SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
BIO BACLOFEN (tablets)

COMPOSITION:
BIO BACLOFEN: Each tablet contains 10 mg baclofen.
Excipients: colloidal silicon dioxide, lactose, magnesium stearate, maize starch, pregelatinised starch, sodium starch glycollate.
BIO BACLOFEN containing 10 mg baclofen contains lactose. Contains Sugar

PHARMACOLOGICAL CLASSIFICATION:
A 2.10 Centrally active muscle relaxants

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Baclofen is a derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA). Baclofen exerts its antispastic effects by depressing monosynaptic and polysynaptic transmission in the spinal cord. It reduces excitatory postsynaptic potentials in motorneurons in the ventral horn without affecting their membrane potential or input resistance. These effects superficially resemble those of GABA, which is released by interneurons in the spinal cord and depolarises the axonal terminals of primary afferent fibres.
This results in presynaptic inhibition of motorneurons. Baclofen does not cause depolarisation of primary afferent nerve terminals.
Pharmacokinetic properties
Baclofen is well absorbed after oral administration and its plasma half-life is about 3-4 hours. It is excreted largely unchanged by the kidney.

INDICATIONS:
BIO BACLOFEN is used in adults to treat spasticity of the skeletal muscle due to multiple sclerosis; spastic conditions occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic, or unknown etiology.

CONTRAINDICATIONS:
Galactose-lactose intolerance.
Active peptic ulcer.
Hypersensitivity to baclofen or to any of the excipients of BIO BACLOFEN.
Patients with a history of epilepsy or convulsive disorders.
BIO BACLOFEN should not be administered to pregnant and lactating women.
Porphyria.

WARNINGS AND SPECIAL PRECAUTIONS:
Psychiatric disorders, schizophrenia, depression and manic disorders, confusional states and Parkinsons disease may be exacerbated by treatment with BIO BACLOFEN. Patients suffering from these conditions should be treated cautiously and kept under surveillance.
Epilepsy: BIO BACLOFEN may exacerbate epileptic manifestations by lowering of the convulsion threshold. Convulsions may occur, particularly in epileptic patients. However, BIO BACLOFEN can be employed provided appropriate supervision and adequate anticonvulsive therapy are maintained.
Extreme caution is needed if BIO BACLOFEN is combined with anti-hypertensive therapy because of the risk of potentiating the hypotensive effect.
The use of BIO BACLOFEN may lead to drowsiness, visual disturbances and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients taking BIO BACLOFEN should not take charge of vehicles, or operate machinery when loss of attention may result in accidents. Patients experiencing these adverse reactions should be advised to refrain from driving or using machines (refer to EFFECTS ON ABILITY TO DRIVE AND USE MACHINES).
Patients who have suffered from a stroke, tolerate BIO BACLOFEN poorly.
Withdrawal of BIO BACLOFEN should be gradual. Sudden withdrawal of BIO BACLOFEN after chronic administration may cause muscle rigidity and exaggerated rebound spasticity, severe high fever (hyperthermia), altered mental status, manic or paranoid states, convulsions (status epilepticus), and has progressed in rare instance to rhabdomyolysis, multiple organ-system failure and death. Other withdrawal symptoms are auditory and visual hallucinations, anxiety, confusional state, delirium, hallucination, diskinesia and tachycardia. Treatment should be gradually discontinued by successively reducing the dosage (over a period of approximately one to two weeks).
Concomitant treatment of BIO BACLOFEN and levodopa (alone or in combination with carbidopa) in patients with Parkinson's, will result in mental confusion, hallucinations, headaches, nausea and agitation (see INTERACTIONS).
Worsening of the symptoms of Parkinsonism has also been reported.
BIO BACLOFEN should be used with caution in patients with renal insufficiency.
Particular caution is required when combining BIO BACLOFEN with medicines that affect renal function. Renal function should be closely monitored and BIO BACLOFEN daily dosage adjusted accordingly to prevent baclofen toxicity.
BIO BACLOFEN stimulates gastric acid secretion and should be used with caution in patients with a history of peptic ulcer and avoided in those with active peptic ulcer disease (see CONTRAINDICATIONS).
BIO BACLOFEN should be used with caution in patients with cerebrovascular disease.
BIO BACLOFEN can cause increased blood sugar concentrations, caution is advised in patients with diabetes mellitus.
Urine retention may be exacerbated in patients with hypertonic bladder sphincters.
BIO BACLOFEN should be used with caution in patients in whom spasticity is used to maintain posture or increase functional capacity.
BIO BACLOFEN should be used with caution in patients with respiratory impairment, and hepatic impairment.
Some cases of elevated AST, alkaline phosphatase, and glucose levels in the serum have been reported. Appropriate laboratory test should therefore be performed periodically in patients with liver disease or diabetes mellitus.
BIO BACLOFEN contains lactose and should not be administered to patients with rare hereditary problems, or a history of lactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption.
Effects on ability to drive and use machines:
BIO BACLOFEN can cause drowsiness, dizziness, light-headedness and hypotension. Patients affected should not be driving a motor vehicle or operate machinery.

