

# PHYTOCOR PHYTOCOR PLUS

## **SCHEDULING STATUS:**

Not applicable

## **PROPRIETARY NAME AND DOSAGE FORM**

Phytocor tablets

Phytocor Plus capsules

## **COMPOSITION:**

Each **PHYTOCOR** tablet contains 10 mg policosanol.

Each **PHYTOCOR PLUS** capsule contains:

Policosanol	10 mg
Omega 3	300 mg
Thiamine (Vitamin B <sub>1</sub> )	5 mg
Riboflavin (Vitamin B <sub>2</sub> )	4 mg
Nicotinamide (Vitamin B <sub>3</sub> )	6 mg
Pyridoxine (Vitamin B <sub>6</sub> )	6 mg
Folic acid (Vitamin B <sub>9</sub> )	400 µg
Cyanocobalamin (Vitamin B <sub>12</sub> )	5 µg
D-Biotin (Vitamin H)	100 µg
Calcium Pantothenate	4 mg
Zinc (elemental)	15 mg

## **PHARMACOLOGICAL CLASSIFICATION:**

A: 32.2 Other substances or agents, other

## **PHARMACOLOGICAL ACTION**

Policosanol is a natural ingredient derived from the waxy component of sugar cane. It is a natural concentrated form of the long chain aliphatic fatty alcohol (not a sugar) derived from sugar cane. The major component is octacosanol, a potent policosanol.

About 75% - 80% of cholesterol is synthesized in the liver and the balance is derived from food sources such as meat and dairy products.

Cholesterol is transported in the blood stream by lipoproteins. AcetylCoA is the enzyme responsible for the synthesis of cholesterol in the cells.

There are four main classes of lipoproteins, which are:

- High-density lipoproteins (HDL)
- Low-density lipoproteins (LDL)
- Very low density lipoproteins (VLDL)
- Chylomicrons.

Various clinical trials using the sugar cane extract have demonstrated that policosanol lowers low-density lipoproteins (LDL or "bad" cholesterol) in the blood. It improves blood cholesterol levels by reducing serum cholesterol levels and increasing HDL levels.

Policosanol exhibits anti-oxidant effect on LDL cholesterol.

It has been suggested that it contributes to the “thinning” of the blood by inhibiting platelet aggregation by reducing blood clots and improving circulation.

The various vitamins and minerals have been known to play a symbiotic role in maintaining the lipid balance in the body.

In addition, studies support the homocysteine lowering effects of the B-vitamins, especially folic acid.

**INDICATIONS:**

**PHYTOCOR** can assist in reducing “bad” cholesterol in those individuals with elevated cholesterol levels equal to or above 5 mmol/L.

**PHYTOCOR PLUS** has added vitamins and minerals which can assist the body’s fight in reducing “bad” cholesterol.

**CONTRA-INDICATIONS**

Sensitivity to any of the ingredients in the formulations.

**WARNINGS:**

Always consult your Healthcare professional about your cholesterol status. If you are on any cholesterol lowering medication, consult your doctor before taking policosanol.

Omega 3 has antithrombotic activity and should be used with caution in patients with haemorrhagic disorders or in those receiving anticoagulants or who are on any medication that affects blood coagulation.

Use with caution, in patients with peptic ulcer disease, gout or hepatic impairment.

**PHYTOCOR PLUS** should be used with caution in diabetics due to the possibility of interaction with the various vitamins and minerals in the formulation and medication.

**INTERACTIONS:**

Nicotinic acid may interact with statin medication and may increase the requirements for insulin or oral hypoglycaemics so caution is advised. Pyridoxine could reduce the effects of levodopa and there have been reports that it could decrease serum concentrations of phenobarbital and phenytoin. There is a potential that policosanol could enhance the effects of warfarin and other blood thinning agents and lead to prolonged bleeding times.

**PREGNANCY AND LACTATION:**

Safety during pregnancy and lactation has not been established.

**DOSAGE AND DIRECTIONS FOR USE:**

One (1) tablet or capsule, with water or any other fluid, after the evening meal or as directed by your Healthcare Professional.

