ProSure®
Therapeutic Nutrition
for People with Cancer

Frequently Asked Questions
2009
1. **Can ProSure be used by people who follow vegetarian diets?**

ProSure contains purified proteins (caseinate and whey) sourced from cow’s milk and the fatty acid EPA derived from fish oil. While a total vegan diet excludes all animal products, some vegetarians consume diets that include milk, eggs, and/or fish. Those vegetarians who strictly avoid cow’s milk and fish should be aware of the source of our ingredients.

2. **Why was iron removed in ProSure powder?**

Metals such as iron and copper can interact with the polyunsaturated fatty acids in fish oil to cause fishy or metallic taste. Having a great tasting product is important for compliance. The removal of iron significantly improves the sensory profile of the ProSure product.

3. **Can ProSure be used by people with liver cancer and with stomach cancer who have undergone surgical treatment?**

Yes, ProSure is being used successfully throughout the world by people with many types of cancer, including those who need surgical treatment. In fact, a recent report demonstrated benefits to consuming ProSure before and after surgery, including maintenance of lean body mass, less loss of weight, and lessening of inflammatory responses.

4. **In the study by Weed et al, why is the increase in LBM greater than the increase in total body weight?**

In almost all the studies we see the same thing. We think that with the increase in LBM, there is also improvement in physical activity and physical functioning as measured by EORTC QLQ C30, as in the study by Moses and colleagues. When patients increase activity, they use fat for energy and preserve the LBM; weight goes down.
5. Should recovering patients continue taking Prosure after treatment is finished?

ProSure is an excellent nutritional supplement. It provides high energy and all the essential nutrients that are particularly important for cancer patients to maintain or restore their nutritional status during recovery. ProSure is recommended during and after radio- chemo- or surgical therapy; it has been tested clinically in these situations and has shown benefits.

6. Can ProSure be used by people with liver cancer or who have cirrhosis?

Because the liver has important roles in basic metabolism, liver disease (including liver cancer and cirrhosis) is often associated with inflammation and malnutrition. A diet with high protein, high carbohydrate, and moderate fat is desirable for many people with liver disease. ProSure is protein and energy dense (300 kcal, 16g protein per 240ml serving). ProSure also contains EPA, which may be helpful for reducing inflammation. However, some individuals with advanced liver disease have reduced tolerance of protein. Nutritional supplements such as ProSure should be prescribed at the discretion of an expert clinician who considers the specific nutritional needs and limitations of the individual patient.

7. Can ProSure be used by people with kidney cancer who have kidney failure?

Nutrition for people with kidney failure involves nutrient adjustments according to individual needs. Protein needs vary from enough to maintain tissue integrity while avoiding damaging excess. ProSure (16g protein per 240ml serving) can be included in their diet, but the amount of protein a patient requires should be determined by the treating clinicians. Depending on the cause of renal failure, ProSure may be an excellent choice. Often times renal patients experience a pro-inflammatory state, and the EPA in ProSure could help reduce the inflammation.

8. What are the Osmolarity and RSL (Renal Solute Load) values for ProSure?

Such information is available in ProSure technical documents, but it is important to review content by specific list numbers.
9. In some studies of ProSure, EORTC-QLQ C30 is mentioned as a tool to measure quality of life for cancer patients. How can we conduct and measure EORTC-QLQ C30? What are the advantages of EORTC-QLQ C30 in comparison with the Karnofsky performance status scale?

The EORTC QLQ-C30 is a multidimensional, cancer-specific quality of life questionnaire developed by the European Organization for Research and Treatment of Cancer (EORTC) Study Group on Quality of Life for use in international clinical trial settings. The EORTC QLQ-C30 is a self-administered patient questionnaire that includes scales for function and symptoms, as well as a scale for global health/quality of life, and assessments of specific symptoms and perceived financial impact. To learn more about use of EORTC questionnaires, go to http://www.eortc.be/qol.

The Karnofsky performance status scale is a subjective assessment of patient function, which is done by a health care professional. The Karnofsky performance status is reported as a percentage between 0 (dead) and 100 (perfect health).
and describes the patient’s ability to work and carry out activities of daily living. Performance status is an important and revealing measure of outcome. Originally developed for assessment of patients with cancer, the Karnofsky scale has more recently been used for patients with AIDS and other debilitating conditions as well.

EORTC QLQ-C30 and the Karnofsky performance status are different types of measurements, but both measurements reveal information about the ability of the patient to function, which affects the patient’s quality of life. The main difference is that one is a self-administered patient questionnaire, and the other is a score assigned by a physician.

