SCHEDULING STATUS:
S5

PROPRIETARY NAME AND DOSAGE FORM:
BIO-SULPIRIDE 200 Tablets.

COMPOSITION:
Each tablet contains 200 mg sulpiride.
Other excipients: lactose, magnesium stearate, povidone, pregelatinised maize starch and sodium starch glycollate.
Contains sugar (lactose).

PHARMACOLOGICAL CLASSIFICATION:
A 2.6.5 Tranquillisers: Miscellaneous structures

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Sulpiride has antipsychotic actions. It is a substituted benzamide with both anti-depressant and neuroleptic properties. Antipsychotic actions are believed to be due to a selective blockade of central dopamine D_2 receptors.
Pharmacokinetic properties
Sulpiride is absorbed from the gastrointestinal tract; bioavailability (30 – 40 %) is low and is subject to individual variation.
Plasma concentrations may be increased in elderly patients due to renal insufficiency (see WARNINGS AND SPECIAL PRECAUTIONS for dosage adaption.) Peak sulpiride serum levels are reached 3 – 6 hours after an oral dose. Sulpiride is rapidly distributed to the tissues but passage across the blood-brain barrier is poor. Sulpiride is less than 40 % bound to plasma proteins and is reported to have a plasma half-life of about 6 – 9 hours. 95 % of the parent compound is excreted in the urine and faeces, mainly as unchanged sulpiride. Hepatic metabolism does not appear to be significant, although traces of metabolites can be found in the urine. Sulpiride is distributed into breast milk. As sulpiride is eliminated mainly unchanged in the urine, the pharmacokinetic parameters are altered in patients with impaired renal function. There is a progressive diminution in the rate of elimination and an increase in half-life with decreasing renal function (see WARNINGS AND SPECIAL PRECAUTIONS).

INDICATIONS:
Schizophrenia.
The management of acute episodes and the prevention of acute relapses in chronic cases.

CONTRAINDICATIONS:
- Hypersensitivity to sulpiride or to any of the excipients of BIO-SULPIRIDE 200.
- BIO-SULPIRIDE 200 is contraindicated in patients with known or suspected phaeochromocytoma.
- Pregnancy and Lactation (see PREGNANCY AND LACTATION).
- BIO-SULPIRIDE 200 should be avoided in patients with bone marrow depression.
- BIO-SULPIRIDE 200 should not be given with other medicines that may induce leucopenia and blood dyscrasias.
- Porphyria.
- Concomitant prolactin-dependent tumours e.g. pituitary gland prolactinomas and breast cancer.
- Congenital QT prolongation.
- Concomitant use with anti-Parkinson dopaminergic medicines (see INTERACTIONS).

WARNINGS AND SPECIAL PRECAUTIONS:
Neuroleptic malignant syndrome:
In case of unexplained hyperthermia, it is essential to discontinue BIO-SULPIRIDE 200 since this may be indicative of the malignant syndrome described with neuroleptic medicines such as BIO-SULPIRIDE 200 (pallor, hyperthermia, vegetative disturbances, alteration of consciousness and muscle rigidity). Neuroleptic malignant syndrome may occur more frequently in catatonic schizophrenia. Symptoms of vegetative dysfunction such as sweating and unstable blood pressure can occur prior to the occurrence of hyperthermia and consequently represent early onset warning signs. Even though this neuroleptic-related adverse event can result from an individual idiosyncrasy to BIO-SULPIRIDE 200, certain risk factors appear to predispose to it such as dehydration or organic brain disease.
Prolongation of the QT interval:
BIO-SULPIRIDE 200 produces a dose-dependent prolongation of the QT interval. This effect, known to potentiate the risk of serious ventricular dysrhythmias such as Torsades de Pointes, is enhanced by the presence of bradycardia, hypokalaemia, or congenital or acquired long QT interval as in combination with other medicines that increase the QT interval. Refer to INTERACTIONS for combinations of medicines with BIO-SULPIRIDE 200 which could induce "Torsades de Pointes".
Before administering BIO-SULPIRIDE 200, the absence of factors which can promote the occurrence of this dysrhythmias should be verified:
- Bradycardia less than 55 bpm
- Hypokalaemia
- Congenital prolongation of the QT interval
- Ongoing treatment with a medication which can cause marked bradycardia (< 55 bpm), hypokalaemia, slowing of intracardiac conduction or prolongation of the QT interval.