Positive results have been observed within 8 weeks.

It is recommended that you inform your Healthcare Professional that you are taking **PHYTOCOR**.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

Policosanol has been found to be safe and well tolerated . The most frequently reported adverse effects were weight loss, increased urination, and headache.

Other side-effects reported were insomnia, excessive eating, nervousness, somnolence, dizziness, excitability, hypotension, hypertension, itching, skin rash, nausea, epigastric pain, diarrhoea and constipation.

Policosanol has been found to be well tolerated in patients with hypercholesterolaemia and concomitant coronary risk factors.

Type II diabetics can use policosanol. Documented studies have demonstrated safety in those with liver and kidney problems.

No liver toxicity has been demonstrated during long-term use of policosanol at high doses in experimental laboratory studies in Sprague Dawley rats.

Adverse effects reported with omega 3 includes gastrointestinal disturbances including nausea, vomiting, abdominal distention, diarrhoea and constipation. There have been rare reports of acne and eczema.

Other adverse effects reported with the various vitamins and minerals are flushing, sensation of heat, faintness, pounding in the head, dryness of the skin, pruritis, hyperpigmentation, abdominal cramps and pain, anorexia, activation of peptic ulcer, vision impairment, jaundice, impairment of liver function, hyperglycaemia, hyperuricaemia, decrease in glucose tolerance and bright yellow discolouration of urine which could interfere with certain laboratory tests.

*Special precautions:*

Use with caution in insulin dependent diabetics and sugar levels need to be monitored.

Hepatic function should be monitored in patients taking high doses of omega 3.

Caution is advised in asthmatic patients that are sensitive to aspirin.

A life-threatening eosinophilic pleuropericarditis has been associated with biotin and pantothenic acid. Symptoms resolved upon discontinuation of these vitamins.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

No known symptoms of overdosage have been documented with policosanol.

Acute zinc overdosage is corrosive due to the formation of zinc chloride by the stomach acid; treatment consists of administration of milk or alkali carbonates and activated charcoal.

Treatment is symptomatic and supportive.

**IDENTIFICATION:**

**PHYTOCOR:** White, round, flat, slightly mottled bevelled-edge tablet with a breakline on one side and plain on the other.

**PHYTOCOR PLUS:** Opaque dark maroon body and opaque navy cap containing a yellowish powder.

**PRESENTATION:**

**PHYTOCOR:** Blister packs containing 30 tablets.

**PHYTOCOR PLUS:** Blister packs containing 30 capsules.

**STORAGE INSTRUCTIONS:**

Store in a cool (below 25°C), dry place. Protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

**NAME AND BUSINESS ADDRESS:**

Pharma Dynamics (Pty) Ltd

F02 Grapevine House

Steenberg Office Park

Westlake

7945

**DATE OF PUBLICATION OF THIS INSERT:**

October 2005

## PHYTOCOR PHYTOCOR PLUS

### SKEDULERINGSSTATUS:

Nie van toepassing nie.

### EIENDOMSNAAM EN DOSEERVORM:

Phytorcor tablette  
Phytorcor Plus kapsules

### SAMESTELLING:

Elke **PHYTOCOR** tablet bevat 10 mg polikosanol.

Elke **PHYTOCOR PLUS** kapsule bevat:

Polikosanol	10 mg
Omega-3	300 mg
Tiamien (Vitamiën B <sub>1</sub> )	5 mg
Riboflaviën (Vitamiën B <sub>2</sub> )	4 mg
Nikotienamied (Vitamiën B <sub>3</sub> )	6 mg
Piridoksien (Vitamiën B <sub>6</sub> )	6 mg
Foliensuur (Vitamiën B <sub>9</sub> )	400 µg
Sianokobalamien (Vitamiën B <sub>12</sub> )	5 µg
D-Biotien ( (Vitamiën H)	100 µg
Kalsiumpantotenaat	4 mg
Sink (elementeel)	15 mg

### FARMAKOLOGIESE KLASSIFIKASIE:

A: 32.2 Ander stowwe of middels, ander

### FARMAKOLOGIESE WERKING:

Polikosanol is 'n natuurlike bestanddeel wat van die wasagtige komponent van suikerriet afgelei word. Dit is 'n natuurlike gekonsentreerde vorm van die lang-ketting alifatiese vetterige alkohol (nie 'n suiker nie) wat van suikerriet afgelei word. Die hoofkomponent is oktakosanol, 'n potente polikosanol.