INTERACTIONS:
Alcohol and other central nervous system (CNS) depressants may exacerbate the CNS effects of BIO BACLOFEN, especially sedation, and should be avoided.
Severe aggravation of hyperkinetic symptoms may occur in patients taking lithium.
There may be increased muscular weakness if BIO BACLOFEN is given to patients taking a tricyclic antidepressant.
There may be an increased hypotensive effect if it is given to patients receiving antihypertensive therapy.
NSAIDs and other medication that produce renal insufficiency may reduce BIO BACLOFEN excretion leading to toxicity.
In patients with Parkinson's disease receiving treatment with BIO BACLOFEN and levodopa resulted in mental confusion, hallucinations, headaches, nausea and agitation (refer to WARNINGS AND SPECIAL PRECAUTIONS).

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established. BIO BACLOFEN should not be administered during pregnancy and lactation (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE:
Treatment should be initiated with small, gradually increasing doses of BIO BACLOFEN. The optimum daily dosage should be individually adapted to the patient's requirements in such a way that clonus, flexor and extensor spasms, and spasticity are reduced, but that a sufficient degree of muscle tone is maintained to permit active movements and adverse effects are avoided as far as possible.
In order to prevent excessive weakness and falling, BIO BACLOFEN should be used with caution when spasticity is needed to sustain upright posture and balance in locomotion or whenever spasticity is used to maintain function. It may be important to maintain some degree of muscle tone and allow occasional spasms to help support circulatory function.
BIO BACLOFEN should be taken during meals with a little liquid.

The daily dosage should be given in at least 3 divided doses in adults.
Adults:
Treatment should be started with a dosage of 5 mg three times daily, and subsequently be increased at three-day intervals by 5 mg three times daily until the requisite daily dosage has been attained, see dosage below:
ie: 5 mg three times daily for 3 days
10 mg three times daily for 3 days
15 mg three times daily for 3 days
20 mg three times daily for 3 days
In some patients, it may be advisable to begin with a lower daily dosage (5 mg or 10 mg) and to raise this dosage more gradually. The optimum dosage generally ranges from 30 mg to 80 mg daily.
Doses of more than 80 mg to 100 mg daily are not generally recommended although higher doses have been given to carefully supervised patients in hospital.
Renal Impairment:
In patients with impaired renal function or undergoing chronic haemodialysis, a particularly low dosage of BIO BACLOFEN should be selected, i.e. approximately 5 mg daily.
Elderly:
Since unwanted effects are more likely to occur in elderly patients or in patients with spastic states of cerebral origin, in such cases it is recommended that a very cautious dosage schedule be adopted and that the patient be kept under appropriate surveillance.
Withdrawal Effects:
Withdrawal of BIO BACLOFEN should be gradual. Abrupt discontinuation of the treatment should be avoided (see WARNINGS AND SPECIAL PRECAUTIONS).

