SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
BIO METOCLOPRAMIDE (Tablets)

COMPOSITION:
Each tablet contains 10 mg metoclopramide hydrochloride.
Excipients: Lactose, Pre Gelatinized Starch, Maize Starch, Collidal Silicone Dioxide, Magnesium Stearate.
Contains: sugar (Lactose)

PHARMACOLOGICAL CLASSIFICATION:
A 5.7.2 Anti-emetics and antivertigo preparations

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
BIO METOCLOPRAMIDE acts peripherally to enhance the action of acetylcholine at the muscarinic synapses, thereby increasing the motility and tone of the stomach and intestine, relaxing the sphincters and stimulating gastric secretion. It also acts centrally by antagonizing dopamine.

INDICATIONS:
Digestive disorders:
BIO METOCLOPRAMIDE is indicated in conditions associated with gastric stasis or hypomotility.
Anti-emetic use:
BIO METOCLOPRAMIDE is used in the control of nausea in the following conditions: drug-induced vomiting and gastro-intestinal disorders.

CONTRAINDICATIONS:
BIO METOCLOPRAMIDE should not be used where gastro-intestinal conditions might be adversely affected as in intestinal obstruction or immediately after surgery.
Not recommended in patients with suspected or confirmed phaeochromocytoma, because this medicine may cause a hypertensive crisis (see WARNINGS AND SPECIAL PRECAUTIONS).
BIO METOCLOPRAMIDE is contraindicated in patients with known sensitivity to the medicine.
BIO METOCLOPRAMIDE should not be used during pregnancy and lactation (see PREGNANCY AND LACTATION and WARNINGS AND SPECIAL PRECAUTIONS).

WARNINGS AND SPECIAL PRECAUTIONS:
The use of metoclopramide during pregnancy is considered unsafe as teratogenicity has been demonstrated in animal studies.
Hypertensive crises have occurred in patients with phaeochromocytomas given BIO METOCLOPRAMIDE.
Tardive dyskinesia has been reported during prolonged therapy and long-term treatment should be regularly reviewed.
BIO METOCLOPRAMIDE should be used with care in children and young patients.
Care should be exercised when concomitant medication that can also cause extrapyramidal side effects such as the phenothiazines, are taken. Anticholinergic agents antagonize the effects of BIO METOCLOPRAMIDE; narcotic analgesics may act similarly. BIO METOCLOPRAMIDE may affect the adsorption of other medicines by either diminishing absorption from the stomach or by enhancing absorption from the small intestine. The effects of central nervous system depressants may be enhanced.
An increase in mammary neoplasms has been found in rodents after chronic administration of metoclopramide.
Care should be taken when using BIO METOCLOPRAMIDE in patients with parkinsonism.

INTERACTIONS:
(See WARNINGS AND SPECIAL PRECAUTIONS).

PREGNANCY AND LACTATION:
Safety and/or efficacy have not been established (see CONTRAINDICATIONS and WARNINGS AND SPECIAL PRECAUTIONS).

DOSAGE AND DIRECTIONS FOR USE:
Adults:
One tablet three times daily.
Children:
(5 to 14 years)
Half a tablet three times daily.
The total daily dose in children and young adults should not exceed 0,5 mg/kg body mass.

SIDE EFFECTS:
BIO METOCLOPRAMIDE may cause extrapyramidal side effects. These may include feelings of restlessness, involuntary movements of limbs and facial grimacing, torticollis, oculgyric crisis, rhythmic protrusion of tongue, bulbar type of speech or trismus. Dystonic reactions resembling tetanus have been reported.
Side effects of BIO METOCLOPRAMIDE include depression, lassitude, insomnia, headache, constipation, diarrhoea, nausea, oedema of tongue, periorbital oedema and skin rashes.
Other adverse effects include bowel upsets, drowsiness and fatigue, dizziness, restlessness and anxiety. Galactorrhoea, gynaecomastia, breast engorgement, amenorrhoea and impotence have been reported.
Tardive dyskinesia has been reported during prolonged therapy.
Hypertensive crises have occurred in patients with phaeochromocytomas given BIO METOCLOPRAMIDE.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Refer to side effects for symptoms to be expected in the event of overdosage.
In severe overdosage, stomach should be emptied by aspiration and lavage. Emetics should not be used. Further treatment is symptomatic and supportive.

IDENTIFICATION:
White biconvex tablets, with breakline on one side, plain on other side.

PRESENTATON:
Tablets are packed in 10 and 500.

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

REGISTRATION NUMBER:
V/5.7.2/352

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:
Date of registration: 22 November 1988
Date of latest revision of the text as approved by Council: 17 December 1992
Date of notification with regard to amended Reg. 9 and 10: 06 February 2015

Namibia: Reg. No.: 13/5.7.2/0136	NS2

SKEDULERENGSTATUS:
S4

EIENDOMSNAAM EN DOSEERVORM:
BIO METOCLOPRAMIDE (Tablette)

SAMESTELLING:
Elke tablet bevat 10 mg metoklopramiedhidrochloried.
Eksipiënte: Laktose, Pregelatinized Stysel, Mielie Stysel, Kolloïdale Silisiedioksied, Magnesium Stearaat.
Bevat: Suiker (Laktose)

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.7.2 Anti-emetika en antivertigopreparate.

