PACKAGE INSERT

PROPRIETARY NAME AND DOSAGE FORM

Diaclin™ Capsules

COMPOSITION

Each capsule contains:

Potentiated Absorbatox® CEC 3.5 $[(Na,Ca,K)_6Si_{30}Al_6O_{72}•nH_2O]$	350 mg
Diosmectite	350 mg
Inactive ingredients:	
Magnesium Stearate	7 mg
Total per size 0 capsule	707 mg

CHEMICAL PROPERTIES

Absorbatox® is an un-absorbable potentiated natural occurring mineral, consisting of a three-dimensional network of AlO_4 and SiO_4 tetrahedra.

Major Exchangeable Ions: The selectivity series for ions which are adsorbed by Absorbatox® on a scale reflecting affinities are:
Pb>Cs>Rb>NH_4>Ba>Sr>Pb>Zn>Cu>Co>Ni>Hg>Na>Fe>Al>Li.
Gases Absorbed: at 25 °C
NH_3: Absorbatox®, 7,8 g / 100 g.
SO_2: Absorbatox®, 15,7 g / 100 g.
Absorbatox® also absorbs CO_2, Ar, N_2
Absorbatox® also adsorbs amines such as histamine.
Diosmectite is a natural occurring clay from the bentonite family.

PHARMACEUTICAL FORM

Capsule for oral dosing. Box of 10 capsules in a blister pack.

PHARMACO-THERAPEUTIC CLASSIFICATION

Anti-diarrhoeal Gastro-intestinal protectant.
(A: Alimentary tract and metabolism).
Mechanism of action: Inert Ab- and adsorbing agents which act by binding water as well as toxins, and other harmful substances and thereby protecting the gut lining simultaneously.

PHARMACOLOGICAL ACTION

Diaclin™ is primarily a mineral adsorbent due to its un-absorbable three-dimensional negatively charged microporous alumino-silica structure. It has anti-oxidant absorbent and adsorbent properties by means of its potentiated cation exchange capacity and acts as a free-radical scavenger.

PHARMACODYNAMICS

Diaclin's™ unique molecular structure adsorbs specific potentially harmful substances, which may occur in a normal daily diet. It adsorbs toxins, nitrates, and heavy metals such as mercury, cadmium and other cations on a scale of affinity. **Diaclin™** also demonstrates binding to mycotoxins (toxins produced by fungi). It has also been used for its anti-diarrhoeal properties due to the possible binding of the offending enterotoxin from *Escherichia coli*. **Diaclin™** is a non-toxic compound with a strong adsorptive and ion-exchange capacity. Due to its ab- and adsorbent properties **Diaclin™** has been tested in individuals suffering from various gastrointestinal disturbances including diarrhoea. The components contained in **Diaclin™** have demonstrated a significant reduction in associated symptoms of diarrhoea in clinical studies and may aid in the relief of this condition.

PHARMACOKINETICS

Diaclin™ passes through the intestinal system without being systemically absorbed by the body.

SUMMARY OF CLINICAL STUDIES

(Data on file Absorbatox® (Pty) Ltd)
Absorbatox® and Diosmectite have been tested in humans and laboratory animals for safety and efficacy. They demonstrate, similar to other alumino-silicates, an effect on reducing loose stools in humans and in animals.

INDICATIONS

Diaclin™ may aid in the relief of symptoms associated with gastrointestinal disturbances and discomfort such as diarrhoea and loose stools.

CONTRAINDICATIONS

This product is contraindicated for individuals allergic or sensitive to any of the listed ingredients (see **COMPOSITION**).

WARNINGS AND SPECIAL PRECAUTIONS

Since the active device in **Diaclin™** is Absorbatox® CEC 3.5, it may adsorb metal containing medicines such as lithium salts and iron; it is advised not to take **Diaclin™** within 2 hours of any medication.
Special precaution: **Diaclin™** is not a rehydration product and should be taken with sufficient and copious amounts of clean water. If the symptoms worsen or do not improve within 7 days, consult your Doctor or Pharmacist.