SIDE EFFECTS:
Nervous system disorders
Frequent: Confusion, sedation, somnolence, drowsiness, fatigue, light-headedness, lassitude, exhaustion, dizziness, headache, insomnia, tremor, nystagmus, asthenia.
Less frequent: Paraesthesia, dysarthria, dysgeusia, convulsions, slurred speech, paradoxical increase in spasticity, hypothermia, coma, encephalopathy, incoordination, dystonia, seizures.
Frequency not known: Aseptic meningitis, encephalopathy.
Psychiatric disorders
Frequent: Mental confusion, euphoria, hallucination, nightmares.
Less frequent: Depression.
Frequency not known: Catatonic reaction, mania, mood disorder, amnesia.
Respiratory, thoracic and medistinal disorders
Frequent: Respiratory depression.
Frequency not known: Acute bronchospasm, bronchial hyper responsiveness, dyspnoea and chest tightness, decreased cough reflex, nasal congestion.
Musculoskeletal disorders
Frequent: Myalgia, muscular weakness and pain, ataxia.
Rare: Muscle rigidity.
Eye disorders
Frequent: Accommodation disorders, visual disturbances.
Less frequent: Nystagmus, strabismus, diplopia, mydriasis.
Ear and labyrinth disorders
Less frequent: Tinnitus.
Cardiac disorders
Frequent: Decrease cardiac output, cardiac depression.
Less frequent: Chest pain, palpitations, syncope.
Frequency not known: Bradycardia.
Vascular disorders
Less frequent: Hypotension, ankle oedema.
Frequency not known: Increased sweating.
Gastrointestinal disorders
Frequent: Nausea, gastrointestinal disturbances, retching, vomiting, constipation or diarrhoea, dryness of mouth, taste alterations, xerostomia.
Less frequent: Abdominal pain.
Hepato-biliary disorders
Less frequent: Abnormal hepatic function, elevated liver enzymes.
Skin and subcutaneous tissue disorders
Frequent: Hyperhydrosis, rash.
Frequency unknown: Allergic skin reactions, pruritus, urticaria.
Renal and urinary disorders
Frequent: Urinary disturbances, pollakiuria.
Less frequent: Urinary retention, dysuria, haematuria.
Frequency not known: Enuresis, urinary incontinence.
Endocrine disorders
Frequency not known: Blood sugar changes, weight gain or anorexia.
Reproductive system and breast disorders
Less frequent: Erectile dysfunction, impotence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Signs and symptoms of an overdosage are predominantly coma, respiratory depression, seizures and impairment of consciousness. Convulsions occur mainly in patients with a history of epilepsy. Deterioration in the condition may occur if various substances acting on the central nervous system have been taken at the same time.
No specific antidote is known. Elimination of baclofen from the gastro-intestinal tract (induction of vomiting, gastric lavage; comatose or convulsing patients should be intubated prior to gastric lavage). Treatment is symptomatic and supportive.

IDENTIFICATION:
BIO BACLOFEN: White, bevelled edge tablet embossed BCN 10 and a break line on one side, and plain on the reverse side.

PRESENTATION:
BIO BACLOFEN:
Securitainers containing 30 and 100 tablets.
Silver aluminium, clear transparent PVC/PVdC blister packs. Each strip containing ten tablets.
White HDPE ontainer (50 cc) with white opaque screw cap and induction sealing wad, containing 30 tablets.