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
BIO METOCLOPRAMIDE werk perifeer om die werking van aseteilcholien by die muskariniese sinapse te potensieer. Daardeur verhoog dit die motiliteit en tonus van die maag en dunderm, verslap dit die sfinkters, en stimuleer dit maagsapsekresie. Dit werk ook sentraal om dopamien te antagoniseer.

INDIKASIES:
Spysverteringsongesteldhede:
BIO METOCLOPRAMIDE word aangedui in toestande gepaard met gastriese stase of hipomotiliteit.
Anti-emetiese gebruik:
BIO METOCLOPRAMIDE word by die behandeling van naarheid in die volgende toestande aangedui: geneesmiddelgeïnduseerde braking en gastroïntestinale afwykings.

KONTRA-INDIKASIES:
BIO METOCLOPRAMIDE moet nie gebruik word waar gastroïntestinale toestande ongunstig beïnvloed word nie, soos by intestinale obstruksie of onmiddelik na chirurgie.
Nie aanbeveel vir pasiënte met vermoedelike of bevestigde feochromositoom, omdat die middel 'n hipertensiewe krisis kan veroorsaak.
BIO METOCLOPRAMIDE word teenaangedui by pasiënte met 'n bekende sensitiwiteit vir die middel.
BIO METOCLOPRAMIDE moet nie gebruik word tydens swangerskap en laktasie (sien SWANGERSKAP EN LAKTASIE en WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).
BIO METOCLOPRAMIDE behoort nie tydens swangerskap en laktasie gebruik te word nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS:
Die gebruik van metoklopramied tydens swangerskap word beskou as onveilig as teratogenisiteit is gedemonstreer in dierestudies.
Hipertensiewe krisisse het by pasiënte met feochromositoom voorgekom, toe hulle metoklopramied gegee is.
Tardiewe diskinesie is gedurende langdurige terapie gemeld. Langtermynterapie moet gereeld beoordeel word.
BIO METOCLOPRAMIDE moet met sorg gebruik word in kinders en jong pasiënte.
Sorg moet aan die dag gelê word wanneer metoklopramied saam met ander middels soos fenotiasiene wat ekstrapiramidale newe-effekte kan veroorsaak, toegedien word. Narkotiese analgetika kan 'n soortgelyke uitwerking hê.
Metoklopramied kan die absorpsie van ander geneesmiddels beïnvloed of deur die vermindering van absorpsie van die maag of deur absorpsie in die dunderm te verhoog. Die effekte van sentrale senuweesisteem onderdrukkers kan verhoog word.
Na chroniese toediening van metoklopramied is 'n verhoging in melkklierneoplasmas by knaagdiere gevind.
Sorg moet gedra word wanneer metoklopramied aan pasiënte met parkinsonisme toegedien word.

INTERAKSIES
(Sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

SWANGERSKAP EN LAKTASIE:
Veiligheid en / of doeltreffendheid nie vasgestel (sien KONTRA EN WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes:
Een tablet drie keer per dag.
Kinders:
(5 tot 14 jaar)
'n Halwe tablet drie keer per dag.
Die totale daaglikse dosis in kinders en jong volwassenes moet nie meer as 0,5 mg / kg liggaamsmassa.

NEWE-EFFEKTE
BIO METOCLOPRAMIDE kan ekstrapiramidale newe-effekte veroorsaak. Dit kan 'n gevoel van rusteloosheid, onwillekeurige bewegings van die ledemate en gesig trekkings, torrikollose, okulogiriese krisis, ritmiese uitsteek van die tong, bulbêre spraaktipe of trismus insluit. Distoniese reaksies soortgelyk aan tetanus is gemeld.
Newe-effekte van BIO METOCLOPRAMIDE sluit depressie, lusteloosheid, slaaploosheid, hoofpyn, hardlywigheid, diarree, naarheid, edeem van tong, periorbital edeem en veluitslag in.
Ander newe-effekte sluit in dermongesteldhede, lomerigheid en moegheid, duiseligheid, rusteloosheid en angs. Galaktoree, ginekomastie, borsoorvulling, amenoree en impotensie is aangemeld.
Gevolglike dyskinesia is aangemeld tydens langdurige terapie.
Hipertensiewe krisisse het by pasiënte met feochromositoom voorgekom, toe hulle metoklopramied gegee is.

IDENTIFIKASIE
Wit bikonvekse tablette, met break lyn aan die een kant, Vlakte ander kant.

AANBIEDING
Tablette word verpak in 10 en 500.

BERGINGSAANWYSINGS
Bewaar benede 25 °C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMERS
V/5.7.2/352

NAAM EN BESIGHEID VAN DIE APPLIKANT
Biotech Laboratories (Edms) Bpk.
Grond Vloer, Blok K Wes, Central Park,
400 16de Weg, Midrand, 1685
Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOOUBILJET
Datum van registrasie: 22 November 1988
Datum van laaste hersiening van die teks soos goedgekeur deur die Raad: 17 Desember 1992
Datum van kennisgewing met betrekking tot gewysig Reg. 9 en 10: 6 Februarie 2015

Namibië: Reg. Nr.: 13/5.7.2/0136	NS2