INTERACTIONS

In literature no significant interactions were reported for **Diaclin™** to date. Studies have reported no significant change in the absorption rates for several co-administered drugs. **Diaclin™** may however interact with the co-administration of medications containing cations such as Zinc, Calcium, Iron, Magnesium and Lithium. It is therefore recommended that **Diaclin™** should be taken at least 2 hours before or after any medication.

PREGNANCY AND LACTATION

Safety during pregnancy and lactation has not been established. Please consult your Healthcare Practitioner prior to use.

DOSAGE AND DIRECTIONS FOR USE

Age	Initial dose	Dose to be taken after next loose stool*	Maximum daily dose	Instructions per dose
6 months to 1 year of age	Content of 1 capsule	Content of 1 capsule	Content of 2 capsules	Open capsule and mix content of 1 capsule with soft food. Oral administration (Give by mouth). Immediately follow with rehydration fluid or clean water.
1 – 2 years of age	Content of 1 capsule	Content of 1 capsule	Content of 3 capsules	Open capsule and mix content of 1 capsule with soft food. Oral administration (Give by mouth). Immediately follow with rehydration fluid or clean water.
2 – 12 years of age	2 capsules	1 capsule	4 capsules	Capsule may be swallowed or open capsule and mix content of capsule with soft food. Oral administration (Give by mouth). Immediately follow with rehydration fluid or clean water.
Adults and children over the age of 12 years	2 capsules	2 capsules	6 capsules	Take 2 capsules orally (by mouth). Immediately follow with rehydration fluid or clean water.

* Wait at least 1 hour before taking the next dose.

• Start immediately with symptoms of diarrhoea or loose stools.

SIDE EFFECTS

There are no reported side effects, however **Diaclin™** should not be taken if constipation occurs. **Diaclin™** should not be inhaled.
Discontinue use if any adverse effects occur and once diarrhoea symptoms improve.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

No known symptoms of over dosage have been established. If suspected overdose occurs, please consult your Healthcare Practitioner immediately. Treatment should be symptomatic and supportive.

IDENTIFICATION

Diaclin™: orange coloured, size zero gelatine capsules containing a beige odourless and tasteless powder.

PRESENTATION

10 capsules in one foil backed blister pack inserted in an outer carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a cool, dry place.
Keep capsules in the blister until required for use.

KEEP OUT OF REACH OF CHILDREN

NAME AND BUSINESS ADDRESS OF APPLICANT

Absorbatox® (Pty) Ltd
Gast Liberty Park, 96 Achilles Street,
Zwavelpoort, Pretoria, 0081
South Africa
E-Mail: info@absorbatox.com

MARKETED BY

Lamar International (Pty) Ltd
13 Pasita Street,
Rosen Heights,
Rosen Park,
Bellville
7530
Cape Town
South Africa

E-Mail: info@lamar.co.za

DATE OF PUBLICATION OF THIS INSERT

January 2019

ABSORBATOX® PRODUCTS ARE PROTECTED BY INTERNATIONAL TRADEMARKS AND PATENTS

VOUBILJET

HANDELSNAAM EN DOSEERVORM

Diaclin™ Kapsules

SAMESTELLING

Elke kapsule bevat:

Gepotensieerde Absorbatox® CEC 3.5 $[(Na,Ca,K)_6Si_{30}Al_6O_{72}•nH_2O]$	350 mg
Diosmektiet	350 mg
Onaktiewe bestanddeel:	
Magnesiumstearaat	7 mg
Totaal per grootte 0 kapsule	707 mg

CHEMIESE EIENSKAPPE

Absorbatox® is 'n onabsorbeerbare, gepotensieerde mineraal wat natuurlik voorkom, bestaande uit 'n driedimensionele netwerk van AlO_4 en SiO_4 tetrahedra.

