SCHEDULING STATUS:
S2

PROPRIETARY NAME (AND DOSAGE FORM):
PYRIDIUM (tablets)

COMPOSITION:
Each tablet contains 100 mg Phenazopyridine hydrochloride.

PHARMACOLOGICAL CLASSIFICATION:
A: 18 Medicines acting on genito-urinary system.

PHARMACOLOGICAL ACTION:
Urinary tract analgesic. Phenazopyridine is excreted in the urine where it exerts a topical analgesic effect on the mucosa of the urinary tract. Up to 90 % of a dose is excreted within 24 hours, 65 % as unchanged drug and the remainder as metabolites. One of the metabolites is paracetamol.

INDICATIONS:
Short term symptomatic relief of pain, burning, urgency and frequency arising from irritation of the lower urinary tract mucosa. These symptoms may result from infection, trauma, surgery, endoscopic procedures, or passage of sounds or catheters. The underlying cause of the irritation must be determined and treated (e.g. antibacterial therapy for infection).

CONTRA-INDICATIONS:
Hypersensitivity to phenazopyridine. Contra-indicated in glomerulonephritis, uraemia, impaired renal function and severe hepatitis. PYRIDIUM should not be used for repeated or prolonged treatment without full diagnostic investigation.
Glucose-6-phosphate dehydrogenase (G6PD) deficiency-patients have an increased risk of severe haemolytic anaemia.
Safaty in pregnancy and lactation has not been established.

WARNINGS:
1. The use of phenazopyridine for relief of symptoms should not delay definitive diagnosis of the underlying cause. Prompt appropriate treatment of the cause of pain must be instituted and phenazopyridine should be discontinued when symptoms are controlled.
2. When phenazopyridine is used concurrently with an antibacterial agent in the treatment of a urinary tract infection, the duration of phenazopyridine therapy should not exceed 2 days.
3. It symptoms persist or recur, a doctor should be consulted.

DOSAGE AND DIRECTIONS FOR USE:
Tablets should not be chewed.
Adults: Two tablets three times daily with or after meals.
When used concurrently with an antibacterial agent for the treatment of a urinary tract infection, the duration of PYRIDIUM therapy should not exceed two days.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
The following side-effects have been reported:
Central Nervous System: Headache.
Gastrointestinal: Nausea, vomiting and diarrhoea.
Dermatologic and Hypersensitivity: Rash, pruritus, discolouration, anaphylactoid reaction and hypersensitivity hepatitis.
Haematologic: Methaemoglobinaemia, haemolytic anaemia, potential haemolytic agent in G6PD deficiency, sulfhaemoglobinaemia.
Other: Visual disturbances, renal and hepatic toxicity usually associated with overdose, renal calculi, jaundice, discolouration of body fluids, and aseptic meningitis.

Precautions:
PYRIDIUM produces an orange to red colour in the urine and faeces and may stain clothing*. Staining of contact lenses has been reported. A yellowish colour of the skin or sclerae may indicate accumulation of phenazopyridine resulting from impaired renal function and necessitates discontinuance of the drug. PYRIDIUM may mask pathological conditions and interfere with laboratory test values using colourimetric, spectrophotometric or fluorometric analysis methods.
May cause false urine sugar and urine ketone test results in diabetics.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Exceeding the recommended dose in patients with normal renal function or administering the recommended dose to patients with impaired renal function (common in elderly patients) may lead to increased serum levels and toxic reactions.
Methaemoglobinaemia generally follows a massive, acute overdose. Methylene blue, 1 to 2 mg/kg bodyweight given intravenously as a 1 % solution, may be used to treat the methaemoglobinaemia. This will usually lead to a reduction of the methaemoglobinaemia and disappearance of the cyanosis which is an aid in diagnosis. Oxidative Heinz body haemolytic anaemia also may occur, and "bite cells" (degmacytes) may be present in a chronic overdosage situation. Red blood cell G6PD deficiency may predispose to haemolysis; however, haemolysis may occur at normal doses in patients with G6PD Mediterranean.
Hepatic impairment and occasional renal failure may also occur.
Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:
A dark maroon, round, smooth, biconvex sugar-coated tablet.

PRESENTATION:
Two blisters of 10 tablets each.

STORAGE INSTRUCTIONS:
Store in a cool (below 25 °C), dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
H/18/1728

NAME AND BUSINESS ADDRESS OF APPLICANT:
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park, 400 16th Road
Midrand, South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
23 December 1996
*A 0,25 % solution of sodium hydrosulphite (available from photographic development outlets) has been used to remove phenazopyridine stains.

NAMIBIA: Reg. No. 18/32.2/0030	NS1
BOTSWANA: Reg. No. BOT2003660	S2

PIH1728/2

SKEDULERINGSTATUS:
S2

EIENDOMSNAAM (EN DOSEERVORM):
PYRIDIUM (tablette)

SAMESTELLING:
Elke tablet bevat 100 mg Fenasopiridienhidrochlorled.

FARMAKOLOGIESE KLASSIFIKASIE:
A : 18 Middels met uitwerking op urogenitale stelsel.

FARMAKOLOGIESE WERKING:
Urienweg pynstiller. Fenasopiriden word deur die urien uitgeskei waar dit 'n topikale analgetiese effek op die mukosa van die urienweg uitoefen. Tot 90 % van die dosis word binne 24 uur uitgeskei. 65 % as onveranderde geneesmiddel en die res as metaboliete. Een van die metaboliete is parasetamol.

