SCHEDULING STATUS: S2

PROPRIETARY NAME (and dosage form):
MEBESTEND (Film-coated tablets)

COMPOSITION:
Each film-coated tablet contains: Mebeverine hydrochloride 135 mg.
Contains lactose monohydrate 100,0 mg (sugar)

Excipients: microcrystalline cellulose PH101, microcrystalline cellulose PH102, povidone K30, sodium starch glycollate, purified talc, and magnesium stearate. Film-coating: Opadry white, hypromellose, titanium dioxide, macrogol.

PHARMACOLOGICAL CLASSIFICATION:
A 11.2 Gastrointestinal anti-spasmodics and cholinolytics.

PHARMACOLOGICAL ACTION:
Pharmacodynamics:
Mebeverine hydrochloride is a derivative of hydroxybenzamide that appears to have a direct effect on the smooth muscle cell, blocking K+, Na+ and Ca2+ channels and has antispasmodic properties.

Pharmacokinetics:
Mebeverine is rapidly absorbed after oral doses with peak plasma concentrations occurring in 1 to 3 hours. It is 75 % bound to albumin in plasma. Mebeverine is completely metabolized by hydrolysis to veratric acid and mebeverine alcohol, the latter of which may then be conjugated. The metabolites are excreted in the urine.

INDICATIONS:
Primary irritable colon characterised by persistent diarrhoea, alternating constipation and diarrhoea, abdominal pain and postprandial distension.
Secondary irritable colon due to organic lesions such as regional enteritis, diverticulitis, specific and non-specific inflammatory conditions of the gastrointestinal tract.

CONTRAINDICATIONS:
Hypersensitivity to MEBESTEND or any of the ingredients in the tablets.

Safety in pregnancy and lactation has not been established.

MEBESTEND is considered to be unsafe in patients with porphyria because it has shown to be porphyrinogenic in *in vitro* systems.

MEBESTEND should not be used for the symptomatic treatment of distal intestinal syndrome in cystic fibrosis.

MEBESTEND should not be used in patients with paralytic ileus.

WARNINGS:
MEBESTEND should be used with care in patients with:
(a) hepatic or renal impairment.
(b) cardiac disorders such as heart block.

INTERACTIONS:
No information is available regarding a possible interaction between MEBESTEND and other medicines.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.
(See **CONTRAINDICATIONS**)

DOSAGE AND DIRECTIONS FOR USE:
Adults:
One tablet three times daily preferably before meals.
After a period of a few weeks when the desired effect has been obtained, the dosage may be gradually reduced.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Side effects:
Gastrointestinal disorders:
Less frequent: Gastrointestinal disturbances, anorexia.

Central nervous system disorders:
Less frequent: Dizziness, headache, insomnia.

Cardiovascular disorders:
Less frequent: Decreased heart rate.

Skin and appendages disorders:
Less frequent: Erythematous rash, urticaria, angioedema.

Special Precautions:
MEBESTEND film-coated tablets contain lactose; therefore, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take MEBESTEND.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "SIDE EFFECTS AND SPECIAL PRECAUTIONS"
Treatment is symptomatic and supportive.

IDENTIFICATION:
Round, white, film-coated tablet.

PRESENTATION:
Opaque, white, HDPE securitainers of 20, 100 and 500 tablets.
PVC/Aluminium blisters containing 10 tablets per strip in unit cartons of 20 and 100 tablets

STORAGE INSTRUCTIONS:
Store in airtight containers. Protect from light.
Store below 30 °C.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
32/11.2/0598

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Trinity Pharma (Pty) Ltd.
106 16th Road, Building 2
Midrand
1686

DATE OF PUBLICATION OF THE PACKAGE INSERT:
19 July 2001

SKEDULERINGSTATUS: S2

EIENDOMSNAME (en doseervorm):
MEBESTEND (Filmbedekte tablet)

SAMESTELLING:
Elke filmbedekte tablet bevat: Mebeverienhidrochloried 135 mg.
Bevat laktose monohidraat 100,0 mg (suiker).

