FLORA ProActiv® PROFESSIONAL

ProActiv

with plant sterols

CLINICALLY PROVEN TO ACTIVELY LOWER CHOLESTEROL

Small changes *can* make a difference

Information for healthcare professionals

Foreword

Dear reader,

Cardiovascular disease (CVD) including coronary heart disease (CHD) and stroke, is the leading cause of morbidity and mortality globally. Lowering blood LDL-cholesterol is a key factor in reducing the risk of developing CVD.

There are many diet and lifestyle changes that may help reduce elevated LDL-cholesterol. Dietary recommendations highlight the need to lower blood cholesterol and the important role that diet and lifestyle change must play. They include recommendations for the use of specific foods with cholesterol-lowering benefits such as plant sterols. These additional options can enhance the effectiveness of a typical healthy diet low in saturated fat and controlled in energy intake[1,2].

Flora ProActiv foods contain plant sterols and in many human studies it has been shown that plant sterols significantly lower total and LDL-cholesterol.

This brochure contains information on plant sterols and Flora ProActiv for healthcare professionals. It is divided into three tabbed sections, to offer an easy-to-use reference tool, for optimal benefit to your day-to-day practice.

We hope you enjoy using this brochure as both an informative guide and a practical reference tool.

Kind regards,

The Flora ProActiv team

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FOR MORE INFORMATION AND PATIENT RESOURCES VISIT:
WWW.FLORAPROACTIV.CO.UK/HEALTHCAREPROFESSIONALS

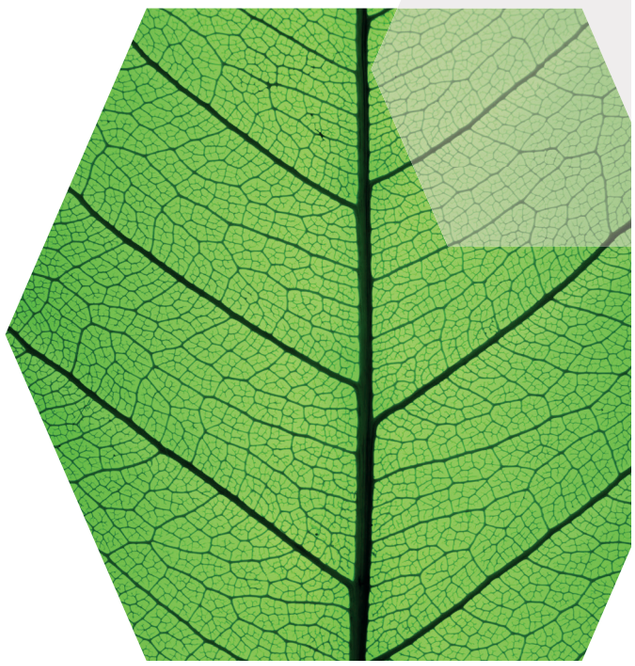
1 The benefits of plant sterols

The global burden of cardiovascular disease

- Cardiovascular disease (CVD), including coronary heart disease (CHD) and stroke, is the leading cause of morbidity and mortality globally[3]
- Elevated LDL-cholesterol is a key modifiable risk factor in the development of CVD[4,5]
- According to the World Health Organization (WHO), 80% of premature CHD and stroke could be prevented by positive lifestyle changes such as eating a healthy diet, regular exercise and abstinence from smoking[6]

Diet and lifestyle play a key role in reducing risk of CVD

- Diet and lifestyle play an important role in lowering LDL-cholesterol and preventing CVD risk[3]
- **Dietary changes that are well-known to lower LDL-cholesterol levels include:**
  - reducing the intake of saturated fatty acids (SAFA)[7];
  - keeping intakes of trans fatty acids (TFA) to a minimum[7];
  - replacing them with omega-6 and omega-3 polyunsaturated fatty acids (PUFA)[7];
  - increasing intake of viscous dietary fibres (for example, from oats or barley)[8];
  - and including plant sterols into the daily diet[9]
- Evidence demonstrates that following a low-fat diet alone does not reduce CHD risk. However, replacing saturated fatty acids (SAFA) in the diet with omega-6 and omega-3 polyunsaturated fatty acids (PUFA) does reduce CHD risk[10,11,12]



