

Vir die voorkoming van reissiekte, moet een tablet 20 tot 30 minute voor vertrek geneem word. Hierdie dosis kan, indien nodig, elke vier tot ses uur herhaal word. Die dosis vir kinders tussen die ouderdomme 6 en 12 jaar is helfte van die volwassenes dosis.

NEWE-EFFEKTE

Die mees algemene newe-effek van EMITEX TABLET is sedasie, wat kan wissel van ligte lomerigheid tot ’n diep slaap, en sluit in die onvermoë om te konsentreer, lusteloosheid, duiseligheid, hipotensie, spierswakheid en inkoördinasie.

Ander newe-effekte sluit in gastroïntestinale versteurings soos naarheid, diarree of

hardlywigheid en epigastriese pyn. Hoofpyn, tinnitus, opgewondenheid of depressie, prikkelbaarheid, nagmerries, anoreksie, moeilike urinering, droogheid van die mond, styfheid van die bors en prikkelende sensasie, swaarheid en swakheid van die hande kan voorkom.

Vaste middel uitbarstings, algemene chorea en hipersensitiwiteit-hepatitis is aangemeld na mondelikse toediening.

By kinders kan dit as ’n serebrale stimulant werk. Simptome van stimulasie by volwassenes sluit in slaaploosheid, senuweeagtigheid, tagikardie, bewing, spiersametrekkings en konvulsies.

Allergieë en anafilakse kan voorkom. Bloed diskrasieë insluitende agranulositose en hemolitiese bloedarmoede is aangemeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Simptome

Simptome van akute toksisiteit is as gevolg van die effekte van die preparaat op die sentrale senuweestelsel en sluit lomerigheid, duiseligheid, inkoördinasie, swakheid, konvulsies, hiperpireksie en respiratoriese onderdrukking in. Agitasie, ataksie en hallusinasies kan voorkom.

Behandeling

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

Wit, plat afgeskuinste tablet met ’n breeklyn op die een kant. Reukloos.

AANBIEDING

10, 20 of 200 tablette word verpak in ‘n wit hoëdigtheidspoliëtileen houer en verseël met ‘n wit, ondeursigtige polipropileen skroefdop met ‘n induksieseël saam met ‘n wit skuimprop. Die houer word in ‘n buitenste kartonhouer saam met ‘n voubiljet verpak.

10, 20 of 200 tablette word verpak in ‘n wit polipropileen houer en verseël met ‘n wit, lineêre laedigtheidspoliëtileen dop saam met ‘n wit skuiminsetsel. Die houer word in ‘n buitenste kartonhouer saam met ‘n voubiljet verpak.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C en beskerm teen vog.

Bêre in oorspronklike verpakking totdat dit benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

28/5.7.2/0435

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 MEDISYNE VIR MENSLIKE GEBRUIK

Datum van registrasie: 24 Februarie 1994

Datum van mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 24 Februarie 1994

Namibië: NS1 04/5.7/0421

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