STORAGE INSTRUCTIONS:
Store at or below 25 °C and protect from moisture.
Keep the tablets in the original container until required for use.
Keep the PP container well closed.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:
BIO BACLOFEN: W/2.10/433

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION :
BIOTECH LABORATORIES (PTY) LTD.
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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SKEDULERINGSTATUS:
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EIENDOMSNAAM EN DOSEERVORM:
BIO BACLOFEN (tablette)

SAMESTELLING:
BIO BACLOFEN: Elke tablet bevat 10 mg baklofen.
Onaktiewe bestanddele: kolloïdale silikondioksied, laktose, magnesiumstearaat, mieliestysel, pregelatiniseerde stysel, natrium styselglikolaat.
BIO BACLOFEN bevat laktose.
Bevat Suiker

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.10 Sentraalwerkende spierverslappers

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Baklofen is 'n afbraakproduk van die inhiberende neurotransmitter gamma-aminobutiriesesuur (GABA). Baklofen is nuttig in die vermindering van die frekwensie van fleksor of ekstensor spasmas en in die vermindering van verhoogde fleksor tonus. Baklofen werk spierverslappend deur mono- en polisinaptiese refleksoroordrag in die rugmurg te onderdruk. Dit verminder eksitatoriese postsinaptiese potensiaal in motorneurons in die ventrale horing sonder dat hul membraanpotensiaal of weerstandsinsette geaffekteer word. Hierdie effekte kom oppervlakkig ooreen met dié van GABA, wat vrygestel word deur interneurons in die rugmurg en depolariseer die aksonterminale van primêre afferente vesels. Dit lei tot die presinaptiese inhibering van motorneuron. Baklofen veroorsaak nie depolarisasie van primêre afferente senuweeterminale nie.
Dit lei tot die presinaptiese inhibering van motorneuron. Baklofen veroorsaak nie depolarisasie van primêre afferente senuweeterminale nie.
Farmakokinetiese eienskappe
Baklofen word vinnig geabsorbeer na orale toediening en die plasmahalfleeftyd is ongeveer 3-4 uur. Dit word grootliks onveranderd deur die niere uitgeskei.

INDIKASIES:
BIO BACLOFEN word gebruik by volwassenes om spastisiteit van die skeletspier te behandel as gevolg van veelvuldige sklerose; spastiese toestande wat voorkom in rugmurgsiektes van aansteeklike, degeneratiewe, traumatiese, neoplastiese of onbekende oorsprong.