The role of plant sterols – small changes CAN make a difference

- Plant sterols have been shown to reduce blood cholesterol[9], a risk factor in the development of coronary heart disease*
- A very effective way to reduce cholesterol with a dietary change is to include 1.5-3g plant sterols into the daily diet, whereby intakes of:
  - 1.5-2.4g plant sterols daily can lower (LDL-)cholesterol by 7 to 10%[13,14]

  in 2-3 weeks as part of a healthy diet and lifestyle including plenty of fruit and vegetables
- Research also demonstrates that plant sterols have a modest triglyceride-lowering effect[17]

Consider recommending plant sterols alongside other diet and lifestyle changes in the following patients**:

- ✓ Patients with **elevated blood cholesterol levels**
- ✓ Patients on **lipid-lowering medications** such as **statins**
- ✓ Patients with **type II diabetes**
- ✓ Patients with **familial hypercholesterolaemia (FH)**

* High cholesterol is a risk factor in the development of coronary heart disease. As coronary heart disease has multiple risk factors, more than one may need to be improved to reduce overall risk of it.

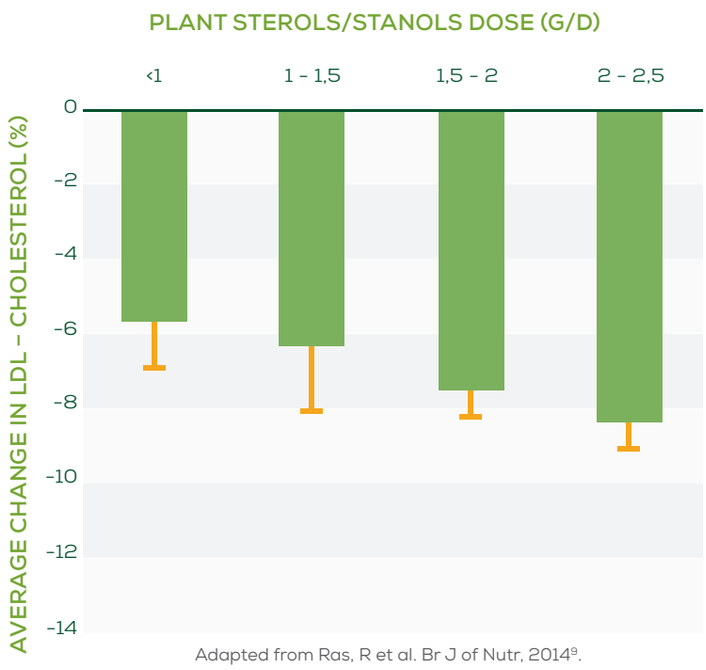
** Foods with added plant sterols should not be consumed by people that do not need to control blood cholesterol levels, children under 5, pregnant or breast-feeding women. People who are already taking cholesterol lowering medication should always consult their doctor before starting a regime involving the consumption of products containing plant sterols.

Proven efficacy

For patients who want to actively lower elevated cholesterol levels

1 Plant sterols significantly reduce LDL-cholesterol concentrations in a dose-dependent manner (P<0·001)[9]

- Plant sterols and plant stanols have a similar dose-dependent cholesterol-lowering effect, which continues to increase to an average effect of 12% LDL-concentration reduction for intakes of up to approximately 3g/day[9]



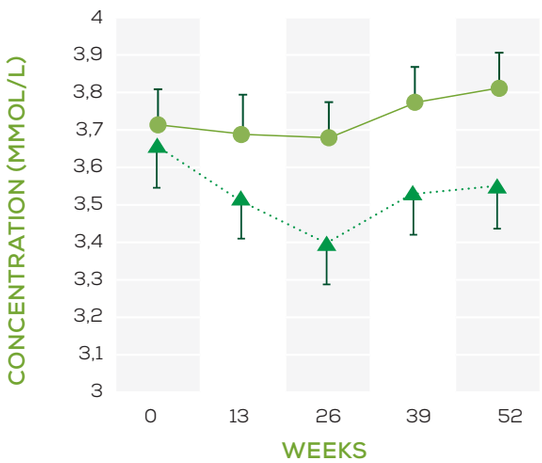
Adapted from Ras, R et al. Br J of Nutr, 2014[9].

Average effects on LDL-cholesterol concentration for different dose ranges of phytosterols (PS) up to 4g/d.

Results from 124 human studies with a total of 201 study arms. In 116 study arms, a parallel design was used whereas in eighty-five study arms, a cross-over design was used. Plant sterols and stanols were administered in 129 and fifty-nine study arms, respectively; in the remaining thirteen study arms, a mix of plant sterols and stanols was administered. The number of subjects per study arm was, on average, 48 (range 7–201). The average dose was 2.1 (range 0.2 to 9.0) g/d.