10. Does ProSure have any side effects?

ProSure is well tolerated. There was no difference in the number of side effects experienced by patients consuming ProSure and the control product in prospective, randomized, controlled trials. Patients with pancreatic cancer may need to be monitored for adjustment of pancreatic enzyme coverage. Patients consuming ProSure increase their total dietary intake from meals and may therefore need more pancreatic enzymes.

11. EPA helps attenuate some of the metabolic abnormalities associated with tumor-induced weight loss. Does EPA have any effect on the development of normal cells?

Phospholipids are important structural components of cell membranes; there is evidence that dietary EPA is incorporated into the membranes of normal cells such as red blood cells and immune system cells. There is no evidence that EPA affects development or function of normal cells, aside from its recognized benefit of lessening excessive inflammatory responses.

12. Can the nutrients in ProSure promote tumor growth?

Tumor cells prefer glucose as an energy source, but the carbohydrate content of ProSure does not appear to increase tumor growth. Cancer patients consuming ProSure do not have any higher levels of tumor markers or rates of mortality than do patients on usual diets.

On the other hand, there is absolutely no evidence that a low-carbohydrate diet can slow tumor growth. In fact, a diet low in carbohydrate predisposes the host’s
body to break down protein stores to amino acids for subsequent synthesis of glucose. This process is associated with muscle weakening, decreased strength, and lower activity levels.

13. **Experimental studies found elevated levels of vitamin B\textsubscript{12} in patients with different kinds of malignancy. Is it safe for cancer patients to use ProSure, which contains vitamin B\textsubscript{12}?**

Research studies have shown that cobalamin (vitamin B\textsubscript{12}) levels are elevated in oncology patients—the more severe the disease, the greater the elevation. However, laboratory studies have shown that vitamin B\textsubscript{12} can inhibit growth of malignant cells, and no evidence shows the opposite, i.e. stimulation of malignant cell growth by vitamin B\textsubscript{12}. It has therefore been suggested that this B\textsubscript{12} elevation may represent part of the host’s compensatory response to the growing malignancy.\(^6\)

Further studies are needed to explore the relationship between vitamin B\textsubscript{12} and tumor growth, particularly whether high levels of vitamin B\textsubscript{12} can provide any protective effects against proliferation of malignant cells. However, vitamin B\textsubscript{12} is essential for normal blood formation and for proper function of the nervous system and therefore necessary for human health.
14. How is blood sugar managed in cancer patients who use ProSure?

Elevation of blood sugar is a normal consequence of eating a regular meal (or consuming ProSure). Excessive or prolonged elevation of blood sugar after eating occurs in people with diabetes; for such individuals, blood sugar must be regulated by use of oral medications or insulin. Other individuals may experience a diabetes-like state of insulin resistance as a result of a tumor and the body’s response to its presence. This condition may be managed by eating multiple small meals and by consuming ProSure servings over an extended period of time. Blood glucose monitoring is the standard way to recognize abnormal blood glucose elevation. Elevated blood glucose should be managed while providing the energy and protein needed to maintain or gain weight in patients undergoing treatment for cancer.

15. How is ProSure different from standard oral supplement such as Ensure in cancer patients?

When patients were randomized to receive either ProSure or isocaloric, isonitrogenous control formula (such as Ensure) in clinical trials, the positive effects in weight gain, preservation of lean body mass, increase in physical activity and improved quality of life were only demonstrated in ProSure group, and not control. The high levels of protein, energy and efficacious dose of EPA in ProSure are believed to contribute to these clinical benefits.

16. Is there any pharmaco-economic data for cancer patients taking Prosure?

No, such data are not yet available.

17. Novartis Resource Support promotes the benefits of leucine, arginine and EPA. How do we counteract their claim? Is there any clinical evidence of leucine or arginine in cancer patients?

According to Novartis, the 2 amino acids leucine and arginine support synthesis of lean muscles, hence counterbalancing cachexia and cancer-associated weight
loss. However, the benefits of leucine is not yet conclusive since there are also reports that branched chain amino acids (BCAA)-enriched IV solutions provide no clear advantage compared to conventional IV nutrition in colorectal cancer patients (McNurlan et al. Clin Science 1994; 86:339-345).

Novartis claims that arginine supports the immune response and prevents the risks of complications after cancer patients had surgery. But not all cancer patients have surgery, so such benefits are not useful for all patients. Furthermore, if arginine stimulates the immune response, it may also strengthen the pro-inflammatory series of events that lead to cancer-related weight loss and cachexia. Two studies reported positive in vitro effects of arginine deprivation in tumor growth.\textsuperscript{9,10}

More conclusive research findings are necessary to demonstrate the clinical risks or benefits of leucine and arginine in cancer patients. There are no studies with Resource Support to document the claims.

