

Phytofare® catechin complex providing inhibiting benefits with metabolic syndrome conditions of obesity, type-2 diabetes and cardiovascular risk (MetS)

Metabolic syndrome (MetS) is a cluster of several cardiometabolic health risk factors including hyperglycaemia, dyslipidaemia and elevated blood pressure, wherein abdominal obesity and insulin diabetes resistance are the core parameters of this cluster (*Eckel et al., 2005*)

Currently the South African government and healthcare providers are faced with an enormous health burden, which is evaluated according to the economic impact through the increasing prevalence of obese and ageing population. Furthermore it is widely understood that physical inactivity and imbalanced diets contribute significantly to the global emergence of obesity and diabetes. At the same time, there is an urgent need for the population to implement lifestyle changes including weight reduction, increased physical activity and dietary modification

Pharmaceutical drugs will continue to play a role in the treatment of MetS as the industry has recognized the huge commercial potential. However, the solutions to these chronic health issues lies in evoking changes in the individual lifestyle which is relevant for prevention and early management of MetS. Continued poor lifestyle and unhealthy diets are a major factor behind this increase, manifesting in a cluster of chronic conditions that include increased blood pressure, Type 2 diabetes, excess body fat around the waist and abnormal cholesterol (low HDL cholesterol) and high blood fat levels (triglyceride).

In South Africa, over 10% (5.8 million) of adults aged between 20-79 years have diabetes and it is now known that up to 80% of all diabetes goes undiagnosed in Africa. Moreover, it is getting worse. In 2000, diabetes was estimated to directly affect 171 million people worldwide and to account for at least 3.2 million deaths. In 2007, the International Diabetes Federation predicted that by 2025, some 380 million people would have diabetes, with approximately 70% living in low and middle-income countries. By 2015, the IDF revised this estimate and its data reveals that more than 382 million people already have diabetes.

Assessing risk

How do you know if you are at risk of developing diabetes? Males with a waist circumference greater than 102 cm have a 22 times greater risk of developing diabetes, while women with a waist circumference greater than 89 cm are 32 times more likely to develop diabetes.

Other risk factors include increasing age, a family history of diabetes, a sedentary lifestyle, hypertension, impaired glucose tolerance and especially ethnicity. However, increasing exercise and improved diet has been shown to reduce the risk of developing Type 2 diabetes in people in high-risk groups. High carbohydrate diets are a well-known contributing factor to increased insulin resistance, which in turn is associated with obesity and Type 2 diabetes."

Insulin resistance means that cells have lost some of their sensitivity to the hormone insulin. Insulin is secreted by the pancreas in response to a rise in blood sugar (glucose), which comes mainly from starch, sugar and other refined carbohydrates. Bread, pasta, biscuits, cakes, breakfast cereals, sweets and chocolate, sugar sweetened beverages, fruit juice as well as the overconsumption of some fruits and vegetables are just some of products that drive higher insulin levels.

Re-establishing an insulin balance is key in terms of managing and preventing diabetes, and restricting the amount of carbohydrates in the diet is one of the most effective interventions for reducing all of the features of metabolic syndrome.

However, it's important to note that approximately 90% of all Type 2 diabetes can be prevented by modifying lifestyle and adopting an appropriate 'food as medicine' approach". Prevention, rather than treatment, is the most cost-effective way of addressing this very serious chronic disease, and with the benefits of significant health promoting foods and plants including the benefits of green tea catechins ([Balentine et al., 1997](#)).

The biological mechanisms of green tea catechins in the area of MetS have been positively researched demonstrating several pathways that inhibit MetS (Kao et al 2006; Wolfram et al., 2006); but the limitations to producing an affordable solution has been met with the challenges of bioavailability including the barriers of dosage, solubility, permeability, metabolism, excretion, target uptake and disposition (*Ming Hu et al., Molecular Pharmaceuticals Volume 4 -6*)

Phytofare® catechin complex commercially produced from live green tea leaf at the Senteeko tea estate, South Africa, is a clinically proven biopharmaceutical complex that contains all eight known catechins. The formulation is supported by clinical studies undertaken by NW University Pharmacology 2015 that has addressed in oral and topical formulations the previous bioavailability barriers of dosage, solubility, permeability, metabolism, excretion, target uptake and disposition. Formulated in Pheroid®, (an Omega 3/6 delivery system, developed by NW University and Department of Trade and Industry and licensed to Plandai) Phytofare® catechins are delivered protected to the blood plasma and with increased efficacy.

Phytofare® catechin complex formulated in Pheroid (pH2catechins™ and produced by Capsugel, France on behalf of Plandai is now commercially available in South Africa through the brand Origine 8™ (refer to attached document)

Proposal

Our approach to doing business with you is very simple.

- 1 Plandai sells the license of pH2 catechins™ orals to SA Investment group for distribution to the SADC countries addressing the health factors of metabolic syndrome
- 2 Plandai produces the finished pH2Capsules®
- 3 Plandai undertakes with NW University and University of Mauritius a clinical study for metabolic syndrome, especially diabetes 2 which will form part of the license agreement. Investigation to commence October 2016, with results and product launch second quarter 2017.
- 4 The investment group sell the product at an affordable price to the population through distribution agreements with the government