Ongeveer 75% - 80% van cholesterol word in die lewer gesintetiseer en die balans word van voedselbronne soos vleis en suiwelprodukte verkry. Cholesterol word in die bloedstroom deur lipoproteïene vervoer. Asetiel-KoA is die ensiem verantwoordelik vir die sintese van cholesterol in selle.

Daar is vier hoofklasse lipoproteïene, naamlik:

- Hoë-densiteit lipoproteïene (HDL)
- Lae-densiteit lipoproteïene (LDL)
- Baie-lae-densiteit lipoproteïene (BLDL)
- Chilomikrone.

Verskeie kliniese studies wat suikerriet-ekstrak gebruik het, het gedemonstreer dat polikosanol lae-densiteit lipoproteïene (LDL of "slegte" cholesterol) in die bloed verlaag. Dit verbeter bloedcholesterolvlakke deurdat dit serumcholesterolvlakke verlaag en HDL-vlakke verhoog.

Polikosanol oefen 'n anti-oksidente effek op LDL-cholesterol uit.

Daar is gesuggereer dat dit tot "verdunding" van die bloed bydra deur inhibisie van plaatjie- aggregasie deur vermindering van bloedklonte en verbetering van die bloedsomloop.

Dit is bekend dat die verskeie vitamien en minerale 'n simbiotiese rol in die handhawing van die lipiedbalans van die liggaam speel. Daarbenewens ondersteun studies die homosisteïen-verlagende uitwerkings van die B-vitamien, veral van foliensuur.

#### **INDIKASIES:**

**PHYTOCOR** kan help met die verlaging van "slegte" cholesterol in daardie individue met verhoogde cholesterolvlakke wat gelyk is aan, of 5 mmol/L oorskry.

**PHYTOCOR PLUS** het toegevoegde vitamien en minerale wat die liggaam se stryd teen "slegte" cholesterol kan help.

#### **KONTRA-INDIKASIES:**

Sensitiwiteit teenoor enige van die bestanddele in die formulerings.

#### **WAARSKUWINGS:**

Raadpleeg altyd jou lid van die gesondheidsorgpersoneel oor jou cholesterolstatus. Indien jy enige cholesterol-verlagende medikasie neem, moet jy jou dokter raadpleeg voordat jy polikosanol neem.

Omega-3 besit antitrombotiese aktiwiteit en moet met omsigtigheid gebruik word in pasiënte met hemorragiese siektes of by persone wat antistollingsmiddels ontvang of wat enige medikasie neem wat bloedstolling beïnvloed.

Gebruik met omsigtigheid in pasiënte met peptiese ulkus, jig of lewerinkorting.

**PHYTOCOR PLUS** moet met omsigtigheid gebruik word in diabetie as gevolg van die moontlikheid van interaksie tussen die verskeie vitamien en minerale in die formulering en medikasie.

#### **INTERAKSIES:**

Nikotiensuur mag interaksies met statien-medikasie veroorsaak en die behoefte vir insulien of orale hipoglisemiese middels verhoog. Omsigtigheid word dus aanbeveel.

Piridoksien kan moontlik die uitwerkings van levodopa verminder en berigte is ontvang dat dit serumkonsentrasies van fenobarbital en fenitoïen mag verlaag.

Daar bestaan ook 'n moontlikheid dat polikosanol die uitwerkings van warfarien en ander middels wat die bloed verdun mag versterk en tot verlengde bloeitye kan lei.