Belangrikste uitruilbare ione: Die selektiwiteitsreeks vir ione wat deur Absorbatox® geadsorbeer word op 'n skaal wat die affiniteit reflekteer, is:
Pb>Cs>Rb>NH_4>Ba>Sr>Pb>Zn>Cu>Co>Ni>Hg>Na>Fe>Al>Li.
Gasse geabsorbeer by 25 °C
NH_3: Absorbatox®, 7,8 g/100 g.
SO_2: Absorbatox®, 15,7 g/100 g.
Absorbatox® absorbeer ook CO_2, Ar, N_2.
Absorbatox® adsorbeer ook amiene soos histamien.
Diosmektiet is 'n tipe klei wat natuurlik voorkom, behorende aan die bentoniet familie.

FARMASEUTIESE VORM

Kapsule vir orale dosering. Karton met 10 kapsules in 'n stulpstrook.

FARMAKO-TERAPEUTIESE KLASSIFIKASIE

Anti-diarree, gastro-intestinale beskermer.
(A: Spysverteringskanaal en metabolisme).
Meganisme van werking: Inerte ab- en adsorberende substanse wat werk deur water asook toksiene en ander skadelike stowwe te bind, en sodoende terselfdertyd die voering van die ingewande te beskerm.

FARMAKOLOGIESE WERKING

Diaclin™ adsorbeer hoofsaaklik minerale, weens die onabsorbeerbare driedimensionele negatief-gelaaide mikroporeuse aluminosilika-struktuur daarvan. Dit het anti-oksidant absorberende en adsorberende eienskappe deur middel van die gepotensieerde katioonuitruilingskapasiteit daarvan en dit werk deur vry radikale op te ruim.

FARMAKODINAMIKA

Diaclin™ se unieke molekulêre struktuur adsorbeer spesifieke potensieel skadelike stowwe, wat in 'n normale daaglikse dieet kan voorkom. Dit adsorbeer toksiene, nitrate en swaarmetale soos kwik, kadmium en ander katione op 'n skaal van affiniteit. **Diaclin™** bind ook aan mikotoksiene (toksiene wat deur swamme geproduseer word). Dit is ook gebruik vir sy eienskappe wat diarree teëwerk weens die moontlike binding van die *Escherichia coli* enterotoksien, wat die simptome veroorsaak. **Diaclin™** is 'n nie-toksiese verbinding met 'n sterk adsorptiewe en ioonuitruilingskapasiteit. Weens die ab- en adsorberende eienskappe daarvan, is **Diaclin™** getoets in individue wat aan verskeie gastro-intestinale steurings ly, insluitend vermindering van los stoelgange. In kliniese studies demonstreer die bestanddele in **Diaclin™** 'n beduidende vermindering van die geassosieerde simptome van diarree en mag help om hierdie toestand te verlig.

FARMAKOKINETIKA

Diaclin™ beweeg deur die ingewandstelsel sonder dat dit sistemies deur die liggaam geabsorbeer word.

OPSOMMING VAN KLINIESE STUDIES

(Data op lêer Absorbatox® (Edms.) Bpk.)
Absorbatox® en Diosmektiet is in mense en laboratoriumdiere vir veiligheid en doelmatigheid getoets. Soortgelyk aan ander aluminosilikate, toon hulle 'n uitwerking op die vermindering van los stoelgange by mense en diere.

INDIKASIES

Diaclin™ mag help om simptome wat geassosieer word met gastro-intestinale versteurings en ongemak, soos diarree en los stoelgange, te verlig.

KONTRA-INDIKASIES

Diaclin™ word teenaangedui vir individue wat allergies of sensitief is vir enige van die gelyste bestanddele (sien **SAMESTELLING**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Die aktiewe toestel in **Diaclin™** is Absorbatox® CEC 3.5, daarom mag dit metaal-bevattende medikasie soos litiumsoute en yster adsorbeer; dit word aanbeveel dat **Diaclin™** nie binne 2 uur van enige medikasie geneem word nie.
Spesiale voorsorgmaatreël: **Diaclin™** is nie 'n rehidrasiemiddel nie en moet met voldoende, groot hoeveelhede skoon water geneem word. Indien die simptome vererger of nie binne 7 dae verbeter nie, raadpleeg u dokter of apteker.