It is recommended to perform an ECG in the initial evaluation of patients who are to be treated with BIO-SULPIRIDE 200.
BIO-SULPIRIDE 200 is not recommended in hypomanic patients, in the manic or pre-manic phase of manic-depressive psychosis, or in patients with acute mania, as BIO-SULPIRIDE 200 may precipitate manic states, which can last up to two days in certain patients prone to these conditions. If this should occur, BIO-SULPIRIDE 200 may either be discontinued or, if the therapeutic effect is required notwithstanding, BIO-SULPIRIDE 200 must be combined with sedative neuroleptics or other psychotropic medicines.
Psychotic suicidal cases:
BIO-SULPIRIDE 200, because of its disinhibitory effect, should be administered with care and combined with psychotherapy.
Parkinson's disease:
BIO-SULPIRIDE 200 should not be used in patients with Parkinson's disease (see INTERACTIONS). BIO-SULPIRIDE 200 inhibits the action of levodopa and may potentiate the adverse effects of other antimuscarinics, including antimuscarinic anti-parkinsonian medicines.
Renal impairment:
Patients with renal impairment, with creatinine clearance of 30 to 60 ml/minute require a reduction of 70 % of normal dose, 10 to 30 ml/minute require a reduction of 50 % of normal dose and creatinine clearance of less than 10 ml/minute require a reduction of 35 % of normal dose. Alternatively, increase the dosage interval between doses by a factor of 1,5; 2 and 3, respectively.
Caution is required in patients with impaired liver, kidney or respiratory function, and in patients receiving other central nervous system depressant medicines, in whom central nervous system depression may be potentiated.
Elderly patients:
Elderly patients are more susceptible to postural hypotension, sedation and extrapyramidal effects.
There is an increased mortality in elderly people with dementia who are treated with BIO-SULPIRIDE 200. BIO-SULPIRIDE 200 is not indicated for the treatment of dementia-related behavioural disturbances. BIO-SULPIRIDE 200 should only be administered with caution to patients with hypertension. BIO-SULPIRIDE 200 should be given with caution to patients in whom a sudden drop in blood pressure would be undesirable, and cardiovascular disorders. Concomitant use with medicines that produce postural hypotension may require dosage adjustments. The antihypertensive action of adrenergic neurone blockers is reduced by BIO-SULPIRIDE 200.
BIO-SULPIRIDE 200 effects on the vomiting centre may mask the symptoms of overdosage of other agents, or of disorders such as gastrointestinal obstruction. BIO-SULPIRIDE 200 should be given with care in patients with diabetes. Care is required in epileptic patients receiving anticonvulsant therapy as BIO-SULPIRIDE 200 may lower the seizure threshold. Patients receiving BIO-SULPIRIDE 200 therapy should receive regular examinations for abnormal ocular pigmentation or ocular changes. In children, under the age of 18 years, efficacy and safety of BIO-SULPIRIDE 200 has not been established. Ingestion of alcohol as well as ingestion of any medication containing alcohol are strongly discouraged throughout duration of treatment with BIO-SULPIRIDE 200 (see INTERACTIONS).
Effects on ability to drive and use machines:
Because of the drowsiness and impaired concentration that may ensue, affected patients should not drive or operate machines where loss of attention might be hazardous. Alteration of vigilance when using alcohol, and enhancement of central nervous system depression, is observed. Alteration of vigilance can occur when driving and using machines. The sedative effect must be fully assessed on the individual before driving or operating heavy machinery is allowed. BIO-SULPIRIDE 200 contains lactose and should not be administered to patients with rare hereditary problems, or a history of lactose intolerance, e.g. galactosaemia, Lapp lactose deficiency or glucose-galactose malabsorption.

INTERACTIONS:
Co-administration of BIO-SULPIRIDE 200 and the following combinations are contraindicated (see CONTRAINDICATIONS):
Dopaminergic anti-Parkinson medicines:
Amantadine, bromocriptine, cabergoline, levodopa, lisuride, pergolide, piribedil, ropinirole.
Due to the reciprocal antagonism between these anti-Parkinson medicines and neuroleptics such as BIO-SULPIRIDE 200, concomitant use is contraindicated.
- In case of an extrapyramidal syndrome induced by BIO-SULPIRIDE 200, do not administer an anti-Parkinson dopaminergic medicine (blockade of dopaminergic receptors by neuroleptic medicines) to patients, but rather use an anticholinergic medicine (see WARNINGS AND SPECIAL PRECAUTIONS).

