



# Product File

Exclusively for Professional Use

Successfully sold in the Netherlands, Belgium, Italy, Switzerland and Germany

## ■ General Concept of Diabecinn™

The causes and control of Type 2 Diabetes and cardiovascular diseases are multifactorial, but there is strong evidence that dietary factors and some phytomedicines play an important role in the regulation and prevention of these diseases.(1,4) Type 2 diabetics are two-four times more likely to develop cardiovascular diseases.(4) Phytomedicines are especially important for people with elevated blood glucose levels or glucose intolerance who are at greater risk of developing diabetes and heart disease.(1)

DIABECINN™ is a nutritional food supplement, containing a water-based extract (ZN112) of the phytomedicine, Cortex Cinnamomi (cinnamon). A recent placebo-controlled clinical trial in humans has shown that whole ground cinnamon (*Cinnamomum cassia*) significantly **reduced fasting glucose levels by up to 29%, triglycerides by up to 30%, LDL cholesterol by up to 27% and total cholesterol by up to 26%.**(1,2,3,4)



DIABECINN™ could have significantly beneficial effects on the overall health of diabetic patients.

### ■ Indications

DIABECINN™ is a food supplement that may help reduce blood sugar levels, triglycerides, LDL cholesterol and total cholesterol in patients with Type 2 Diabetes. **(Product dossier submitted to the South African Medicines Control Council pursuant to the resolution published in the Government Gazette, Government Notice R204, 22 February 2002).**

### ■ Presentation

DIABECINN™ capsules are sealed in blister packs of 15 capsules, packed in cartons of 30's and 60's standard capsules (i.e. 1 box of Diabecinn™ contains either 30 or 60 capsules) and 30's vegetarian capsules (Halaal certified/S.A.N.H.A.). Inserted in each carton, there is an explicit package insert and the product carries a 3-year shelf-life.

### ■ Composition

#### Active Component

Each capsule contains:

Water-based *Cinnamon extract (ZN112)* 112mg  
(Equivalent to approx. 1 232mg dried, whole ground Cortex Cinnamomi bark)

#### Inactive Components

Microcrystalline cellulose, Dicalcium phosphate,  
Rice starch, Silicon dioxide, Magnesium stearate.



DIABECINN™ is **naturally free from Sugar and Lactose and contains no added Preservatives**

### ■ Dosage and Directions for Use

Adults with Type 2 Diabetes: 1 capsule daily with the main meal. If after one month a sufficiently beneficial result is not achieved, the dose can safely be increased to up to 3

capsules a day. Split the daily dose by taking 1 capsule with each meal.  
To be used by children under 12 years of age only after appropriate medical consultation.

## ■ Warnings and Contra-indications

- Keep out of reach of children
- Dosage adjustments to concurrent antidiabetic medication might be necessary
- Contra-indicated during pregnancy and lactation
- Contra-indicated in hypersensitivity to cinnamon or Peruvian balsam

## ■ Side Effects and Special Precautions

The oil in whole ground cinnamon has been associated with mucous membrane sensitization and irritation due to its cinnamaldehyde content. The oil also contains coumarin and eugenol, both having the potential to increase bleeding. Diabecinn™ does not contain coumarin (species specific) and because Diabecinn™ is a water-based extract, the overwhelming majority of oils has been removed.

This significantly decreases the potential for Diabecinn™ to cause toxic effects i.e. GIT irritation and enhanced antiplatelet activity (1). As a precaution however, it is advised to discontinue the use of Diabecinn™ one month prior to surgery and to start again 2-3 weeks afterwards.

## ■ Mechanisms of Action

DIABECINN™ contains water-soluble polyphenol polymers from Cortex Cinnamomi. A recent study by Anderson A et.al (2004) has shown that these polymers are specifically responsible for insulin-enhancing biological activity in vitro, in rat adipocytes.(1) This biological activity is unique to these specific polymers and does not extend to other constituents of Cortex Cinnamomi. (1)

During aqueous extraction, the overwhelming majority of lipid-soluble components of Cortex Cinnamomi remain behind, thus significantly decreasing the potential for toxic effects of raw Cortex Cinnamomi if ingested at higher doses or after chronic use.(1)

The biological **hypoglycaemic effects of DIABECINN™** are three-fold:

### 1. Increased Glucose Uptake (4,5)

Symptoms of insulin resistance include defective glucose uptake. Extracts of Cortex Cinnamomi have been shown to increase glucose uptake in vitro, in rat adipocytes.