KONTRA-INDIKASIES:
Galaktose-laktose intoleransie.
Aktiewe peptiese ulkus.
Hipersensitiwiteit vir baklofen of vir enige van die onaktiewe bestanddele van BIO BACLOFEN.
Pasiënte met 'n geskiedenis van epilepsie of konvulsiewe afwykings.
BIO BACLOFEN moet nie vir swanger vrouens of vrouens wat borsvoed gegee word nie.
Porfirie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Psigiatriese versteurings, skisofrenie, depressie of maniese versteurings, verwardheid of Parkinson se siekte mag vererger word deur BIO BACLOFEN behandeling. Pasiënte wat aan hierdie toestande ly, moet met omsigtigheid behandel en gemonitor word.
Epilepsie: BIO BACLOFEN kan epileptiese manifestasies vererger deur die konvulsiedrempel te verlaag. Konvulsies kan by veral epileptiese pasiënte voorkom. Genoegsame behandeling met antikonvulsante moet voortgesit word en die pasiënt moet noukeurig gemonitor word.
Uiterste omsigtigheid is nodig wanneer BIO BACLOFEN gekombineer word met antihipertensiewe behandeling as gevolg van die risiko van potensiëring van die hipotensiewe effek.
Die gebruik van BIO BACLOFEN kan tot lomerigheid, visuele versteurings en verswakte konsentrasie lei wat vererger kan word deur die gelyktydige inname van alkohol of ander medisyne wat inwerk op die sentrale senuweestelsel.
Pasiënte wat BIO BACLOFEN gebruik moet nie voertuie bestuur of masjinerie hanteer nie, aangesien verswakte konsentrasie aanleiding kan gee tot ongelukke.
Pasiënte wat hierdie newe effekte ervaar, moet aangeraai word om nie te bestuur of masjiene te gebruik nie (verwys na UITWERKING OP VERMOË OM 'n VOERTUIG TE BESTUUR EN MASJINERIE TE GEBRUIK)
Pasiënte wat beroerte gehad het, verdra BIO BACLOFEN swak.
Die behandeling met BIO BACLOFEN moet geleidelik gestaak word.
Indien BIO BACLOFEN skielik gestaak word kan spierrigiditeit en tydelike verergering van spastisiteit as 'n terugslagverskynsel, erge hoë koors (hipertermie), veranderde geestestoestand, maniese of paranoïese toestande, stuiptrekkings (status epilepticus) veroorsaak word veral na langtermynbehandeling, en kan in seldsame gevalle tot rabdomiolise, veelvoudige orgaanversaking en dood lei. Ander onttrekkingsimptome soos ouditiewe en visuele hallusinasies, angstigheid en tagikardie kan ook ervaar word na skielike staking van BIO BACLOFEN, veral na langtermynbehandeling.
Gelyktydige behandeling van BIO BACLOFEN en levodopa (alleen of in kombinasie met karbidopa) by pasiënte met Parkinson se siekte, sal lei tot verstandelike verwarring, hallusinasies, hoofpyn, naarheid en agitasie (sien INTERAKSIES). Verergering van Parkinsonisme simptome is ook aangemeld.
BIO BACLOFEN moet met omsigtigheid gebruik word by pasiënte met nierontoereikendheid.
Spesiale sorg en omsigtigheid is nodig wanneer BIO BACLOFEN gekombineer word met medisyne wat die nierfunksie beïnvloed. Nierfunksie moet noukeurig gemonitor word en die daaglikse dosis van BIO BACLOFEN moet dienooreenkomstig aangepas word om baklofen toksisiteit te voorkom.
BIO BACLOFEN stimuleer maagsuursekresie en moet met omsigtigheid gebruik word by pasiënte met 'n geskiedenis van peptiese ulkusse en moet vermy word by diegene met 'n aktiewe peptiese ulkussiekte (sien KONTRAINDIKASIES).
BIO BACLOFEN moet met omsigtigheid gebruik word by pasiënte met serebrovaskulêre siektes.
BIO BACLOFEN kan verhoging in bloedglukose konsentrasies veroorsaak en pasiënte met diabetes mellitus moet kennis neem daarvan.
Urienretensie kan vererger word by pasiënte met blaassfinkter hipertonie.
BIO BACLOFEN moet met omsigtigheid gebruik word by pasiënte wanneer spastisiteit benodig word om 'n regop postuur te handhaaf of om sekere funksies te verhoog.
BIO BACLOFEN moet met omsigtigheid gebruik word by pasiënte met verswakte respiratoriese en lewerfunksie.
Verhoogde SGOT, alkaliese fosfatase, en glukosevlakke in die serum is in seldsame gevalle aangemeld. Toepaslike laboratoriumtoetse moet dus gereeld op pasiënte met lewersiektes of diabetes mellitus uitgevoer word.
BIO BACLOFEN bevat laktose. Pasiënte met die seldsame oorerflike toestande van galaktose-onverdraagsaamheid, bv. galaktosemie, Lapp Laktase tekort, glukose-galaktose wanabsorpsie moet nie BIO BACLOFEN gebruik nie.
Uitwerking op vermoë om 'n voertuig te bestuur en masjinerie te gebruik:
BIO BACLOFEN kan lomerigheid, duiseligheid, lighoofdigheid en hipotensie veroorsaak. Pasiënte wat hierdie newe effekte ervaar , moet nie 'n motorvoertuig bestuur of masjinerie gebruik nie.