Only a limited amount of study arms investigated doses exceeding 4g/d (3 studies with 5 study arms [strata]). Furthermore, these studies were scattered across a wide range of phytosterols (PS) doses (5.8-9.0g/d). Pooling these studies into a single category was judged to be inappropriate and they have therefore been omitted from graphical representation.

2 Plant sterols demonstrate a sustained cholesterol-lowering effect[18]

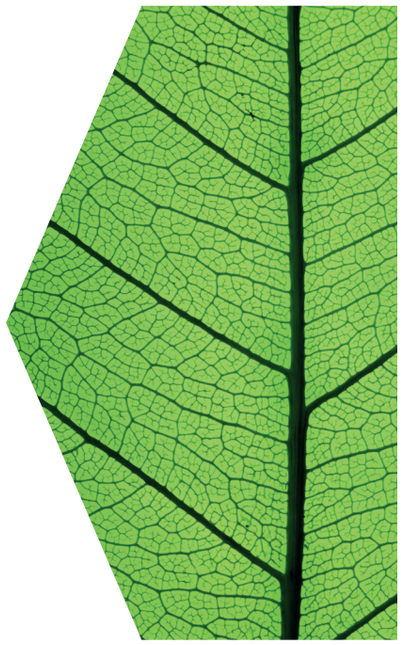


Adapted from Hendriks, H et al. European Journal of Nutrition, 2014[18].

Randomized, double blind placebo controlled parallel trial in 185 healthy volunteers consuming 20g daily of a control spread vs a spread with 1.6g added plant sterols for one year.

LDL-cholesterol control spread

LDL-cholesterol plant sterol spread



- In normo- and hypercholesterolaemic patients, consumption of a spread with added plant sterols demonstrated a sustained LDL-cholesterol lowering effect during a 1 year period by an average 6% vs. control ($p<0.05$)[18]

3 Plant sterols demonstrate effectiveness in a community setting[19]

- A follow up study from 1998 to 2003, demonstrated that total serum cholesterol concentration was reduced by[19]:

  -29% in combination users (using margarine with added plant sterols/stanols and cholesterol-lowering drugs);

  -17% in the cholesterol-lowering drug users;

  -4% in the margarine with added plant sterol/stanol users;

  +2% in the non-users of margarine with added plant sterols/stanols or drugs

- Average spread consumption in this study was 14g/day[19], equivalent to 1.3g plant sterols/stanols daily (below the recommended 2g daily)

The study population consisted of 2,379 subjects that participated in a community intervention study ('Hartslag Limburg') aged 28–76 years. In 1998 and 2003, blood samples for total and high-density lipoprotein (HDL) cholesterol were obtained. A general questionnaire and food frequency questionnaire (FFQ) were administered. From 1999 onwards, margarines with added plant sterols / stanols were introduced on the Dutch market. On the basis of 2003 data, subjects were classified in users of (a) margarine with added plant sterols/stanols, (b) cholesterol-lowering drugs, (c) the combination (both margarine with added plant sterols/stanols and drugs) and (d) neither margarines with added plant sterols /stanols, nor cholesterol-lowering drugs.

Key findings are presented here, but for a full description of all studies and outcomes please refer to **The detail is in the science** section or visit: **www.floraproactiv.co.uk/healthcareprofessionals**

CLINICALLY PROVEN PLANT STEROLS

FLORA PROACTIV FOODS CONTAIN PLANT STEROLS. OVER 50 CLINICAL STUDIES HAVE PROVEN THAT PLANT STEROLS IN PROACTIV ACTIVELY LOWER CHOLESTEROL*

* High cholesterol is a risk factor in the development of coronary heart disease. As coronary heart disease has multiple risk factors, more than one may need to be improved to reduce overall risk of it.

Proven efficacy in different patient groups*

The EAS consensus panel recommends that food with added plant sterols/stanols may be considered:

1. for patients with high cholesterol levels at intermediate or low global cardiovascular risk who do not qualify for pharmacotherapy;
2. as an adjunct to pharmacologic therapy in high and very high risk patients who fail to achieve LDL-C targets on statins or are statin-intolerant;
3. and in adults and children (>6 years) with familial hypercholesterolaemia, in line with current guidance.

Adapted from Gylling, H et al. Atherosclerosis, 2014[20].

