SCHEDULING STATUS: S1

PROPRIETARY NAME (AND DOSAGE FORM):

CIPEX (Suspension)

CIPEX TABLETS (Tablets)

COMPOSITION:

CIPEX TABLETS: Each tablet contains mebendazole 100 mg.

Inactive ingredients include colloidal silicon dioxide, polysorbate 80, maize starch, magnesium stearate, microcrystalline cellulose, orange flavour, saccharin sodium, sodium starch glycollate, Sunset Yellow Supra and talc.

Sugar free formulation.

CIPEX: Each 5 mℓ contains mebendazole 100 mg.

Preservatives : Methylparaben 0,2 % m/v
Propylparaben 0,02 % m/v

Inactive ingredients include Avicel RC 591, banana flavour, cardamom flavour, Carmoisine supra, methylcellulose, citric acid, purified water, SAPMG (simethicone emulsion), sodium lauryl sulphate.

CIPEX contains 2,8 g sorbitol per 10 mℓ (the maximum daily recommended dose).

Products containing sorbitol may have a laxative effect or cause diarrhoea.

PHARMACOLOGICAL CLASSIFICATION:

A.12 Anthelmintics, bilharzia medicines, filaricides, etc.

PHARMACOLOGICAL ACTION:

Mebendazole is a broad spectrum anthelmintic. Its action is independent of its systemic concentration. It causes selective disappearance of cytoplasmic microtubules in the tegumental and intestinal cells of affected worms. Secretory substances accumulate in the Golgi areas, secretion of acetylcholinesterase and uptake of glucose is impaired, and glycogen is depleted, resulting in depletion of the worms' energy sources and their slow death.

INDICATIONS:

CIPEX is indicated for the treatment of single and mixed helminth infestations, such as:

- Ascariasis (large roundworm).
- Intestinal capillariasis.
- Enterobiasis (pinworm).
- Trichuriasis (whipworm).
- *Ancylostoma duodenale* (hookworm).
- *Necator americanus* (hookworm).
- *Strongyloides stercoralis* (threadworm).
- *Taenia* spp (tapeworm).
- *Ternidens deminutus*.

CIPEX is also indicated in the treatment of infestations by *Moniliformis moniliformis.*

CONTRA-INDICATIONS:

- Hypersensitivity to mebendazole or any of the other ingredients.
- Pregnancy and lactation.

PREGNANCY AND LACTATION:

CIPEX is contra-indicated during pregnancy and lactation (see **"CONTRA-INDICATIONS"**).

DOSAGE AND DIRECTIONS FOR USE:

Tablets can be swallowed whole, chewed or crushed and given with food or liquid.

For infestations with all worms; excluding tapeworm, threadworm and *Capillaria philippinensis*:

Adults and children over 2 years:

One 5 ml medicine measure of **CIPEX** suspension or one **CIPEX** tablet twice daily (morning and evening) for three consecutive days.

If the patient is not cured within three to four weeks a second course of treatment should be given.

For tapeworm infestations (*Taenia* species):

Adults and children over 2 years:

One 5 ml medicine measure of **CIPEX** suspension or one **CIPEX** tablet twice daily (morning and evening) for six consecutive days.

For threadworm infestations (*Strongyloides stercoralis*):

Adults:

Two 5 ml medicine measures (10 ml) of **CIPEX** suspension or two (2) **CIPEX** tablets twice daily (morning and evening) for three consecutive days.

Children:

One 5 ml medicine measure of **CIPEX** suspension or one **CIPEX** tablet twice daily (morning and evening) for three consecutive days.

The dosage should be repeated if the patient is still infested after three to four weeks.

For *Capillaria philippinensis* infestations:

Adults and children over 12 years:

Two 5 ml medicine measures (10 ml) of **CIPEX** suspension or two (2) **CIPEX** tablets to be given twice daily (morning and evening) for at least 20 days. This medicine is not recommended for children under the age of 12 years with capillariasis.

For children under 2 years:

See **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**.

In worm eradication campaigns the standard course for each specific species should be administered every quarter during the first year.

If a helminth is not susceptible to the standard dosage, the treatment course should be increased and/or higher doses than the standard dosage for a specific species is recommended.

The efficacy of **CIPEX** is dependent upon the duration of physical contact between the medicine and the parasite. When gastrointestinal transit time is accelerated, e.g., in diarrhoea, it is necessary to repeat the dose at more frequent intervals daily.

Fasting or purging is not required.

High dose therapy should be taken with meals, preferably with a high fat content.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Blood and lymphatic system disorders:

Less frequent: Neutropenia.

The following side-effects have been reported and frequencies are unknown: Bone marrow depression, which can be severe, has been reported with high doses. Agranulocytosis can occur.