INTERAKSIES:
Alkohol en ander sentrale senuweestelsel depressante kan sentrale senuweestelsel effekte van BIO BACLOFEN vererger, veral sedasie en die gebruik daarvan moet vermy word.
Ernstige verergering van hiperkinetiese simptome kan moontlik voorkom in pasiënte wat litium gebruik.
Verhoogde spierswakheid kan veroorsaak word as BIO BACLOFEN aan pasiënte wat trisikliese antidepressante gebruik, gegee word.
'n Verhoogde val in bloeddruk sal voorkom by pasiënte wat behandel word vir hoë bloeddruk.
Anti-inflammatoriese medisyne en ander medisyne wat nierontoereikendheid veroorsaak, kan BIO BACLOFEN se uitskeiding verminder en tot toksisiteit lei.
By pasiënte met Parkinson se siekte wat behandeling met BIO BACLOFEN en levodopa ontvang het, het dit gelei tot verstandelike verwarring, hallusinasies, hoofpyne, naarheid en agitasie (verwys na WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

SWANGERSKAP EN LAKTASIE:
Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie.
BIO BACLOFEN moet nie tydens swangerskap en laktasie gegee word nie (sien KONTRA-INDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS:
Behandeling moet begin word met klein, geleidelik toenemende dosisse BIO BACLOFEN. Die maksimum daaglikse dosis moet individueel aangepas word volgens die pasiënt se toestand sodat die klonus-, fleksor- en ekstensor spasmas en spastisiteit verminder word, maar 'n voldoende

mate van spiertonus gehandhaaf word om te verseker dat aktiewe bewegings en nadelige effekte so ver as moontlik vermy word.
Om oormatige swakheid en val te voorkom, moet BIO BACLOFEN versigtig gebruik word wanneer spierkontraksie nodig is om 'n regop postuur en balans tydens beweging te onderhou, of wanneer spastisiteit gebruik word vir sekere funksies. Dit mag belangrik wees om 'n sekere mate van spiertonus te behou en spasmas nou en dan toe te laat ten einde sirkulêre funksies te ondersteun.
BIO BACLOFEN moet tydens etes met 'n bietjie vloeistof geneem word.
Die daaglikse dosis by volwassenes moet in minstens 3 verdeelde dosisse gegee word.
Volwassenes:
Behandeling moet met 'n dosis van 5 mg driekeer daagliks begin word en daarna in drie daaglikse intervalle met 5 mg driekeer daagliks verhoog word tot die vereiste daaglikse dosis bereik is, sien dosering hieronder.
d.w.s: 5 mg driekeer daagliks vir 3 dae
10 mg driekeer daagliks vir 3 dae
15 mg driekeer daagliks vir 3 dae
20 mg driekeer daagliks vir 3 dae
Dit word aanbeveel dat by sekere pasiënte met 'n laer daaglikse dosis (5 mg of 10 mg) begin word en om hierdie dosis daagliks stadiger te verhoog. Die optimale dosis wissel gewoonlik tussen 30 mg en 80 mg per dag.
Dosisse van meer as 80 mg tot 100 mg per dag word gewoonlik nie aanbeveel nie, alhoewel hoër dosisse al toegedien is aan gehospitaliseerde pasiënte onder noukeurige toesig.
Verswakte nierfunksie:
By pasiënte met verswakte nierfunksie of wat kroniese hemodialise ondergaan, moet 'n besonder lae dosis BIO BACLOFEN gekies word, d.w.s ongeveer 5 mg per dag.
Bejaardes:
Aangesien ongewenste effekte meer waarskynlik by bejaarde pasiënte of by pasiënte met spastiese toestande van serebrale oorsprong voorkom, word 'n dosis skedule aanbeveel wat met omsigtigheid bepaal word en met toepaslike toesig oor die pasiënt.
Ontrekkingsimtome:
Ontrekking van BIO BACLOFEN moet geleidelik wees. Skielike staking van die behandeling moet vermy word (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS)