Hulpstowwe: Mikrokristallyne sellulose PH101, mikrokristallyne sellulose PH102, povidone K30, natriumstyselglikolaat, gesuiwerde talk en magnesiumstearaat.
Filmbedekking: Opadry wit, hipromellose, titaandioksied, makrogol.

FARMAKOLOGIESE KLASSIFIKASIE:
A 11.2 Maagdermkanaal spasmolitiese en cholinolitiese middels.

FARMAKOLOGIESE WERKING
Farmakodinamika:
Mebeverienhidrochloried, 'n derivaat van hidroksibensamied, het 'n direkte effek op gladdespiersel, blokkeer K +, Na + en Ca2 + kanale en het spasmolitiese eienskappe.

Farmakokinetika:
Mebeverien word vinnig na orale dosisse geabsorbeer met piek plasmakonsentrasies wat binne 1 tot 3 uur bereik word. Dit is 75 % aan albumien in plasma gebonde. Mebeverien word volledig deur hidrolise gemetaboliseer tot veratriese suur en mebeverien-alkohol, waarvan laasgenoemde dan gekonjugeer kan word. Die metaboliete word in urine uitgeskei.

INDIKASIES:
Primêre prikkelbare dikderm gekenmerk deur aanhoudende diarree, hardlywigheid en diarree om die beurt, buikpyn en postprandiale distensie.
Sekondêre prikkelbare dikderm veroorsaak deur organiese letsels soos lokale enteritis, divertikulitis, spesifieke en nie-spesifieke inflammatoriese toestande van die maagdermkanaal.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir MEBESTEND tablette of enige van die bestanddele.

Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie.

MEBESTEND word as onveilig beskou in pasiënte met porfirie, aangesien dit in in vitro sisteme as porfirinogenies bewys is.

MEBESTEND moet nie vir die simptomatiese behandeling van distale intestinale sindroom in sistiese fibrose gebruik word nie.

MEBESTEND moet in pasiënte met paralitiese ileus vermy word.

WAARSKUWINGS:
MEBESTEND moet met omsigtigheid gebruik word by pasiënte met:
(a) lewer- of nierinkorting.
(b) hartversteurings soos hartblok.

INTERAKSIES:
Geen inligting rakende 'n moontlike interaksie tussen MEBESTEND en ander medisyne is beskikbaar nie.

SWANGERSKAP EN LAKTASIE:
Veiligheid in swangerskap en laktasie is nog nie vasgestel nie.
(Sien **KONTRA-INDIKASIES**)

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes:
Een tablet drie keer per dag, verkieslik voor maaltye.
Na 'n paar weke se behandeling, wanneer die verlangde effek verkry is, kan die dosis geleidelik verminder word.

NEWE EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte:
Gastro-intestinale versteurings:
Minder dikwels: Gastro-intestinale ongesteldhede, anoreksie.

Sentrale Senuweestelsel versteurings:
Minder dikwels: Duiseligheid, hoofpyn, slaaploosheid.

Kardiovaskulêre versteurings:
Minder dikwels: Afname in harttempo.

Vel- en aanhangsel versteurings:
Minder dikwels: Eritematiese uitslag, urtikarie, angio-edeem.

Spesiale voorsorgmaatreëls:
MEBESTEND filmbedekte tablette bevat laktose; derhalwe moet pasiënte met raar oorerflike probleme van galaktose intoleransie, die Lapp laktase-tekort of glukose-galaktose wanabsorpsie nie MEBESTEND neem nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS".**
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Ronde, wit, filmbedekte tablet.

AANBIEDING
Ondeursigtige, wit, HDPE securitainers met 20, 100 en 500 tablette.
PVC/Aluminium stulpstroke met 10 tablette per strokie in eenheidskartonne van 20 en 100 tablette.

BERGINGSINSTRUKSIES
Stoor in 'n lugdigte houers. Beskerm teen lig.
Bewaar benede 30 °C.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER
32/11.2/0598

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
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