INDIKASIES:
Kort-termyn simptomatiese verligting van pyn, branderigheid, drang en frekwensie wat ontstaan as gevolg van prikkelbaarheid van die onderste urienwieë slymvlies. Hierdie simptome mag die gevolg wees van infeksie, trouma, chirurgie, endoskopiese prosedures, of beweging van klank of kateters. Die onderliggende oorsaak van die irritasie moet vasgestel en behandel word (bv. antibakteriële behandeling van infeksie).

KONTRA-INDIKASIES:
Hipersensitiwiteit vir fenasopiridien. PYRIDIUM moet ook nie herhalend of vir langtermyn behandeling gebruik word sonder volledige diagnostiese ondersoek nie. Teenaangewys by glomerulonefritis, uremie, ingekorte nierfunksie en ernstige hepatitis.
Pasiënte wat aan 'n gebrek aan glukose-6-fosfaatdehidrogenase (G6FD) ly, het 'n verhoogde risiko van ernstige hemolitiese anemia.
Veiligheid gedurende swangerskap en borsvoeding is nog nie vasgestel nie.

WAARSKUWINGS:
1. Die gebruik van fenasopiridien vir verligting van simptome behoort die beslissende diagnose van die onderliggende oorsaak nie te vertraag nie. Geskikte behandeling van die oorsaak van pyn moet vinnig ingestel word en fenasopiridientoediening moet gestaak word sodra simptome onder beheer is.
2. Indien fenasopiridien gelyktydig met 'n antibakteriële middel vir die behandeling van 'n urienweginfeksie gebruik word, moet behandeling met fenasopiridien nie langer as 2 dae duur nie.
3. Indien simptome aanhou of herhaal, raadpleeg 'n geneesheer.

DOSIS EN GEBRUIKSAANWYSINGS:
Die tablette moet nie gekou word nie.
Volwassenes: Twee tablette drie keer per dag met of na maaltye.
Wanneer dit saam met 'n antibakteriële middel vir die behandeling van 'n urienweginfeksie gebruik word, moet die tydsduur van PYRIDIUM-terapie nie twee dae oorskry nie.

NEWE-EFFEKTE EN SPESIALE VOORSORG MAATREËLS:
Die volgende newe-effekte is aangemeld:
Sentrale senuweestelsel: Hoofpyn.
Gastroïntestinaal: Naarheid, vomering en diaree.
Dermatologies en Hipersensitiwiteit: Uitslag, pruritus, verkleuring, 'n anafilaktiese reaksie en hipersensitiwiteits-hepatitis.
Hematologies: Methemoglobinemie, hemolitiese anemia, 'n potensiële hemolitiese middel in G6FD tekort, sulfhemoglobinemie.
Ander: Gesigssteurings, nier- en lewervergiftiging gaan gewoonlik met oordosering gepaard, nierstene, geelsug, verkleuring van liggaamsvloeistowwe en aseptiese meningitis.
Voorsorgmaatreëls:
PYRIDIUM veroorsaak 'n oranje tot rooi verkleuring van urien en feses en mag kleding vlek*. Verkleuring van kontaklense is aangemeld. 'n Geel verkleuring van die vel of sklera mag dui op 'n ophoping van fenasopiridien as gevolg van vertraagde nierfunksie. Laasgenoemde noodsaak onttrekking van die middel.
PYRIDIUM mag patologiese kondisies verberg en mag inmeng met laboratoriumtoetswaardes waar daar gebruik gemaak word van kolorimetriese, spektrofotometriese of fluorometriese metodes van analise.
In diabete mag dit lei tot vals toetsresultate ten opsigte van uriensuiker en urienketone.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Oorskryding van die aanbevole dosis in pasiënte met normale nierfunksie of toediening van die aanbevole dosis aan pasiënte met vertraagde nierfunksie (algemeen in bejaarde pasiënte) mag lei tot verhoogde serumvlakke en toksiese reaksies.
Methemoglobinemie volg gewoonlik na 'n groot, akute oordosis. Toediening van 'n 1 tot 2 mg/kg liggaamsmassa intraveneuse 1 % metileenblou-oplossing kan gebruik word om die methemoglobinemie te behandel. Dit sal gewoonlik lei tot 'n afname van die methemoglobinemie asook die sianose wat as hulpmiddel in die diagnose gebruik kan word.
Oksidatiewe Heinzliggaam hemolitiese anemie mag ook voorkom en "bytselle" (degmasiete) mag tydens 'n situasie van chroniese oordosering teenwoordig wees. Rooibloedsel G6FD tekort mag predisponeer tot hemolise; hemolise mag egter teen normale dosisse in pasiënte met meditereense G6FD voorkom.
Lewervertraging en selde nierversaking mag ook voorkom.
Behandeling van oordosering is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Donker bruinrooi, ronde, gladde, bikonvekse suikerbedekte tablet.

AANBIEDING:
Twee stulpverpakkings met 10 tablette elk.

BERGINGSINSTRUKSIES:
Bewaar op 'n koel (benede 25 °C), droë plek.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
H/18/1728

NAAM EN BESIGHEIDSADRES VAN APPLIKANT:
Biotech Laboratories (Edms) Bpk
Grond Vloer, Block K West, Central Park, 400 16de Weg
Midrand, Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
23 Desember 1996.
*'n 0,25 % oplossing van natriumhidrosulfiet (beskikbaar by fotografiese ontwikkelingswinkels) was al gebruik om fenasopiridien-vlekke te verwyder.

NAMIBIË: Reg. No. 19/32.2/0030	NS1
BOTSWANA: Reg. No. BOT2003660	S2