The following combination with BIO-SULPIRIDE 200 is not recommended:
Alcohol:
The sedative effect of BIO-SULPIRIDE 200 can be enhanced by alcohol. Alteration of concentration can be dangerous when driving and/or operating machinery. The intake of alcohol and medications containing alcohol should be avoided.
Careful consideration should be given before administration of the following combinations:
Antihypertensive medicines:
The antihypertensive effect and risk of postural hypotension are enhanced (additive effect).
Other central nervous system depressants:
Morphine-related compounds; barbiturates; benzodiazepines; carbamates, etifoxine; hypnotic agents; sedative antidepressants; sedative H1 histamine antagonists; central antihypertensive medicines; baclofen, thalidomide.
Concomitant administration of BIO-SULPIRIDE 200 with the following medication could induce Torsades de Pointes or prolong the QT interval:
- Medicines that induce electrolyte imbalance e.g. stimulant laxatives, tetracosactides, hypokalaemic diuretics, glucocorticoids and IV amphotericin B. The electrolyte balance of the patients should be corrected.
- Class Ia antidysrhythmic agents such as quinidine, disopyramide.
- Class III antidysrhythmic agents such as amiodarone, sotalol.
- Bradycardia-inducing medications such as beta-blockers, bradycardia-inducing calcium channel blockers such as diltiazem and verapamil, clonidine, digoxin, guanfacine.
- Methadone, pimozide, imipramine, haloperidol, antidepressants, pentamidine, halofantrine, lithium, cisapride, thioridazine, IV erythromycin, sultopride, bepridil, IV vincamine, sparfloxacin.

The use of alcoholic beverages and medicines containing alcohol should be avoided as alcohol enhances the sedative effects of BIO-SULPIRIDE 200.

PREGNANCY AND LACTATION:
The safety and/or efficacy of BIO-SULPIRIDE 200 during pregnancy and lactation has not been established.
BIO-SULPIRIDE 200 is contraindicated during pregnancy and lactation (see CONTRAINDICATIONS).
BIO-SULPIRIDE 200 is excreted in breastmilk. Mothers on BIO-SULPIRIDE 200 should not breastfeed their infants.

DOSAGE AND DIRECTIONS FOR USE:
Initial Treatment:
200 to 800 mg orally in divided doses 8 or 12 hourly over 24 hours. Duration one to six weeks.
Maintenance treatment:
600 to 800 mg per day (three to four BIO-SULPIRIDE 200 tablets) in divided doses. Duration as long as necessary.
Plasma concentrations may be increased in elderly patients due to renal insufficiency (see WARNINGS AND SPECIAL PRECAUTIONS for dosage adaption).
There is a progressive reduction in the rate of elimination and an increase in half-life with decreasing renal function (see WARNINGS AND SPECIAL PRECAUTIONS).
Patients with renal impairment or the elderly, with creatinine clearance of 30 to 60 ml/minute require a reduction of 70 % of normal dose, 10 to 30 ml/minute require a reduction of 50 % of normal dose and creatinine clearance of less than 10 ml/minute require a reduction of 35 % of normal dose. Alternatively, increase the dosage interval between doses by a factor of 1,5; 2 and 3, respectively.

SIDE EFFECTS:
Immune system disorders
Frequency unknown: Allergic reactions that include urticaria, exfoliative dermatitis, and contact sensitivity.
Nervous system disorders
Frequency unknown: Neuroleptic malignant syndrome (see WARNINGS AND SPECIAL PRECAUTIONS).
Neurological events: BIO-SULPIRIDE 200 may produce a degree of sedation. BIO-SULPIRIDE 200 can produce extrapyramidal symptoms. The risk of extrapyramidal symptoms may be reduced by the addition of anticholinergic medication or reduction in dose.
Sleep disturbances, overstimulation and agitation, dry mouth, insomnia, convulsions, depression, sedation and drowsiness.
Extrapyramidal symptoms and related disorders:
- Parkinsonism and related symptoms such as: tremor, hypertonia, hypokinesia and hypersalivation
- acute dyskinesia and dystonia such as spastic torticollis, oculogyric crisis and trismus
- akathisia
- tardive dyskinesia (characterised by rhythmic, involuntary movements primarily of the tongue and/or the face) have been reported. Antiparkinsonian medication is ineffective when this occurs or may induce aggravation of the symptoms.
- akinesia with or without hypertonia, and partially responsive to anticholinergic medicines.
- hyperkinetic-hypertonic syndrome, excitomotor syndrome.