Immune system disorders:

Less frequent: Allergic reactions (with high doses).

Neuropsychiatric system disorders:

Less frequent: Dizziness, headache.

Gastrointestinal system disorders:

Less frequent: Gastrointestinal disturbances, such as transient abdominal pain, diarrhoea, and vomiting, have occurred.

Hepatobiliary system disorders:

The following side-effects have been reported and frequencies are unknown: Raised liver enzymes (with high doses).

Skin and subcutaneous tissue disorders:

Less frequent: Alopecia (with high doses).

Special Precautions:

The use of **CIPEX** in children below two years of age is not well documented, and as there have been very exceptional reports of convulsions in this age group, **CIPEX** oral suspension should only be given to very young children if their worm infestations interfere with nutritional status and physical development.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**.

Treatment is symptomatic and supportive.

IDENTIFICATION:

CIPEX: A light pink coloured homogeneous suspension with a characteristic banana-cardamom odour.

CIPEX TABLETS: Orange coloured and flavoured circular, flat, bevelled tablet, plain on both sides.

PRESENTATION:

CIPEX: 30 ml glass bottles, with measuring cup.

CIPEX TABLETS: Blister strips of 6 tablets packed in 6's, 60's or 300's.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

CIPEX: 30/12/0245

CIPEX TABLETS: 32/12/0538

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Building 9, Parc du Cap,
Mispel Street, Bellville, 7530, RSA.

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

May 2009

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Namibia: NS1
Cipex : 06/12/0074
Cipex Tablets : 10/12/0482

Botswana: S3
Cipex: BOT9900394

4353 K

Cipla

SKEDULERINGSTATUS: S1

EIENDOMSNAAM (EN DOSEERVORM):

CIPEX (Suspensie)

CIPEX TABLETS (Tablette)

SAMESTELLING:

CIPEX TABLETS : Elke tablet bevat mebendasool 100 mg.

Onaktiewe bestanddele sluit kolloïdale silikondioksied, polisorbaat 80, mieliestysel, magnesiumstearaat, mikrokristallyne sellulose, lemoengeursel, natriumsakkarien, natriumstylselglikolaat, Sunset Yellow Supra en talk in.

Suikervrye formulering.

CIPEX : Elke 5 mℓ bevat mebendasool 100 mg.

Preserveermiddels : Metielparabeen 0,2 % m/v
Propielparabeen 0,02 % m/v

Onaktiewe bestanddele sluit Avicel RC 591, piesanggeursel, kardemomgeursel, Carmoisine Supra, metielsellulose, sitroensuur, gesuiwerde water, SAPMG (simetikoonemulsie) en natriumlourielsulfaat in.

CIPEX bevat 2,8 g sorbitol per 10 mℓ (die maksimum daaglikse dosering).

Produkte wat sorbitol bevat kan 'n lakserende uitwerking hê of diaree veroorsaak.

FARMAKOLOGIESE KLASSIFIKASIE:

A.12 Wurmmiddels, bilharzia middels, filariase middels, ens.

FARMAKOLOGIESE WERKING:

Mebendasool is 'n breë spektrum wurmmiddel. Die werking is onafhanklik van die sistemiese konsentrasie. Dit veroorsaak selektiewe verdwyning van sitoplasmiese mikrotubules in die tegumentale en intestinale selle van geaffekteerde wurms. Sekretoriese substanse hoop in die Golgi-areas op, afskeiding van asetielcholienesterase en opname van glukose word belemmer en glikogeen raak uitgeput. Dit lei tot die uitputting van die wurms se energiebronne en hulle stadige dood.

INDIKASIES:

CIPEX is aangedui vir die behandeling van enkel en gemengde wurm infestasies, soos:

- Askariase (groot rondewurm).
- Intestinale kapillariase.
- Enterobiase (naaldwurm).
- Trichuriase (sweepwurm).
- *Ancylostoma duodenale* (haakwurm).
- *Necator americanus* (haakwurm).
- *Strongyloides stercoralis* (haarwurm).
- *Taenia* spp (lintwurm).
- *Ternidens deminutus*.

CIPEX is ook aangedui vir die behandeling van infestasies met *Moniliformis moniliformis.*

KONTRA-INDIKASIES:

- Hipersensitiwiteit vir mebendasool of enige van die ander bestanddele.
- Swangerskap en laktasie.

SWANGERSKAP EN LAKTASIE:

CIPEX is teenaangedui gedurende swangerskap en laktasie (sien **"KONTRA-INDIKASIES"**).

DOSIS EN GEBRUIKSAANWYSINGS:

Tablette kan heel gesluk word, gekou of fyngemaak word en toegedien word saam met voedsel of vloeistof.