### 2. Increased Glycogen Synthesis (4,5)

Decreased stimulation of muscle glycogen synthesis and defects in glycogen synthase are also associated with Insulin resistance. Extracts of Cortex Cinnamomi have been shown to activate glycogen synthase and inhibit glycogen synthase kinase in vitro, in rat adipocytes.

### 3. Improved action of Insulin (1,4,5)

Clinical studies have shown that supplementation of phytochemical antioxidants help maintain the integrity of cell membranes by preventing polyunsaturated fatty acid peroxidation. The phospholipids composition of muscle membranes affects the binding and action of insulin. The more phosphorylated the membrane, the better glucose is utilized; more dephosphorylated membranes hinder insulin efficiency. Extracts of Cortex Cinnamomi have been shown to inhibit dephosphorylation of the insulin receptor and therefore increase insulin efficiency in vitro, in rat adipocytes.



The biological **hypolipidaemic effects of Diabecinn™** are two-fold:

### 1. Potent antioxidant activity (1,4)

Lipid peroxidation and damage by reactive oxygen metabolites are major problems in terms of diabetic complications, including atherosclerosis. As antioxidants, extracts of Cortex Cinnamomi help prevent the formation of fatty build-ups from LDL cholesterol.

### 2. Improved action of Insulin (1,4)

Insulin plays a key role in lipid metabolism. Diabetes is associated with high triglyceride levels and improved insulin activity automatically improves lipid profiles.

## ■ Research

### 1. Randomised, placebo-controlled clinical trial: Reduction of serum glucose and lipid levels – Human (4)

A clinical trial was conducted by the University of Peshawar, Pakistan on 60 individuals with Type 2 Diabetes. All patients were over 40 years of age, on sulphonylureas but not on insulin, not taking medicine for other health conditions and with fasting blood glucose levels between 7.8 and 22.2 mmol/l. Diet and medication did not change during the study. Compliance was considered excellent and all capsules were consumed.

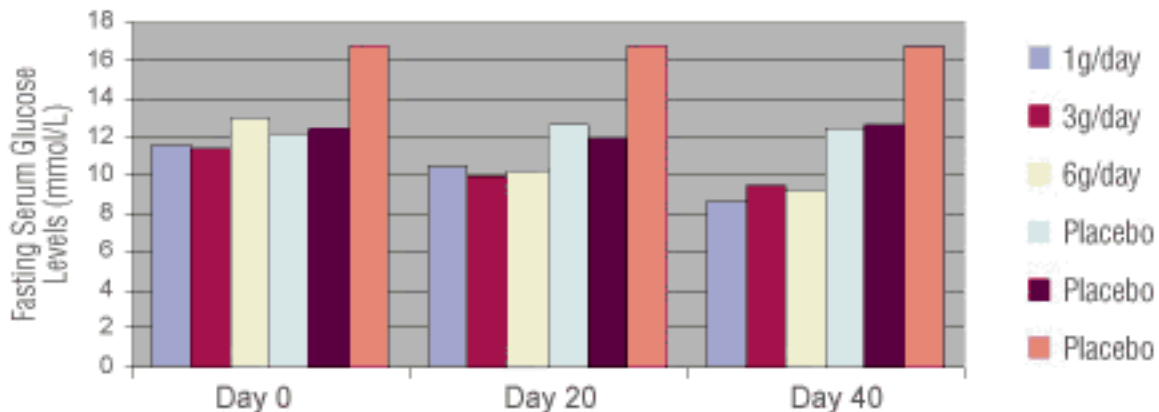
*The addition of 1,3 or 6g whole ground Cinnamomum cassia to the diet led to significant decreases in serum glucose, triglyceride, LDL and cholesterol levels, after 40 days.*