Cardiac disorders
Frequency unknown: QT interval prolongation and ventricular dysrhythmias such as Torsades de Pointes and ventricular tachycardia, which may result in ventricular fibrillation, cardiac arrest and sudden death. Tachycardia, electrocardiographic changes, postural hypotension.
Vascular disorders
Frequency unknown: Hypertension.
Eye disorders
Frequency unknown: Mydriasis, miosis, blurred vision, pigmentary retinopathy, corneal and lens opacities.
Reproductive system and breast disorders
Frequency unknown: Inhibition of ejaculation, impotence or frigidity, priapism, gynaecomastia, amenorrhoea, galactorrhoea, hyperprolactinaemia and related disorders, breast congestion, menstrual irregularities.
Renal and urinary disorders
Frequency unknown: Urinary retention.
Hepato-biliary disorders
Frequency unknown: Abnormalities in liver function tests and jaundice. Increases in hepatic enzymes.
Skin and subcutaneous tissue disorders
Frequency unknown: Photosensitivity reactions.
Blood and lymphatic system disorders
Frequency unknown: Haematological disorders, including haemolytic anaemia, aplastic anaemia, thrombocytopenic purpura, eosinophilia, and a potentially fatal agranulocytosis have been reported. Symptoms of agranulocytosis such as a sore throat or fever should be watched for and monitoring of white cell counts should be instituted should these symptoms appear.
Metabolism and nutrition disorders
Frequency unknown: Weight gain, hyperglycaemia, altered glucose tolerance and increased serum cholesterol concentrations.
General disorders and administrative site conditions
Frequency unknown: Hypo- and hyperthermia, fatigue.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In overdose, side effects will be exacerbated and exaggerated (see SIDE EFFECTS). Dyskinetic manifestations with spasmodic torticollis, protrusion of the tongue and trismus may occur.
Manifestations may vary depending on dose, and range from restlessness, clouding of consciousness, agitation, confusion. Some patients may develop life-threatening QT prolongation, Parkinsonian manifestations and coma.
There is no specific antidote to BIO-SULPIRIDE 200.
Administer symptomatic therapy, intensive care, under close and continuous monitoring of respiratory and cardiac functions (risk of prolongation of QT interval), which will be continued until the patient's recovery. In cases of severe extrapyramidal symptoms, anticholinergics should be administered.
BIO-SULPIRIDE 200 is partly removed by dialysis.

IDENTIFICATION:
White circular flat bevelled edged tablet with a breakline on one side and plain on the other side.

PRESENTATION:
50 tablets in either a polypropylene securitainer, HDPE container with screw cap and induction sealing wad or a Patient-Ready-Pack (LDPE bag).

STORAGE INSTRUCTIONS:
Store at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
30/2.6.5/0511

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 THE PACKAGE INSERT:
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10 March 2011

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SKEDULERINGSTATUS:
S5

EIENDOMSNAAM EN DOSEERVORM:
BIO-SULPIRIDE 200 Tablette.

SAMESTELLING:
Elke tablet bevat 200 mg sulpiried.
Onaktiewe bestanddele: magnesiumstearaat, natriumstyselglikollaat, povidoon, pregelatiniseerde mieliestysel
Bevat suiker (laktose monohidraat).

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.6.5 Kalmeermiddels: Diverse strukture

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Sulpiried het 'n antipsigotiese werking. Dit is 'n gesubstitueerde bensamied met antidepressiewe en neuroleptiese eienskappe. Antipsigotiese effek is vermoedelik te wyte aan 'n selektiewe blokkade van sentrale dopamien D_2-reseptore.
Farmakokinetiese eienskappe
Sulpiried word stadig uit die spysverteringskanaal geabsorbeer; biobeskikbaarheid (30 – 40 %) is laag en onderworpe aan individuele variasie. Plasmakonsentrasies mag by bejaarde pasiënte as gevolg van nierontoereikendheid verhoog wees (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS vir dosisaanpassing).
Piek sulpiriedserumvlakke word 3 – 6 ure na 'n orale dosis bereik. Sulpiried word vinning na die weefsels versprei, maar vervoer oor die bloed-breinskans is swak. Sulpiried is minder as 40 % aan plasmaproteïene gebonde en daar is gerapporteer dat dit 'n plasma halfleeftyd van ongeveer 6 tot 9 uur het. 95 % van die verbinding word in die uriene en feses as onveranderde sulpiried uitgeskei.
Dit wil voorkom dat hepatiese metabolisme nie beduidend is nie, alhoewel spore van metaboliete in die uriene gevind kan word. Sulpiried word in borsmelk versprei. Omdat sulpiried hoofsaaklik onveranderd in die uriene uitgeskei word, word die farmakokinetiese parameters by pasiënte met ingekorte nierfunksie verander. 'n Progressiewe afname in die tempo van eliminasie en 'n toename in halfleeftyd met verminderende nierfunksie vind plaas (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

INDIKASIES:
Skisofrenie.
Die beheer van akute episodes en die voorkoming van akute terugvalle in kroniese gevalle.