Vir infestasies met alle wurms; behalwe lintwurm, haarwurm en *Capillaria philippinensis*:

Volwassenes en kinders ouer as 2 jaar:

Een 5 ml medisynemaat **CIPEX** suspensie of een **CIPEX** tablet twee maal per dag (soggens en saans) vir drie opeenvolgende dae.

Indien die pasiënt nie binne drie tot vier weke genees is nie, moet 'n tweede kursus behandeling toegedien word.

Vir lintwurm infestasies (*Taenia* spesies):

Volwassenes en kinders ouer as 2 jaar:

Een 5 ml medisynemaat **CIPEX** suspensie of een **CIPEX** tablet twee maal per dag (soggens en saans) vir ses opeenvolgende dae.

Vir haarwurm infestasies (*Strongyloides stercoralis*):

Volwassenes:

Twee 5 ml medisynemate (10 ml) **CIPEX** suspensie of twee (2) **CIPEX** tablette twee maal per dag (soggens en saans) vir drie opeenvolgende dae.

Kinders:

Een 5 ml medisynemaat **CIPEX** suspensie of een **CIPEX** tablet twee maal per dag (soggens en saans) vir drie opeenvolgende dae.

Die kursus moet herhaal word indien die pasiënt steeds na drie tot vier weke geïnfesteerd is.

Vir infestasies met *Capillaria philippinensis*:

Volwassenes en kinders ouer as 12 jaar:

Twee 5 ml medisynemate (10 ml) **CIPEX** suspensie of twee (2) **CIPEX** tablette twee maal per dag (soggens en saans) vir ten minste 20 dae.

Hierdie medikasie word nie aanbeveel vir kinders jonger as 12 jaar met kapillariase nie.

Kinders jonger as 2 jaar:

Sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS"**.

Gedurende wurm uitwissingsveldtogte behoort die standaard kursus vir elke spesifieke spesie kwartaalliks gedurende die eerste jaar toegedien te word.

Indien 'n wurm nie vatbaar vir die standaard dosering is nie, word dit aanbeveel dat die duurte van behandeling verleng word en/of dat hoër doserings as die standaard dosering vir 'n spesifieke spesie gebruik word.

Die effektiwiteit van **CIPEX** is afhanklik van die duurte van fisiese kontak tussen die geneesmiddel en die parasiet. Wanneer gastro-intestinale deurgangstyd versnel is, byvoorbeeld met diaree, is dit noodsaaklik om die dosis meer gereeld daagliks toe te dien.

Dit is nie nodig vir pasiënte om te vas of purgeermiddels te gebruik nie.

Behandeling met hoë doserings behoort saam met maaltye geneem te word, verkieslik maaltye met 'n hoë vetinhoud.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Newe-effekte:

Bloed en limfatiese sisteem afwykings:

Minder dikwels: Neutropenie.

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Beenmurgonderdrukking, wat straf kan wees, is gemeld met hoë dosisse. Agranulositose kan voorkom.

Immuunsisteem afwykings:

Minder dikwels: Allergiese reaksies (met hoë doserings).

Neuropsigiatriese sisteem afwykings:

Minder dikwels: Duiseligheid, hoofpyn.

Gastro-intestinale sisteem afwykings:

Minder dikwels: Gastro-intestinale steurings, soos verbygaande abdominale pyn, diaree, naarheid en braking het voorgekom.

Hepatobiliêre sisteem afwykings:

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Verhoogde lewerensieme (met hoë doserings).

Vel- en subkutane weefsel afwykings:

Minder dikwels: Alopesie (met hoë doserings).

Spesiale Voorsorgmaatreëls:

Die gebruik van **CIPEX** in kinders jonger as 2 jaar is nie goed gedokumenteer nie. Vanweë uitsonderlike verslae van konvulsies in hierdie ouderdomsgroep, moet **CIPEX** orale suspensie slegs aan baie jong kinders toegedien word indien hulle wurm infestasies hulle voedingstatus en fisiese ontwikkeling belemmer.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS"**.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

CIPEX: 'n Ligtepienk gekleurde homogene suspensie met 'n kenmerkende piesang-kardemom reuk.

CIPEX TABLETS: Oranjekleurige en lemoengegeurde plat, ronde, afgeplatte tablet, plein aan beide kante.

AANBIEDING:

CIPEX: 30 ml glasbottels met maatproppie.

CIPEX TABLETS: Stulpverpakte stroke van 6 tablette verpak in 6's, 60's of 300's.

BERGINGSINSTRUKSIES:

Bewaar teen of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:

CIPEX: 30/12/0245

CIPEX TABLETS: 32/12/0538

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKATE VAN REGISTRASIE:

CIPLA MEDPRO (EDMS) BPK

Gebou 9, Parc du Cap,
Mispelstraat, Bellville, 7530, RSA.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

Mei 2009

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