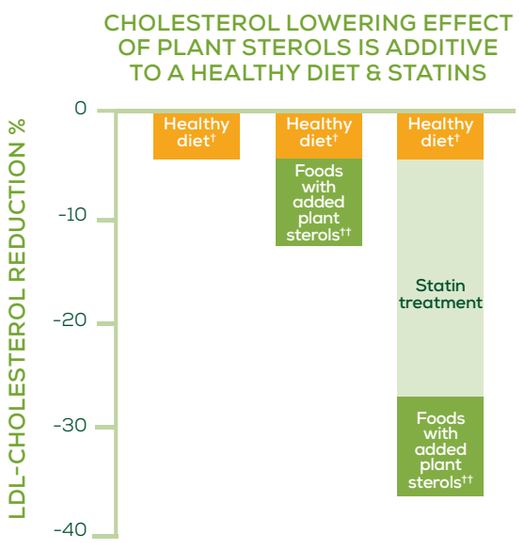
Efficacy for people with type II diabetes and familial hypercholesterolaemia (FH)

- It has been shown that plant sterols lower LDL-cholesterol levels in people with type II diabetes[21] and in people with FH[22]

* Foods with added plant sterols should not be consumed by people that do not need to control blood cholesterol levels, children under 5, pregnant or breast-feeding women. People who are already taking cholesterol lowering medication should always consult their doctor before starting a regime involving the consumption of products containing plant sterols.

Efficacy for patients on statin therapy

- Clinical evidence shows that eating foods with added plant sterols, in combination with statins, can have a greater cholesterol lowering effect than statins alone[23]
- A combination of statins, plant sterols and diet and lifestyle changes can work together to help patients achieve targets for cholesterol reduction.
  - Statins reduce LDL-cholesterol levels by an average of 25%[24]
  - Moving to a healthy diet and lifestyle can lower cholesterol by 5%[25]; and
  - Including a spread with added plant sterols can help lower it by a further 7-10%** [26,27,28]



† Low in saturated fat and cholesterol
†† 2-3g/day of plant sterols consumed from foods with added plant sterols

Graph adapted from Edwards, J and Moore, R. BMC Family Practice, 2003[24]; Cleghorn, C *et al.* European Journal of Clinical Nutrition, 2003[25]; Chen, S *et al.* Lipids, 2009[26]; Jones, P *et al.* American Journal of Clinical Nutrition, 1999[27]; Katan, M *et al.*. Mayo Clinic Proceedings, 2003[28].

- This combination of statins and plant sterols can lead to a greater reduction in cholesterol levels than doubling the statin dose which has been shown to achieve a 7% further reduction of LDL-cholesterol[34]

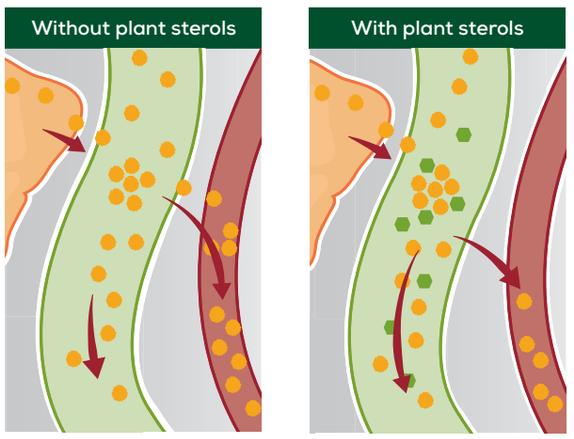
CLINICALLY PROVEN PLANT STEROLS

THE PLANT STEROLS IN FLORA PROACTIV ARE CLINICALLY PROVEN TO ACTIVELY LOWER CHOLESTEROL**

** Flora ProActiv contains plant sterols. A daily intake of 1.5-2.4g plant sterols can lower cholesterol by 7-10% in 2-3 weeks as a part of a healthy diet and lifestyle with sufficient fruit and vegetables.High cholesterol is a risk factor in the development of coronary heart disease. As coronary heart disease has multiple risk factors, more than one may need to be improved to reduce overall risk of it.