INTERAKSIES

Tot op datum is geen beduidende interaksies met **Diaclin™** in die literatuur gerapporteer nie. Studies het geen beduidende verandering in die tempo van absorpsie vir verskeie middels wat gepaardgaande toegedien is, gerapporteer nie. **Diaclin™** mag egter wisselwerking toon wanneer medikasies wat katione bevat, soos sink, kalsium, yster, magnesium en litium, gelyktydig toegedien word. Dit is dus belangrik dat **Diaclin™** nie binne 2 uur voor of na enige medikasie geneem word nie.

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Konsulteer asseblief u gesondheidsorgdeskundige voor gebruik.

DOSIS EN GEBRUIKSAANWYSINGS

Ouderdom	Eerste dosis	Dosis wat geneem moet word na volgende los stoelgang*	Maksimum daaglikse dosis	Instruksies per dosis
6 maande tot 1 jarige ouderdom	Inhoud van 1 kapsule	Inhoud van 1 kapsule	Inhoud van 2 kapsules	Maak die kapsule oop en meng die inhoud van die kapsule met sagte kos (Gee per mond). Volg dadelik met rehidrasievloeistof of skoon water.
1 – 2 jarige ouderdom	Inhoud van 1 kapsule	Inhoud van 1 kapsule	Inhoud van 3 kapsules	Maak die kapsule oop en meng die inhoud van die kapsule met sagte kos (Gee per mond). Volg dadelik met rehidrasievloeistof of skoon water.
2 – 12 jarige ouderdom	2 kapsules	1 kapsule	4 kapsules	Kapsule mag gesluk word of die inhoud van die kapsule mag met sagte kos gemeng word (Gee per mond). Volg dadelik met rehidrasie-vloeistof of skoon water.
Volwassenes en kinders bo die ouderdom van 12 jaar	2 kapsules	2 kapsules	6 kapsules	Neem 2 kapsules mondeliks. Volg dadelik met rehidrasievloeistof of skoon water.

* Wag minstens 1 uur voordat volgende dosis geneem word.

- Begin behandeling dadelik wanneer simptome van diarree of los stoelgange voorkom.

NEWE-EFFEKTE

Geen newe-effekte is gerapporteer nie; **Diaclin™** moet egter nie geneem word indien hardlywigheid voorkom nie. **Diaclin™** moet nie ingeasem word nie.
Staak gebruik indien enige ongewenste newe-effekte voorkom en sodra die simptome van diarree verbeter.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Daar is geen simptome van oordosering bekend nie. Indien oordosering vermoed word, konsulteer asseblief u gesondheidsorgdeskundige onmiddellik. Behandeling moet simptomaties en ondersteunend wees.

IDENTIFIKASIE

Diaclin™: oranje, grootte nul gelatienkapsules wat beige reuklose en smaaklose poeier bevat.

AANBIEDING

10 kapsules in een stulpstrook met 'n foelie-rugkant, verpak in 'n buitenste karton.

BERGINGSAANWYSINGS

Bewaar by of benede 25 °C op 'n koel, droë plek.
Hou die kapsules in die stulpstrook tot benodig vir gebruik.

HOU BUITE BEREIK VAN KINDERS

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT

Absorbatox® (Edms.) Bpk.
Gast Liberty Park, Achillesstraat 96,
Zwavelpoort, Pretoria, 0081
Suid-Afrika
E-pos: info@absorbatox.com

BEMARK DEUR

Lamar International (Edms.) Bpk.
Pasitastraat 13,
Rosen Heights,
Rosen Park,
Bellville
7530
Kaapstad
Suid-Afrika

E-pos: info@lamar.co.za

PUBLIKASIEDATUM VAN HIERDIE VOUBILJET

Januarie 2019

ABSORBATOX® PRODUKTE WORD DEUR INTERNASIONALE HANDELSMERKE EN PATENTE BESKERM

LI0235/18B
Pro-Print