

Pomi-T® (Product information)



A natural anti-oxidant / polyphenol rich super-food boost

Pomi-T® contains a broad range of healthy plant based polyphenols and antioxidants found naturally within four super foods. The whole foods have been dried, concentrated then squeezed into a tablet for a convenient way to boost daily intake. The rationale for combining different food types (berry, vegetable, spice and leaf) was to provide a wide spectrum of polyphenol nutrients, whilst at the same time avoiding over-consumption of one particular type. The unique combination of ingredients was selected following a comprehensive review of published scientific trials by experts in oncology and lifestyle research. It is the only food supplement which is undergoing a UK government approved scientific evaluation in a randomised double blind study. Each supplement tablets contains:



Active ingredients: Broccoli Powder 100mg
 Turmeric Powder 100mg
 Pomegranate seed powder 100mg
 Green Tea 5:1 extract 20mg equivalent to 100mg

Bulking and caking agents: Di Calcium Phosphate Magnesium Stearate

Recommended intake: Pomi-T® is designed to be taken as part of a healthy balanced diet. Daily dosage depends on the other food intake for that day. For example, a day with a good diet including plenty of dark green vegetables, berries, fruit and teas would only require one tablet day, whereas, on an average day then 2-3 would be better. Men within the Pomi-T trial took 2- 3 tablets a day.

Contact information: Pomi-T® is manufactured in the UK, from natural ingredients, to nationally approved assurance standards and EU compliance regulations. Pomi-T® is owned by *nature*Medical Products, Level 1, 3 Esplanade Avenue, Porthcawl, CF36 3YS. Website: www.pomi-t.com | Email: support@pomi-t.com

What are antioxidants and plant polyphenols?

Polyphenols are natural plant based chemicals found in healthy foods which enhance our health and protect us from illnesses. Their anti-oxidant properties protect us from environmental and ingested chemicals which damage our DNA via a process called oxidation. Many studies have linked anti-oxidant rich foods with a lower risk of cancer, and other chronic illnesses such as high cholesterol, dementia, arthritis, skin aging and macular degeneration (blindness). These studies, particularly those related to the ingredients of Pomi-T® (Pomegranate seed, green tea, turmeric and broccoli) are summarised in this document and even more detailed information can be found on our website (www.pomi-t.com).

Scientific evaluation of Pomi-T®

Pomi-T® is currently being investigated in a UK Government approved national scientific study which has the highest possible scientific design - A double blind, randomised (RCT) placebo controlled trial. The study is sponsored by the charity Prostate Action, has been adopted by the National Cancer Research Network, has UK Ethics Committee certification and is independently audited to ensure adherence to European Good Clinical Practice Guidelines (GCP). The chief investigator Professor Robert Thomas is Chair of McMillan Survivorship Expert Advisory Committee; is a consultant Oncologist at Bedford, Cranfield and Cambridge University Hospitals and is an editorial member of the UK's Department of Health complementary therapies and survivorship research advisory boards. The trial is currently the world's largest RCT of a food supplement to date and the full results will be available in early 2013. The trial asks whether, firstly, Pomi-T® benefits men with prostate cancer on active surveillance, or have a PSA relapse after radical treatments and secondly, helps cholesterol, blood sugar and blood pressure.



Future trials are planned aiming to evaluate its role in other stages of prostate cancer including Prostate Intraepithelial Neoplasm, other cancers, other medical conditions to improve cognitive function, eye sight and skin tone. In the mean time, we have summarised below some of the existing evidence for the individual ingredients of Pomi-T®:



Pomegranate fruit originating from the tree *Punica granatum* has long been thought to possess general health and anti-cancer properties via its high concentration of polyphenols and anti-oxidants, particularly ellagic acid. Laboratory studies show it inhibits cell growth and induces apoptosis in androgen sensitive human prostate cancer cells and implanted animal models [Retitig 2008]. In humans, in a phase II study, the PSA doubling time (PSAdt) prolonged from 15 to 54 months in men with PSA relapse given 200ml pomegranate juice a day. The serum baseline oxidative state also significantly lowered after consumption [Pantuck 2006]. This was supported by a study from Johns Hopkins which gave men pomegranate seed extract for 6 months. The PSAdt extended from 12 to 19 months and androgen levels in men did not change [Carducci 2011]. A further study using high performance liquid chromatography confirmed no steroid androgens or estrogens within pomegranates [Choi 2006]. A small study from Edinburgh gave volunteers pomegranate juice daily for 2 weeks. There was a reduction in blood pressure, elevation in mood and lowering of anxiety but they also found that salivary testosterone levels increased [Al-Dujaili 2012]. No explanation was given but as pomegranate has no direct androgen activities this is likely to reflect a general improvement in the metabolism and a reduction in stress, which is associated with higher salivary testosterone [Hellhammer 1985].