Plant sterols – mode of action

- The plant sterols used in ProActiv products are obtained from plant sources, and lower blood cholesterol by partially inhibiting absorption from the gut
- Cholesterol in the gut comes from two sources, dietary and biliary cholesterol. It mixes with bile salts, lecithin and triglycerides to form micelles
- It is thought that when plant sterols reach the gut they replace some of the cholesterol in the micelles[30,31]
- Micelles then deliver less cholesterol to enterocytes, the cells lining the gut wall, after which the cholesterol is released into the bloodstream



Plant sterols partially block the absorption of cholesterol from the gut, significantly lowering blood cholesterol levels

- The cholesterol that is not incorporated into the micelles escapes absorption and is excreted from the body along with >95% of the plant sterols (<5% of plant sterols are absorbed through the gut wall to the blood stream)
- Consuming 2g of plant sterols a day reduces the absorption of cholesterol by 30-40%[32]
- Research also demonstrates that plant sterols have a modest triglyceride-lowering effect, whereby intakes between 1.6-2.5g/d, lowered triglycerides by an average of 6%[17], although the triglyceride-lowering mechanism is not yet fully understood

Derived from natural sources

Plant sterols are naturally occurring substances that are found, in small amounts, in everyday plant-based foods like vegetable oils, nuts, seeds, grains, fruits and vegetables. Plant sterols have a chemical structure similar to that of cholesterol. Plant sterols partly block the uptake (absorption) of cholesterol from the gut. This results in a reduction in blood LDL-cholesterol.

The plant sterols used in ProActiv products are obtained from plant sources using a series of process steps to release them from their natural source. The plant sterols found in ProActiv originate from tall oil (derived from pine trees), and from vegetable oils such as rapeseed or soy bean. When these oils are prepared for food production, the volatile components, amongst which are plant sterols, are purified and then mixed with vegetable oils to form plant sterol esters that are added to ProActiv spreads. The plant sterol molecules themselves remain completely unaffected during this process, and therefore maintain their natural ability to lower cholesterol.

Plant sterols – safety

- Plant sterols are proven to be safe and have been approved for use in foods
- In 2000, Flora ProActiv was the first spread authorized under the European Union Novel Foods legislation. It has been approved as safe by independent authorities in The European Union, Norway, Switzerland, The United States, Canada, Australia, New Zealand, South Africa, Brazil, Israel, Iceland and Japan
- In 2004, the Flora ProActiv range was extended after the European Union authorised milk drink, yoghurt and 'one-a-day' yoghurt mini-drink with added plant sterols as Novel Foods
- Unilever's continuing post-launch monitoring programme confirms that Flora ProActiv is being consumed by the correct target group and there is no evidence of over-consumption or adverse health effects[33,34]

Plant sterols – recommended in international dietary guidelines

- Plant sterols are part of the dietary recommendations of many accredited international and national health organisations and authorities including **The International Atherosclerosis Society**[1] and the **European Society of Cardiology (ESC) / European Atherosclerosis Society (EAS)** guidelines[20, 35]

UK organisations advising on plant sterols use:

- Joint British Societies' Guidelines (JBS3)[39]
- British Heart Foundation (BHF)[40]
- HeartUK[41]

EAS consensus recommendations:

Foods with added plant sterols/stanols in an amount **up to 2g/d** are effective in lowering plasma atherogenic LDL-cholesterol levels by up to 10%. Thus, plant sterols/stanols may be considered as an adjunct to diet and lifestyle approaches in subjects at all levels of CVD risk.

Adapted from Gylling, H et al. Atherosclerosis, 2014[20].

International Atherosclerosis Society recommendations to manage dyslipidaemia:

- Reduce saturated fatty acids to <7% of total energy, and trans fatty acids to 1% of total energy
- Replace excess of saturated fatty acids with monounsaturated/ polyunsaturated fatty acids or complex carbohydrates
- Consume fish rich in omega-3 fatty acids
- Eat foods low in sodium and high in potassium
- Reduce dietary cholesterol to <200mg/day
- Maintain a relatively high intake of fruits, vegetables, and fibre
- For individuals who choose to consume alcohol limit the intake by 2 servings per day for men and 1 serving per day for women
- Increase viscous fibre, if possible to 10-25g/day
- **Consider adding plant sterols/stanols (2g/day) to lower LDL-cholesterol**

The prime aim of lifestyle intervention is to reduce levels of atherogenic cholesterol. A secondary aim is to decrease other risk factors.