18. What are the guidelines for use of ProSure in children aged 1 to 10 yrs?

Nutritional needs and practices are quite different in children compared to adults. ProSure is generally not appropriate for use in children under nine years of age. However, there may be specific situations where a clinician may decide that ProSure is appropriate for a child. The decision to use ProSure in pediatric patient should be based on assessment by a qualified health care professional.

The only ProSure study in pediatric patients is that of Bayram and colleagues.\textsuperscript{11} Young children (aged 7.5 ± 3 years of age) who had diagnosis of leukemia or solid tumors were given ProSure for approximately 3 to 6 months. Eighty percent of children had either gained weight or able to maintain body weight. ProSure has been shown to have a positive effect in body weight in these young children.
19. Does the EPA in ProSure affect the coagulation pathway?

There is no evidence that ProSure consumption alters the coagulation pathway. Testing diets with low ratios of omega-6 to omega-3 fatty acids (by increasing EPA intake) in elderly people showed that plasma triacylglycerol concentrations were lower, but hemostatic risk was neither increased nor decreased. There were no reports of excess bleeding in the head and neck or esophageal cancer surgery studies. Blood coagulation profiles were similar between groups in the esophageal cancer study.

20. What is the recommended daily dose of ProSure?

Two servings of ProSure per day are recommended, and ProSure can be taken as long as there is risk of weight loss or low body weight due to cancer cachexia. At this daily dosage, ProSure intake is associated with an increase in weight, lean body mass, physical activity and improvement in quality of life.

21. How long does a patient need to take ProSure before the desired level of EPA is reached?
How long do EPA levels remain high if the patients are non-compliant to ProSure consumption during periods of illness?

Plasma phospholipid EPA levels increased significantly over the first 3 weeks in patients fed ProSure, but not in control-fed patients. The increase in plasma phospholipid EPA was maintained throughout the 9-week study period when ProSure was given. There are no data on how long this effect is maintained after ProSure intake is discontinued.

In the study by Read et al, positive effects in body weight, lean body mass and nutrient intake were observed within 3 weeks. This effect was attributed to the EPA, high energy, and protein content in ProSure.
22. How does ProSure modulate the inflammatory response?

ProSure is fortified with EPA to decrease the production of pro-inflammatory cytokines and reduce the rate of resting energy expenditure. Clinical studies have demonstrated that ProSure is effective in increasing weight and lean body mass and improving quality of life in patients with cancer cachexia.\textsuperscript{7,8}

23. Can ProSure be administered during the active phases of treatment, i.e. chemo- and radiotherapy, or is just used in the palliative setting?

Yes. ProSure is being used successfully in patients undergoing chemotherapy and radiotherapy throughout the world. ProSure has been studied in cancer patients undergoing chemotherapy and radiotherapy,\textsuperscript{14} and pre- and post surgery.\textsuperscript{1} Favorable clinical findings were demonstrated in patients receiving ProSure while on treatments.

24. Can ProSure be used by people with diabetes?

Yes. ProSure can be included in the meal plan of patients with diabetes.
25. **What is the source of EPA for ProSure?**

   The source of EPA for ProSure is marine oil.

26. **How much EPA is required to achieve the beneficial dose?**

   An intake of 2g EPA (2 servings of ProSure) is associated with weight gain in patients experiencing cancer-induced weight loss.

27. **ProSure research has centered around the area of solid tumors, is their research showing the same benefits in patients with leukaemia (blood cancer)**

   Bayram et al evaluated the effects of ProSure in children with leukemia.\textsuperscript{11} Study results demonstrated an increase or maintenance in body weight in a majority of patients.

28. **How can we improve the taste of ProSure for the patient?**

   ProSure Powder was reformulated (removal of copper and iron) to improve the product taste. The availability of multiple flavors also helps reduce taste fatigue and improve compliance.

29. **Why does Prosure have a low amount of sucrose? A higher sucrose amount would improve the taste of Prosure.**

   Many cancer patients may have an aversion to sweetness. ProSure contains approximately 5g sucrose per 240ml serving. Taste testing of ProSure with patients experiencing cancer demonstrated their preference for mild, less sweet flavors.
30. Could Prosure EPA efficacy be counteracted by consumption of a diet high in saturated fatty acids?

The patients in clinical trials took normal food in addition to 2 servings of ProSure daily. The study results demonstrated improved body weight, lean body mass, and quality of life in the ProSure group, but not in control group. Patients with cancer-induced weight loss should be encouraged to eat anything that they prefer.
References