Both the green and black tea we've been drinking for several hundreds of years come from the same plant, *Camelia Sinensis*. When dried, black tea is fermented, whereas green tea is left unfermented so is thought to be a better, source of natural polyphenols such as epigallocatechin gallate (EGCG) which blocks an enzyme, ornithine decarboxylase, which tells cells to proliferate faster and bypass apoptosis [Yang 2002]. Green tea also blocks the effect of harmful estrogens which explains why a study in humans, regular tea drinkers had a 40% reduction in breast, prostate and ovarian cancer risk [Wu 2006, Ogunleye 2010]. A large combined analysis of several studies encompassing 5,617 cases of breast cancer showed that regular green tea consumption was associated with a lower risk of breast cancer recurrence [Ogunleye 2010]. Research from Shanghai showed it lowered the risk of oesophageal cancer particularly benefit among smokers and alcoholics [Sun 2007]. The Mayo Clinic found that green tea decreased the

abnormal white cell count in 30% of patients with chronic leukaemia. A study from Louisiana University reported a significant reduction in the levels of several growth factors that promote cancer as well as a reduction in PSA among participants [Shanafelt TD et al 2009].

As well as cancer, the polyphenols in green tea have also been shown to protect against heart disease by preventing the oxidation of LDL into cholesterol. Researchers from the University of Pennsylvania and Boston have also shown that EGCG helps protect the brain from the build up of amyloid proteins which could lead to Parkinson's and Alzheimer's, [Rezai-Zadeh 2008]. Researches from the American College of Nutrition found that regular consumption may also prevent colds and flu, to improve skin tone, smooth out wrinkles and even to help you slim. EGCG is also known to help good bacteria in the intestine to flourish, aiding recovery after antibiotics or chemotherapy [Maclarty 2009].



Broccoli contains anti-oxidant phytochemicals such as isothiocyanate (ITCs) and its metabolite sulforaphane which have been found to inhibit growth and promote apoptosis of prostate cancer cells [Sarkar 2004]. Biologists at Britain's Institute of Food Research showed that the healthy chemicals found in broccoli can prevent pre-cancerous cells in the prostate progressing to more aggressive cancers. They found that broccoli sparks hundreds of genetic changes, activating genes that fight cancer and switching off others that fuel them [Moysich 2007]. A further 4 of 8 eight observational studies have suggested

cruciferous vegetables, may decrease risk of cancer and reduce the risk of cancer progressing to more aggressive types by induction of the anti-oxidant enzymes glutathione S-transferases which explains why broccoli is particularly beneficial in the 50% of the population carrying a mutated glutathione gene [Joseph 2004]. Another study from Queensland, Australia, reported a lower rate of new skin cancers among individuals who had been previously treated for skin cancer if they had higher intake of broccoli and leafy green vegetables [Heinen 2007].



Laboratory and clinical studies have unveiled several benefits of curcumin, which gives turmeric its yellow colour. Turmeric slows prostate cancer cell growth by blocking the cell cycle, increasing the rate of apoptosis, preventing the invasion and migration of cells [Somasundaram 2002]. Research conducted at the University of Michigan found that turmeric helped halt the growth of stem cells that give rise to breast cancer without harming normal breast cells. This effect was further enhanced when turmeric was combined with piperine the main anti-oxidant

found in black pepper and ginger according to a team from Columbia University. Researchers from Leicester University postulated that the antioxidants found in curcumin and other spices could be responsible for the low levels of colon cancer in the Asian community [Steward 2008].

Safety information

The individual foods within Pomi-T® are known to be safe if concentrated. An interim analysis of the Pomi-T study showed that 4-6% of men had loosening of the bowels, 2% mild nausea and indigestion. The full results will be available in February 2013. Considerations for the individual ingredients are summarised:

Pomegranate, like many fruit juices, is a weak inhibitor of cytochrome P450 (CYP2C9). There is, therefore, a small potential risk of reducing the metabolism, and thereby increasing serum levels, of warfarin and anti-hypertensives such as captopril, ramipril or anti-consulants such a carbimazole (for more details see; www.rxlist.com). Individuals on warfarin or these blood pressure tablets are not excluded from taking Pomi-t and no adverse changes in blood pressure or INR were reported in the Pomi-T study but it may be advisable repeat a blood pressure and an INR test within two weeks of starting.

Tea Millions of people consume tea daily with no adverse effects. Green tea can cause discolouration of the teeth - this should not be a problem with unless Pomi-T is chewed. In very high doses, patients who

took 6 kg/day, experienced mild to moderate nausea, vomiting, abdominal pain, diarrhoea, agitation, restlessness, insomnia and tremors [Jatoi 2003, Pisters 2001].

Broccoli Very high intakes of cruciferous vegetables, have been found to slightly reduce thyroid activity in animals (Fenwick et al 1983). There has been one case of an elderly woman developing hypothyroidism following consumption of over 1.0 kg/day of raw pak choy for several months [Chu M et al 2010].

Curcumin (Turmeric) is recognised as safe by the FDA as a food additive. Adverse effects have not been reported in humans even taking 8 g/day [Chung 2001]. Curcumin mildly inhibits platelet aggregation in animal studies suggesting a potential to increase the risk of bleeding in people taking anti-platelet medication [Shah 1999] but no reports have been found in humans including those in the Pomi-T study.

Finally, there are cell line data to suggest that anti-oxidants can potentially reduce the action of chemotherapy although this has not been substantiated in humans [Somasundaram 2002]. In view of this potential interaction, taking regular Pomi-T® during chemotherapy is best avoided. There is no evidence that turmeric, broccoli, pomegranate or green tea adversely affects pregnancy, although the safety of these supplements in pregnancy and lactation has not been established.

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