KONTRA-INDIKASIES:
- Hipersensitiwiteit teenoor sulpiried of enigeen van die ander bestanddele van BIO-SULPIRIDE 200.
- BIO-SULPIRIDE 200 is teenaangedui in pasiënte met bekende of vermoede feochromositoom.
- Swangerskap en laktasie (sien SWANGERSKAP EN LAKTASIE).
- BIO-SULPIRIDE 200 is teenaangedui in pasiënte met beenmurgonderdrukking.
- BIO-SULPIRIDE 200 moet nie in kombinasie met ander medisyne wat leukopenie en bloedsiektes induseer, toegedien word nie.
- Porfirie.
- Gelyktydige prolaktien-afhanklike tumore, bv. prolaktinome van die pituïtêre klier en borskanker.
- Aangebore QT-verlenging.

In kombinasie met anti-Parkinsonisme dopaminergiese middels (sien INTERAKSIES).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËL:
Neuroleptiese maligne sindroom:
In geval van onverklaarbare hipertermie is dit noodsaaklik om behandeling met BIO-SULPIRIDE 200 te staak, aangesien dit kan dui op die kwaadaardige sindroom wat deur neuroleptiese medisyne beskryf word, soos BIO-SULPIRIDE 200 (bleekheid, hipertermie, vegetatiewe versteurings, veranderings in bewussyn en spier-rigiditeit). Neuroleptiese maligne sindroom mag meer dikwels voorkom in katatoniese skisofrenie. Simptome van vegetatiewe disfunksie soos sweet en onstabiele bloeddruk kan voor die voorkoms van hipertermie voorkom en verteenwoordig gevolglik vroegtydige waarskuwingstekens. Alhoewel hierdie neuroleptiese-verwante nadelige insident kan voorspruit uit 'n individuele idiosinkrasie teenoor BIO-SULPRIRIDE 200, wil dit voorkom of sekere risikofaktore, soos dehidrasie of organiese breinsiekte, daartoe mag predisponeer.
Verlenging van die QT-interval:
BIO-SULPIRIDE 200 veroorsaak 'n dosisafhanklike verlenging van die QT-interval. Hierdie effek, waar dit bekend is dat dit die risiko van ernstige ventrikulêre disritmieë soos Torsades de Pointes mag potensieer, word versterk deur die teenwoordigheid van bradikardie, hipokalemie of aangebore of verworwe lang QT-interval in kombinasie met ander medisyne wat die QT-interval verleng. Verwys na INTERAKSIES vir kombinasies van medisyne saam met BIO-SULPIRIDE 200 wat "Torsades de Pointes" mag induseer.
Voordat BIO-SULPIRIDE 200 toegedien word, moet die afwesigheid van faktore wat die voorkoms van hierdie disritmie kan versterk, bewys word:
- Bradikardie minder as 55 spm
- Hipokalemie
- Aangebore verlenging van die QT-interval
- Voortgaande behandeling met medisyne wat uitgesproke bradikardie (< 55 spm), hipokalemie, vertraging van intrakardiale geleiding, verlenging van die QT-interval, kan veroorsaak.