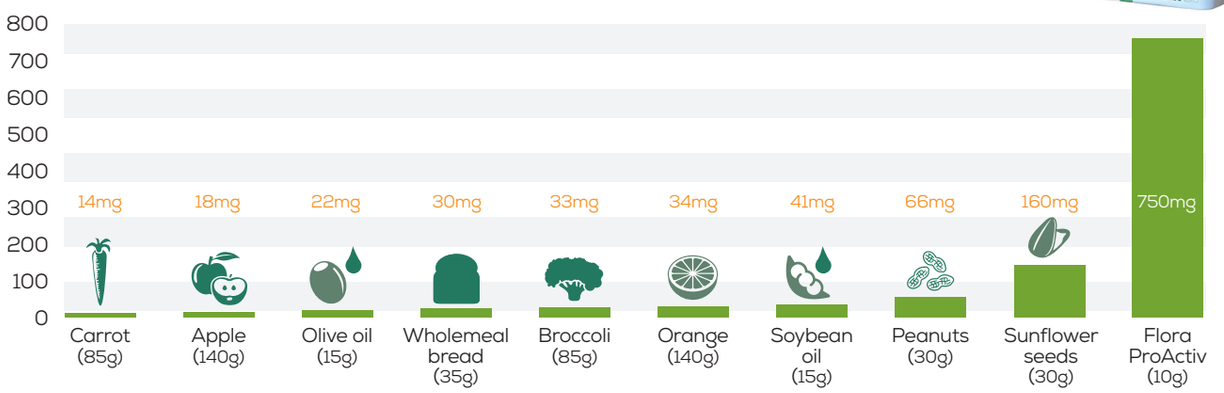
Adapted from IAS Position Paper: Global recommendations for the management of dyslipidemia, 2014[1].

Flora ProActiv – guidance for patients

Recommended dosing

- Plant sterols occur naturally in the diet in small amounts in plant-based foods like vegetable oils, nuts, seeds, grains, fruits and vegetables.[42] It is not possible to consume the recommended dose of 2g per day for cholesterol-lowering with such foods, as the average daily intake of plant sterols from these foods is around 0.3g per day[43,44]

PLANT STEROL CONTENT OF VARIOUS PLANT-BASED FOODS (MG/PORTION)



These regular foods also have other nutritional benefits and should be included in a healthy, balanced diet.

Graph adapted from Normen, L et al. Eur J Nutr, 1999[42]; Normen, L et al. J Food Comp Analysis, 2002[45]; Weihrauch, JL and Gardner, JM. J Am Diet Assoc, 1978[46].

- The recommended intake of plant sterols is around 2g daily, which can be achieved by:
  - either eating three servings from a combination of the Flora ProActiv spreads or milk drink
  - or with the 'one-a-day' yoghurt mini-drink (3 portions in one)

Reduce cholesterol with 2-4 servings*

1 serving =

2 teaspoons (10g)

or

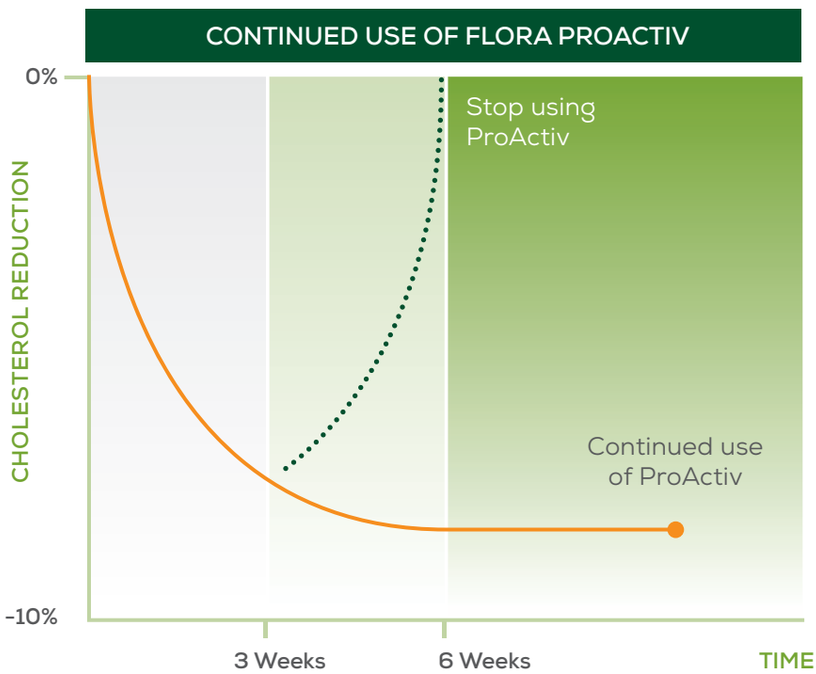
1 glass (250ml)

Recommended dose in one mini drink

ProActiv mini drink contains 2g of plant sterols

*This recommendation is solely based on reaching a daily intake of 1.5 to 3 g plant sterols.