NEWE-EFFEKTE:
Senuweestelselversteurings
Algemeen: Verwarring, sedasie, slaperigheid, lomerigheid, moegheid, lighoofdigheid,
lusteloosheid, uitputting, duiseligheid, hoofpyn, slaaploosheid, bewing, nistagmus, astenie.
Minder algemeen: Parestesie, disartrie, disgeusie, konvulsies, aangetaste spraak, paradoksale verhoging in spastisiteit, hipotermie, koma, enkefalopatie, gebrek aan koördinasie, distonie, aanvalle.
Frekwensie onbekend: Aseptiese meningitis, enkefalopatie.
Psigiatriese versteurings
Algemeen: Geestesverwarring, euforie, hallusinasies, nagmerries.
Minder algemeen: Depressie.
Frekwensie onbekend: Katatoniese reaksie, manie, gemoedversteuring, amnesie.
Respiratoriese, torakale en medistinale versteurings
Algemeen: Respiratoriese onderdrukking.
Frekwensie onbekend: Akute brongospasma, brongiale hiperresponsiwiteit, dispnee en toegetrekte bors, verminderde hoesrefleks, neuskongestie.
Skeletspier versteurings
Algemeen: Mialgie, spierswakheid en pyn, ataksie.
Minder algemeen: Spierrigiditeit.
Oogversteurings
Algemeen: Akkommodasie versteurings, visuele steurnisse.
Minder algemeen: Nistagmus, strabismus, diplopie, midriase.
Oor- en labirintversteurings
Minder algemeen: Tinnitus.
Kardiale versteurings
Algemeen: Verminderde kardiale uitset, kardiale onderdrukking.
Minder algemeen: Borspyn, hartkloppings, sinkopie.
Frekwensie onbekend: Bradikardie.
Vaskulêre versteurings
Minder algemeen: Hipotensie, enkeledeem.
Frekwensie onbekend: Verhoogde sweet.
Gastro-intestinale versteurings
Algemeen: Naarheid, gastro-intestinale verteurings, braking, hardlywigheid of diarree, droë mond, smaakveranderinge, xerostomie.
Minder algemeen: Abdominale pyn.
Hepatobiliêre stelsel versteurings
Minder algemeen: Abnormale lewerfunksies, verhoogde lewerensieme.
Vel- en onderhuidse weefsel versteurings
Algemeen: Hiperhidrose, uitslag.
Frekwensie onbekend: Allergiese velreaksies, pruritus, urtikarie.
Nier- en urienstelsel versteurings
Algemeen: Urinêre versteurings, abnormale gereelde urinering.
Minder algemeen: Urienretensie, disurie, hematurie.
Frekwensie onbekend: Enurese, inkontinensie.
Endokriene versteurings
Frekwensie onbekend: Bloedsuiker veranderinge, gewigstoename of anoreksie.
Reproduktiewe stelsel en borsafwykings
Minder algemeen: Erektiele disfunksie, impotensie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Tekens en simptome van 'n oordosering is hoofsaaklik koma, respiratoriese depressie, aanvalle en bewussynsverlies. Konvulsies kom meestal voor by pasiënte met 'n geskiedenis van epilepsie. Verergering van die toestand kan voorkom indien verskeie stowwe wat inwerk op die sentrale senuweestelsel gelyktydig geneem is.
Geen spesifieke teenmiddel is bekend nie. Eliminasie van baklofen uit die spysverteringskanaal (induksie van braking, maagspoeling; komateuse pasiënte of pasiënte met stuiptrekkings moet geïntubeer word voor 'n maagspoeling). Die behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
BIO BACLOFEN: Wit, skuins afgeplatte tablet met 'n BCN 10 ingedruk en 'n breeklyn aan die een kant, en glad aan die ander kant.

AANBIEDING:
BIO BACLOFEN:
Veiligheidshouers met 30 en 100 tablette.
Silwer aluminium, duidelik deursigtige PVC/PVdC stulpstroke. Elke strook bevat 10 tablette.
Wit HDPE houer (50 cc) met 'n wit ondeursigtige skroefdop en induksie verseëlde prop, wat 30 tablette bevat.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 °C en beskerm teen vog.
Bêre die tablette in die oorspronklike houer totdat dit benodig word vir gebruik.
Hou die PP houer dig gesluit.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
BIO BACLOFEN: W/2.10/433

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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