Dit word aanbeveel dat 'n EKG uitgevoer moet word tydens die aanvanklike evaluering van pasiënte wat met BIO-SULPIRIDE 200 behandel moet word. BIO-SULPIRIDE 200 word nie by hipomaniese pasiënte, in die maniese of premaniese fase van manies-depressiewe psigose, of by pasiënte met akute manie aanbeveel nie, omdat BIO-SULPIRIDE 200 maniese toestande mag presipiteer, wat vir so lank as twee dae kan duur in sekere pasiënte wat geneig is om hierdie toestande te ontwikkel. Indien dit sou voorkom, kan BIO-SULPIRIDE 200 of gestaak word, of as die terapeutiese effek desnieteenstaande benodig word, moet BIO-SULPIRIDE 200 met sedatiewe neuroleptika of ander psigotropiese medisyne gekombineer word.
Psigotiese selfmoord gevalle:
As gevolg van BIO-SULPIRIDE 200 se disinhibirende effek moet dit met sorg toegedien word en met psigoterapie gekombineer word.
Parkinson se siekte:
BIO-SULPIRIDE 200 moet nie by pasiënte met Parkinson se siekte gebruik word nie (sien INTERAKSIES). BIO-SULPIRIDE 200 inhibeer die werking van levodopa en kan die newe effekte van ander antimuskariniese middels, insluitende antimuskariniese anti-Parkinson medisyne, versterk.
Ingekorte nierfunksie/ Nierontoereikendheid:
Pasiënte met ingekorte nierfunksie met 'n kreatinienopruiming van 30 tot 60 ml/minuut benodig 'n dosisvermindering van 70 % van die normale dosis, kreatinienopruiming van 10 tot 30 ml/minuut benodig 'n dosisvermindering van 50 % van die normale dosis en kreatinienopruiming van minder as 10 ml/minuut benodig 'n dosisvermindering van 35 % van die normale dosis. Alternatiewelik kan die dosisinterval tussen dosisse met 'n faktor van 1,5; 2 en 3 onderskeidelik verhoog word.
Versigtigheid by pasiënte met ingekorte lewer, nier of respiratoriese funksie moet gehandhaaf word asook by pasiënte wat ander sentrale senuweestelseldepressante gebruik, aangesien dit sentrale depressie kan versterk.
Bejaardes:
Bejaardes is meer vatbaar vir posturale hipotensie, sedasie en ekstrapiramidale effekte. Daar is toenemende sterftes in bejaardes met demensie wat met BIO-SULPIRIDE 200 behandel word.
BIO-SULPIRIDE 200 word nie aangedui vir behandeling by pasiënte wat dementia verwante gedragsprobleme toon nie.
BIO-SULPIRIDE 200 moet met versigtigheide toegedien word aan pasiënte met hipertensie. BIO-SULPIRIDE 200 moet met omsigtigheid aan pasiënte toegedien word waar 'n skielike daling in bloeddruk nie gewens is nie, asook by pasiënte met kardiovaskulêre siektes.
Gesamentlike gebruik van BIO-SULPIRIDE 200 en ander medisyne wat posturale hipotensie tot gevolg het, mag dosisaanpassing vereis.
BIO-SULPIRIDE 200 verlaag die antihipertensie effek van adrenergiese neuronblokkeerders. BIO-SULPIRIDE 200 se effek op die brakingsentrum kan die simptome van oordosering van ander middels, of van versteurings soos maagdermobstruksie, maskeer.
BIO-SULPIRIDE 200 moet met versigtigheide aan pasiënte met diabetes toegedien word. Pasiënte met epilepsie wat reeds behandeling met 'n antikonvulsant ontvang, moet versigtig gemonitor word, aangesien BIO-SULPIRIDE 200 die epileptogeniese drumpel verlaag. Pasiënte wat behandeling met BIO-SULPIRIDE 200 ontvang moet gereeld oogtoetse laat doen vir vasstelling en voorkoming van abnormale okulêre pigmentasie en okulêre veranderinge. Die doeltreffendheid en effektiwiteit van BIO-SULPIRIDE 200 by kinders onder die ouderdom van 18 jaar is nie vasgestel nie. Inname van alkohol, asook inname van enige medisyne wat alkohol bevat, word sterk afgeraai vir die hele behandelingsduur met BIO-SULPIRIDE 200 (sien INTERAKSIES).
Uitwerking op vermoë om 'n voertuig te bestuur en masjinerie te gebruik
As gevolg van die sedatiewe effek wat tot lomerigheid en verswakte konsentrasie mag lei, moet geaffekteerde pasiënte nie 'n motor bestuur of masjinerie gebruik nie, omdat verlies aan aandag gevaarlik mag wees. Verswakte waaksaamheid en verergering van depressie van die sentrale senuweestelsel is waargeneem met die inname van alkohol. Verswakte waaksaamheid mag tydens die bestuur van 'n motor en gebruik van masjinerie voorkom. Die sedatiewe effek vir elke individu moet volledig geëvalueer word voordat 'n motor bestuur word of die gebruik van swaar masjinerie toegelaat word.
BIO-SULPIRIDE 200 bevat laktose. Pasiënte met seldsame oorerflike toestande of 'n geskiedenis van laktose onverdraagsaamheid bv. galaktosemie, Lapp laktose gebrek of glukose-galaktose wanabsorpsie, behoort nie BIO-SULPIRIDE 200 te neem nie.