- Consuming more than 3g plant sterols daily doesn't provide an additional cholesterol lowering benefit and is therefore not recommended



Each portion of Flora ProActiv contains plant sterols to actively lower cholesterol. To get the best effect, continued use of the recommended amount of Flora ProActiv everyday is required to keep the cholesterol level down.

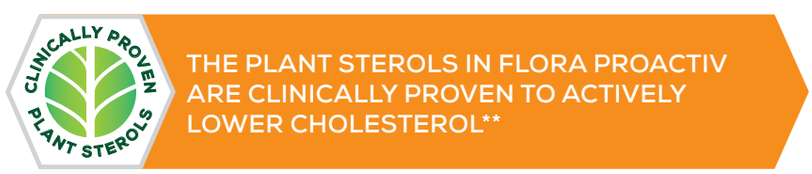
- For continued cholesterol-lowering effects it is recommended to advise patients to consume daily - if foods with added plant sterols are not consumed, the cholesterol-lowering effect is lost
- Foods with added plant sterols significantly lower cholesterol whether they are consumed once a day or frequently throughout the day[47]
- Flora ProActiv foods should be consumed with a main meal for best results[48,49]
- More generally, Flora ProActiv foods should be consumed as a part of a healthy diet and lifestyle with sufficient fruit and vegetables

Flora ProActiv – considerations for recommending

Consider recommending plant sterols alongside other diet and lifestyle changes for*:

- Patients with elevated blood cholesterol levels
- Patients on lipid-lowering medications such as statins
- Patients with type II diabetes
- Patients with familial hypercholesterolaemia (FH)

- We recognise the need for ongoing support for patients aiming to lower cholesterol through diet and lifestyle modifications
  - **Visit the next section 'Support materials for patients', which provides a comprehensive resource of the materials we have available to best support you to support patients**



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** Flora ProActiv contains plant sterols. A daily intake of 1.5 - 2.4g plant sterols can lower cholesterol in 2-3 weeks as a part of a healthy diet and lifestyle with sufficient fruit and vegetables. High cholesterol is a risk factor in the development of coronary heart disease. As coronary heart disease has multiple risk factors, more than one may need to be improved to reduce overall risk of it.

Ted, 70.
Lowered his cholesterol by 4.6 in 3 weeks

Help patients like Ted to be confident about lowering cholesterol:

- **ASK patients** how you can help them with cholesterol-lowering
- **RECOMMEND Flora ProActiv** alongside diet and lifestyle changes to lower cholesterol

Suitability for specific dietary needs*

Flora ProActiv suitable for:	Spreads (all variants)	Milk drink	'One-a-day' yoghurt mini-drink
Low fat diet	Yes (excluding buttery variant)	Yes	Yes
Ovo-lacto vegetarians	Yes	Yes	Yes
Vegans	No	No	No
Dairy/milk free	No	No	No
Coeliac/gluten free	Yes	Yes	Yes
Lactose intolerance	No	No	No
Nut free	Yes	Yes	Yes
Halal diet	No	No	No
Kosher diet	No	No	No

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2 Support materials for patients

Supporting you to best support your patients

- As part of our commitment to support patient behaviour change, we have a range of educational materials available to start intervention and provide inspiration in the journey towards lowering cholesterol
- This section covers advice and practical resources that you may want to share with your patients, to help them achieve their targets

Diet and lifestyle advice:

Key diet and lifestyle changes to lower LDL-cholesterol include:

- **Diet:** Encourage patients to always eat a healthy diet. In particular, reduce intake of saturated and trans fats and replace with monounsaturated and polyunsaturated fats, and increase foods high in fibre (see Table below)
- **Plant sterols:** Recommend that patients incorporate 1.5-3g plant sterols into their diet per day. Foods with added plant sterols – like Flora ProActiv can help to reduce cholesterol-levels
- **Weight and shape:** Encourage patients to maintain a healthy weight and body shape and avoid carrying too much fat around their middle

Dietary changes for a healthy heart:

Increase:	Exchange:		Limit:
Vegetables Pulses	Refined cereals	Wholegrain cereals	Processed meat Red meat
Fruits	Butter, Butter based-spreads	Vegetable oils, Vegetable oil based-spreads	Beverages and foods with added sugar
Fish and seafood	High-fat dairy	Low-fat dairy	Salt
Nuts and seeds			Alcohol

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OVER 50 CLINICAL STUDIES HAVE PROVEN THAT PLANT STEROLS IN PROACTIV ACTIVELY LOWER CHOLESTEROL*

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Practical support resources

Support materials:

There are a number of support materials available for you to use during consultations with your patients or for patients to be directed to independently.