### 2. Randomised, placebo-controlled double blind clinical trial at the University of Hannover, Germany– Human (6)

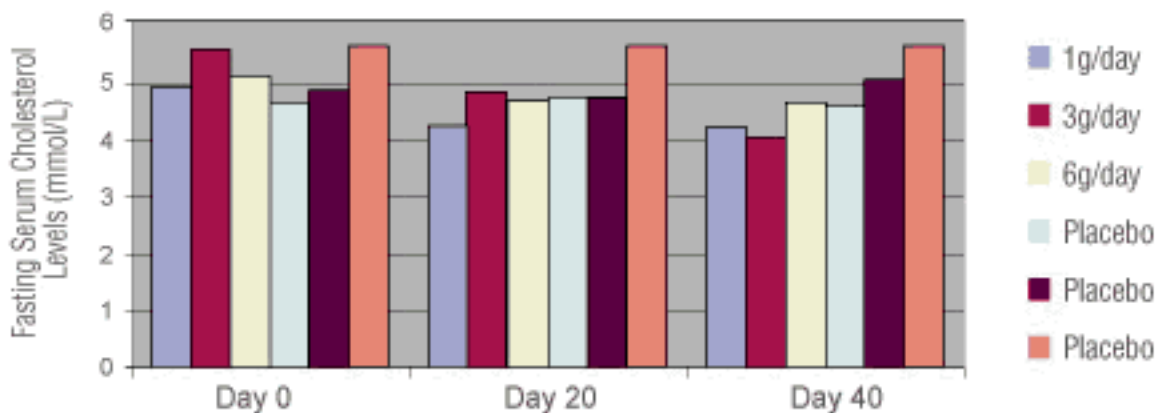
Mang B et. al. (6) administered capsules containing 122mg of a **water-based extract of cinnamomum cassia: equivalent to 1g of whole cinnamon**, to 65 patients with a mean baseline fasting glucose level of **9.26** mmol/l at a dose of 1 capsule three times a day, for 4 months. No adverse effects were reported.

The study showed that the extract produced **a significant (10%) reduction in fasting blood sugar levels**, however no significant reductions were seen with regards to HbA1c or lipid profile. The decrease in glucose levels correlated significantly with baseline concentrations indicating that **more poorly controlled patients** (those with higher mean baseline glucose levels e.g. **11.6-13.0** mmol/l in the study by Khan et. al. 4) **are likely to benefit more** and that in these patients an effect on the lipid profile and HbA1c, could be expected.

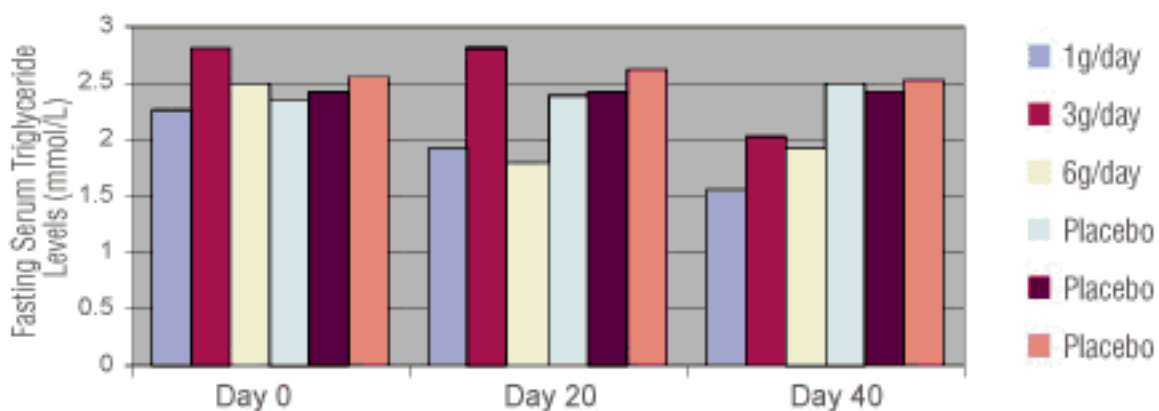
Decreases in glucose levels ranged from 18 to 29%. A dose of 1g was as effective as a dose of 6g.



Decreases in total cholesterol levels ranged from 12 to 26%. A dose of 1g was as effective as a dose of 3g or 6g.



Decreases in triglyceride levels ranged from 23 to 30%. A dose of 1g was as effective as a dose of 3g.