INTERAKSIES:
Gesamentlike gebruik van BIO-SULPIRIDE 200 en die volgende kombinasies is teenaangedui (sien KONTRA-INDIKASIES):
Dopaminergiese anti-Parkinson geneesmiddels:
Amantadien, bromokriptien, kabergolien, levodopa, lisuried, pergolied, piribediel, ropinirool. As gevolg van die resiproke antagonisme tussen die anti-Parkinson medisyne en BIO-SUPIRIDE 200, is die gesamentlike gebruik daarvan teenaangedui.
- In geval van 'n ekstrapiramidale sindroom wat deur BIO-SUPIRIDE 200 geïnduseer word, moet 'n anti-Parkinson dopaminergiese middel (blokkade van dopaminergiese reseptore deur neuroleptiese middels) nie aan pasiënte toegedien word nie, maar 'n anti-cholinerge ergiese middel moet liewer gebruik word (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

Die volgende kombinasie met BIO-SULPIRIDE 200 word nie aangeveel nie:
Alkohol:
Die sedatiewe effek van BIO-SULPIRIDE 200 word deur alkohol versterk. Verandering van waaksaamheid kan gevaarlik wees wanneer daar bestuur en masjiene gebruik word. Vermy inname van alkohol en medisyne wat alkohol bevat.
Versigtige oorweging moet geskied, voor toediening van die volgende kombinasies:
Antihipertensiewe middels:
Die antihipertensie effek en risiko van posturale hipotensie word versterk (additiewe effek).
Ander sentrale senuweestelseldepressante:
Morfien-verwante verbindings (analgetika, hoesonderdrukkers, en plaasvervangingterapieë); barbiturate; bensodiasepiene; angswerende middels benewens bensodiasepiene; karbamate, kaptodiaam, etifoksien; hipnotiese middels; sedatiewe antidepressante; sedatiewe H1-histamienantagoniste; sentrale antihipertensiewe middels; baklofen, talidomied.
Die volgende kombinasies met BIO-SULPIRIDE 200 kan moontlik Torsades de Pointes of verlenging van QT-intervalle induseer:
- Medisyne wat 'n elektroliet wanbalans induseer bv. stimulerende lakseermiddels, tetrakosaktiede, hipokalemiese diuretika, glukokortikoïede en IV amfoterisien B. Die elektrolietbalans van die pasiënte moet herstel word.
- Klas Ia antidisritmiese middels soos kinidien, disopiramied.
- Klas III antidisritmiese middels soos amiodaroon, sotalol.
- Bradikardie-induserende medisyne soos betablokkeerders, bradikardie-induserende kalsiumkanaalblokkeerders soos diltiasem en verapamiel, klonidien, guanfasien; digitalis.
- Metadoon, pimosied, imipraminen, haloperidol, antidepressante, pentamidien, halofantrien, litium, sisapried, tioridasien, IV eritromisien, sultopried, bepridiel, IV vinkamien, sparfloksasien.

Die gebruik van alkohol en medisyne wat alkohol bevat moet vermy word aangesien alkohol die sedatiewe effek van BIO-SULPIRIDE 200 versterk.

SWANGERSKAP EN LAKTASIE:
Die veiligheid en effektiwiteit van BIO-SULPIRIDE 200 gedurende swangerskap en laktasie is nie vasgestel nie. BIO-SULPIRIDE 200 is teenaangedui tydens swangerskap en laktasie (sien KONTRA-INDIKASIES). BIO-SULPIRIDE 200 word in borsmelk uitgeskei. Vrouens wat BIO-SULPIRIDE 200 gebruik moet nie hul babas borsvoed nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Aanvangsbehandelin:
200 tot 800 mg oraal in verdeelde dosisse 8 tot 12 uurliks oor 24 uur. Duur van behandeling is een tot ses weke.
Instandhoudingsbehandeling:
600 tot 800 mg per dag (drie tot vier BIO-SULPIRIDE 200 tablette) in verdeelde dosisse. Duur van behandeling so lank as nodig.
Verhoogde plasma konsentrasies mag by bejaardes as gevolg van die nierontoereikendheid voorkom (sien WAARSKUWING EN SPESIALE VOORSORGMAATREELS vir dosisaanpassing). Daar bestaan 'n progressiewe vermindering in die eliminasietyd en 'n verhoging in die halfleeftyd met ingekorte lewerfunksie (sien WAARSKUWINGS EN SPESIALE VOORSOGMAATREËLS). Pasiënte met nierinkorting of bejaardes, met kreatinienopruiming van 30 tot 60 ml/minuut benodig 'n 70 % vermindering van die normale dosis, kreatinienopruiming van 10 tot 30 ml/minuut benodig 'n vermindering van 50 % van die normale dosis en kreatinienopruiming van minder as 10 ml/minuut benodig 'n vermindering van 35 % van die normale dosis. As alternatief kan die dosisinterval tussen dosisse met 'n faktor van 1,5; 2 en 3 onderskeidelik verhoog word.