Consultation support materials which come in a helpful tear-off pad format:

- **Lowering cholesterol factsheet:** A quick reference factsheet, offering practical advice and information to talk through with patients during their consultation. This includes a chart to record current and target cholesterol readings.Patients can take sheets away with them to retain key consultation points and be clear of their required targets.
- **Choosing the Right Fats for a Healthy Heart:** Provides visual information to help you explain good and bad fats to patients more easily.

VISIT WWW.FLORAPROACTIV.CO.UK/HEALTHCAREPROFESSIONALS FOR DOWNLOADABLE MATERIALS TO USE WITH, OR GIVE TO YOUR PATIENTS TO FACILITATE DIET AND LIFESTYLE CONVERSATIONS.

REFER YOUR PATIENTS TO THE PATIENT SUPPORT SECTION OF THE WEBSITE OR OUR FACEBOOK PAGE WWW.FACEBOOK.COM/FLORAPROACTIV/ FOR FURTHER SUPPORT AND MOTIVATION.

Additional patient support materials

- **Cholesterol Lowering Starter Kit:** Provides patients with all the facts, support and extra motivation they need to successfully lower cholesterol. Patients can receive a kit through registering on Flora ProActiv website. The kit includes:
  - **Cholesterol-lowering guide:** Guide on the dietary and lifestyle changes that patients can make to help reduce cholesterol levels, including how foods with added plant sterols can help
  - **Healthy recipes:** A range of healthy recipes to inspire patients in the kitchen and help them to lower cholesterol
  - **Money off vouchers for Flora ProActiv products:** Coupons for patients to use against purchase of any Flora ProActiv product
- **Cholesterol Lowering Starter Kit eBook:** Online interactive starter kit, providing patients all the facts, support and extra motivation they need to successfully lower their cholesterol, all at the simple click of a finger

TO ACCESS A RANGE OF FURTHER MATERIALS WHICH ARE ALSO AVAILABLE, INCLUDING FAT SWAP CHARTS, LAMINATES AND HEALTHY RECIPE CARDS, PLEASE VISIT: WWW.FLORAPROACTIV.CO.UK/HEALTHCAREPROFESSIONALS

3 The detail is in the science

Detailed evidence supporting the clinical benefits of plant sterols

- As a healthcare professional, we recognise your need to fully understand and be at the forefront of the data supporting the clinical benefits that plant sterols and Flora ProActiv products can offer to patients.

This section therefore provides:

- A comprehensive scientific review of the clinical studies commissioned by Unilever, for which products with added plant sterols were tested
- A plant sterol reference list of the studies that investigated the cholesterol-lowering efficacy of plant sterols, as well as publications of studies on effects beyond cholesterol-lowering, safety studies, mechanism-of-action studies and reviews

CLINICALLY PROVEN PLANT STEROLS

OVER 50 CLINICAL STUDIES HAVE PROVEN THAT PLANT STEROLS IN PROACTIV ACTIVELY LOWER CHOLESTEROL*

Clinical Summaries

1. Panel of Experts reconfirms the effective and safe use of plant sterols/ stanols in the management of dyslipidaemia. Gylling H, et al., Plant sterols and plant stanols in the management of dyslipidaemia and prevention of cardiovascular disease, Atherosclerosis (2013).
2. Study confirms the average intake of foods with added phytosterols is still below the recommended level to significantly lower blood cholesterol. Results from a Post-Launch Monitoring Survey on Consumer Purchases of Foods with Added Phytosterols in 5 European countries. Julie I. Willems, Mireille A.E. Blommaert, Elke A. Trautwein
3. LDL-cholesterol-lowering effect of plant sterols and stanols across different dose ranges: a meta-analysis of randomised controlled studies. Rouyanne T. Ras, Johanna M. Geleijnse and Elke A. Trautwein, British Journal of Nutrition, 2014

* Flora ProActiv contains plant sterols. A daily intake of 1.5 - 2.4g plant sterols can lower cholesterol in 2-3 weeks as a part of a healthy diet and lifestyle with sufficient fruit and vegetables. High cholesterol is a risk factor in the development of coronary heart disease. As coronary heart disease has multiple risk factors, more than one may need to be improved to reduce overall risk of it.