**Data Source:** Khan A, Safdar M, Ali Khan MM, Khattak KN and Anderson RA. Cinnamon

Improves Glucose and Lipids of People with type 2 Diabetes.  
Diabetes Care December 2003;26(12):3215-3218.  
Table 1, 2 and 3.

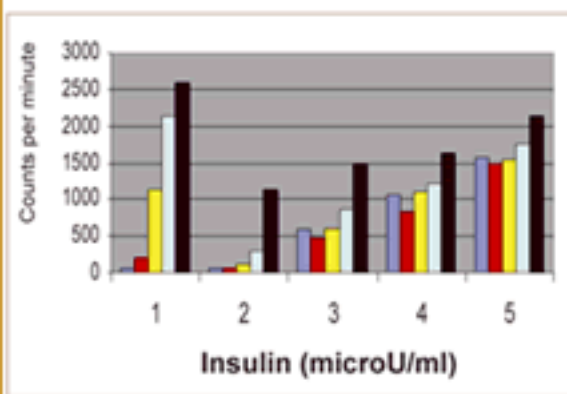
### 3. Insulin-like and antioxidant activity of polyphenol polymers in aqueous extracts of Cortex Cinnamomi (cinnamon)

A study by Anderson RA et al.(1) isolated the insulin-enhancing and antioxidant complexes from aqueous extracts of commercial Cortex Cinnamomi, including that found in Diabecinn™. The strong insulin-enhancing biological activity and potent antioxidant activity was shown to be unique to the **polyphenol polymers** contained in the aqueous extractions.

There was no significant difference in the insulin-enhancing and antioxidant activity between classes.

*The study demonstrates that water-soluble polymeric compounds isolated from Cortex Cinnamomi have insulin-enhancing biological activity (Figure 1) and also function as antioxidants (Figure 2) in vitro, in rat adipocytes.*

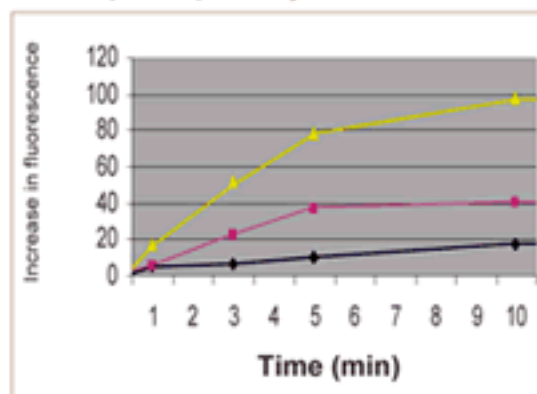
Figure 1: Effects of extract on insulin activity



- 1- No insulin added  
2- 2mcU/ml insulin added  
3- 12 mcU/ml insulin added  
4- 25 mcU/ml insulin added  
5- 500 mcU/ml added
- control with no extract.  
● extract 1:20.  
● extract 1:10.  
● extract 1:5.  
● extract 1:2.

When no insulin was added (control), there was still a maximal amount of insulin-dependent activity at the highest level of Cortex Cinnamomi tested.

Figure 2: Inhibition of production of reactive oxygen species in platelets by extract.



- control.  
● extract eluting at 14min.  
● extract eluting at 19 min.

Higher fluorescence depicts a higher production of oxidative signals in activated platelets in whole blood samples.

## ■ References

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2. Straughan JL. Cinnamon – not just a snappy flavourant, but a spice for life. *SAJNM* **2004**;13:54.
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4. Khan A, Safdar M, Ali Khan MM, Khattak KN and Anderson RA. Cinnamon improves Glucose and Lipids of People with Type 2 Diabetes. *Diabetes Care* December **2003**;26(12):3215-3218.
5. Karalee J. Jarvill-Taylor, Rricher A, Anderson A and Graves DJ. A Hydroxychalcone Derived from Cinnamon Functions as a Mimetic for Insulin in 3T3-L1 Adipocytes. *Journal of the American College of Nutrition*, **2001**;20(4):327-336.
6. Mang B et. al. Effects of cinnamon extract on plasma glucose, HbA1c and serum lipids in diabetes mellitus type 2. *European Journal of Clinical Investigation*, **2006**;36:340-344.

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***The balance is in your hands***