NEWE-EFFEKTE:
Immuunsisteem afwykings
Frekwensie onbekend: Allergiese reaksies insluitend urtikarie, eksfoliatiewe dermatitis en tassensitiwiteit.
Senuweestelsel afwykings
*Frekwensie onbekend:*Neuroleptiese maligne sindroom (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).
Neurologiese inisidente: BIO-SULPIRIDE 200 mag 'n sekere graad van sedasie veroorsaak. BIO-SULPIRIDE 200 kan aanleiding gee tot ekstrapiramidale simptome. Die risiko van ekstrapiramidale simptome kan deur die addisionele gebruik van anticholinergiese medisyne verminder word of deur 'n vermindering van die dosis. Slaapversteurings, oorstimulasie en agitasie, droë mond, slaaploosheid, konvulsies, depressie, sedasie en lomerigheid.
Ekstrapiramidale simptome en verwante afwykings:
- Parkinsonisme en verwante simptome soos: tremor, hipertonie, hipokinesie en oormatige speekselafskeiding
- akute diskinesie en distonie soos spasma tortikollis, okulogiriese krisis, en trismus
- akatisie
- laatdiskinesie (gekenmerk deur ritmiese, onwillekeurige bewegings primêr van die tong en/of die gesig) is gerapporteer. Anti-Parkinsonisme medisyne is oneffektief en mag verergering van simptome induseer
- akineties met of sonder hipertonie, en gedeeltelike reaksie teenoor anticholinergiese middels
- hiperkineties-hipertonies, eksitomotor sindroom

Kardiale afwykings
Frekwensie onbekend: QT-verlenging en ventrikulêre disritmie soos Torsades de Pointes en ventrikulêre tagikardie wat mag lei tot ventrikulêre fibrillasie, hartaanval en dood. Tagikardie, elektrokardiografiese veranderinge, posturale hipotensie.
Vaskulêre afwykings
Frekwensie onbekend: Hipertensie
Oogafwykings
Frekwensie onbekend: Midriase, miose, versteurde visie, pigmentêre retinopatie, korneale en lensdigtheid.
Voortplantingstelsel en borsafwykings
Frekwensie onbekend: Onvermoë om te ejakuleer, impotensie of frigiditeit, priapisme, ginekomastie, amenoree, galaktoree, hiperprolaktinemie en verwante versteurings, borskongestie, menstruele onreëlmatighede.
Renale-en urinêre afwykings
Frekwensie onbekend: Urienretensie.
Hepato-bilière afwykings
Frekwensie onbekend: Abnormale lewerfunksie toetse en geelsug. Verhoogde hepatiese ensieme.
Vel en subkutane weefsel afwykings
Frekwensie onbekend: Reaksies van fotosensitiwiteit.
Bloed- en limfstelsel afwykings
Frekwensie onbekend: Hematologiese afwykings, insluitende hemolitiese anemie, aplastiese anemie, trombositopeniese purpura, eosinofilie, en 'n potensieël noodlottige agranulositose, is aangemeld. Let op simptome van agranulositose soos 'n seer keel of koors en indien hierdie simptome voorkom, moet monitering van witseltellings ingestel word.
Metaboliese en voedingsafwykings
Frekwensie onbekend: Gewigstoename, hiperglisemie, veranderde glukosetoleransie en verhoogde serum cholesterol konsentrasies.
Algemene afwykings en toestande van die plek van toediening
Frekwensie onbekend: Hipo- en hipertermie, moegheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
In die geval van oordosering, mag die newe effekte vererger en oordrewe wees (sien NEWE-EFFEKTE). Diskinetiese verskynsels met spasmodiese tortikollis, uitsteek van die tong en trismus mag voorkom. Verskynsels varieer, afhangende van dosis, en kan wissel van rusteloosheid, beneweling van bewussyn, agitasie, tot verwarring. Sommige pasiënte mag lewensbedreigende verskynsels van QT-interval verlenging, parkinsonisme en koma ontwikkel.
Daar is geen spesifieke teenmiddel vir BIO-SULPIRIDE 200 nie.
Dien simptomatiese terapie, intensiewe sorg onder noukeurige en gedurige monitering van respiratoriese en kardiale funksies (risiko van verlenging van QT-interval) toe wat voortgesit moet word tot die pasiënt herstel. In gevalle van ernstige ekstrapiramidale simptome, behoort anticholinergiese medisyne toegedien te word.
BIO-SULPIRIDE 200 word gedeeltelik deur dialise verwyder.

IDENTIFIKASIE:
Wit sirkelvormige tablet, met afgeplatte kante en gekeep aan een kant.

AANBIEDING:
50 tablette in 'n polipropileen sekuriteitshouer of 'n HDPE-houer met 'n skroefdop en induksie verseëlingstof of 'n pasiënt-gereed-pakket (LDPE-sak).

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 °C.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
30/2.6.5/0511

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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