#### **SWANGERSKAP EN LAKTASIE:**

Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

**DOSIS EN GEBRUIKSAANWYSINGS:**

Een (1) tablet of kapsule, met water of enige ander vloeistof, na aandete, of soos deur jou lid van die gesondheidsorgpersoneel voorgeskryf. Positiewe resultate is binne 8 weke waargeneem.

Dit word aanbeveel dat jy jou lid van die gesondheidsorgpersoneel inlig dat jy **PHYTOCOR** neem.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

Daar is gevind dat polikosanol veilig is en goed verdra word. Die nuwe-effekte wat mees algemeen aangemeld is, was gewigsverlies, verhoogde urinering, en hoofpyn.

Ander nuwe-effekte wat aangemeld is, was slaaploosheid, oormatige voedselinname, senuagtigheid, slaperigheid, duiseligheid, opgewondenheid, hipotensie, hipertensie, jeuk, veluitslag, naarheid, epigastriese pyn, diarree en hardlywigheid.

Daar is gevind dat polikosanol goed verdra word in pasiënte met hipercholesterolemie en gelyktydig bestaande koronêre risikofaktore. Tipe-II diabetes kan polikosanol gebruik. Gedokumenteerde studies het veiligheid gedemonstreer in persone met lewer- en nierprobleme.

Geen lewertoksisiteit is tydens langtermyn gebruik van polikosanol teen hoë dosisse in eksperimentele laboratoriumstudies met Sprague Dawley rotte aangemeld nie.

Nadelige uitwerkings wat met omega-3 aangemeld is, sluit in gastroïntestinale verstoringe, insluitend naarheid, braking, abdominale uitsetting, diarree en hardlywigheid. Seldsame berigte van aknee en ekseem is ontvang.

Ander nadelige uitwerkings wat met die verskillende vitamienes en minerale aangemeld is, was bloesing, sensasie van hitte, floues, kloppende gevoel in die kop, veldroogheid, pruritus, hiperpigmentasie, abdominale krampe en pyn, anoreksie, aktivering van peptiese ulkus, belemmering van visie, geelsug, inkorting van lewerfunksie, hiperglisemie, hiperurisemie, verlaagde glukosetoleransie en helder geel verkleuring van urine wat met sekere laboratoriumtoetse mag inmeng.

*Spesiale voorsorgmaatreëls:*

Gebruik met omsig in insulien-afhanklike diabetes en moniteer suikervlakke. Hepatiese funksie behoort gemoniteer te word in pasiënte wat hoë dosisse omega-3 neem.

Omsigtigheid word aanbeveel in asmaatiese pasiënte wat vir aspirien sensitief is.

'n Lewensbedreigende eosinofiliese pleuroperikarditis is met biotien en pantoteensuur geassosieer. Simptome het verdwyn na staking van hierdie vitamienes.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**

Geen bekende simptome van oordosering is vir polikosanol aangeteken nie. Akute oordosering met sink is korroderend omdat sinkchloried deur maagsuur gevorm word; behandeling bestaan uit toediening van melk of alkaliese karbonate en geaktiveerde houtskool.

Behandeling is simptome en ondersteunend.

**IDENTIFIKASIE:**

**PHYTOCOR:** Wit, ronde, plat, effens gespikkelde tablet met afgeplatte kante, 'n keep aan een kant en onversier op die ander kant.

**PHYTOCOR PLUS:** Ondeurskynende donker wynrooi romp en ondeurskynende marineblou dop wat 'n geelagtig poeier bevat.

**AANBIEDING:**

**PHYTOCOR:** Stulpverpakkings wat 30 tablette bevat.

**PHYTOCOR PLUS:** Stulpverpakkings wat 30 kapsules bevat.

**BERGINGSINSTRUKSIES:**

Bewaar in 'n koel (onder 25°C), droë plek. Beskerm teen vog.

HOU BUITE BEREIK VAN KINDERS.

**NAAM EN BESIGHEIDSADRES:**

Pharma Dynamics (Edms) Bpk

F02 Grapevine House

Steenberg Office Park

Westlake

7945

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

Oktober 2005