



FAQ

Frequently Asked Questions

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1- Way of use of NeOpuntia®

NeOpuntia® must be taken **at the end of each meal**. It can be used in pills : 400mg, in tablets : 500mg , sachets – gels : 1500 mg or incorporated into food. The recommended dosage for optimal effect being 1.6g of NeOpuntia® per meal.

2- Recommended dosages

Standard recommended dosage for optimal effect regarding different studies is **1.6 g of NeOpuntia® per meal, that is 5 g a day**.

For particular formulations :

- Beverages : from 0.1 to 0.5% (solubility is around 50% in water)
- Chocolate : from 1 to 3%
- Bread or soft chews : from 8 to 10%

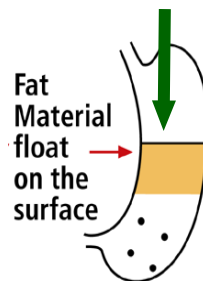
The maximum daily quantity of NeOpuntia®, eaten punctually, would be up to 10g, which corresponds to the standard serving of fresh plant per traditional meal.

These dosages are indicative only. We advise you to conduct your own trials in order to manage the best quality products.

3- Why taking NeOpuntia® AFTER the meal ?

Our advice is to take NeOpuntia® after the meal to optimise its activity. In the stomach the free fats have tendency to float on the surface of the food after the meal. When taken 30 minutes to 1 hour after a meal, NeOpuntia® has the best efficiency.

NeOpuntia® must be taken after the meal



Sketching according to researches conducted by BIO SERAE Laboratoires SA.

4- What kind of other ingredients can be combined with NeOpuntia®?

We recommend 1 to 2 g per meal of NeOpuntia®, which does not leave very much space for other ingredients in a tablet or a capsule form; the risk of a multi-formulation being that NeOpuntia® dosage would not be enough to be efficient.

Should you wish to combine NeOpuntia® with other ingredients, our advice would be as such :

- Avoid oily active ingredients (such as liquid CLA, oleoresin lycopene or vitamins), as the latest would fix with NeOpuntia®;
- Avoid multifunction formulas like Fat + Carb blocker. It would be better to market a product with one pill aiming at fats + one pill aiming at carbs, which must be taken separately.
- Try to combine NeOpuntia® with some detoxifiers and antioxidant (such as green tea, broccoli, rosemary)
- There are already some products available on the market with citrus aurantium or garcinia cambogia in order to add thermogenic effect.

BIO SERAE can supply any of these ingredients, do not hesitate to ask us for a quote, or for any help in formulating your new product !

5- Is NeOpuntia® soluble ?

NeOpuntia® fiber content is divided as follows: half soluble fibers (hydrophilic) and half insoluble (lipophilic) fibers. It is this unique composition that makes NeOpuntia® efficient. As such, NeOpuntia® is about 50% soluble when added to water at 1%.

6- NeOpuntia® stability when heating

NeOpuntia® should not be heated over 80°C (176°F) in aqueous formulation. We are currently testing the stability of fibers during heat treatments. Some more results should be available in the coming months.

7- Food Use of NeOpuntia®

The Stan 185 standard from Codex Alimentarius shows that *opuntia-ficus-indica* from which is made NeOpuntia® has been used over the world as a vegetable before 1993.

See the following link :

http://www.ipfsaph.org/servlet/BinaryDownloaderServlet?filename=kopool_data/codex_0/en_cxs_185e.pdf

The link below is an additional report of 176 pages about the market of the nopalito as a vegetable in Mexico (in 1995).

<http://www.infoaserca.gob.mx/proafex/NOPAL.pdf>

Here is a link for the abstract (1 page) of a study from the International Society for Horticultural Science (ISHS) on cladodes storage for food use : "PASSIVE AND SEMI-ACTIVE MODIFIED ATMOSPHERE PACKAGING OF PRICKLY PEAR CACTUS STEMS"

http://www.actahort.org/books/604/604_82.htm

The *opuntia ficus indica* is also in the book of C.F. Saunders "useful wild plants" in Chapter 6 / Opuntia (page 132).

Title :

http://www.swsbm.com/ManualsOther/UsefulPlants/Useful_Wild_Plants-1.PDF

chapter 6 :

http://www.swsbm.com/ManualsOther/UsefulPlants/Useful_Wild_Plants-5.PDF

We can also provide you with 3 pages scanned of a dictionary of edible plants.

8- Novel Food Procedure

The legal status of NeOpuntia® is clear : cactus, from which it is made, is an everyday consumption vegetable, traditionally used by millions of people around the world.

It is thus exempted from the Novel Food Procedure, as attested by the DGCCRF (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes / French Government Authority).

9- NeOpuntia® side effects

NeOpuntia® is already used by millions of people worldwide, and no discomfort was ever reported.

We are not aware of any interaction with prescription drug.

Furthermore, a preliminary double blind clinical test was conducted by BIO SERAE on 10 humans in order to evaluate the acceptability & efficiency of NeOpuntia® (2003), at dosage of 5g a day.

The product was very well tolerated by the patients, no side effect was observed.

NeOpuntia® is 100% natural and is the result of a gentle, chemical free and solvent free process. You can use it safely.

10-How long can I be using NeOpuntia®? Is it a healthy habit?

We confirm that you can use NeOpuntia® on a regular basis, as long as you want. This will only increase the recommended daily amount of fiber, which you can naturally find in fruits and vegetable.

11-NeOpuntia® & Allergy

NeOpuntia® is 100% natural and is the result of a gentle, chemical free and solvent free process.

NeOpuntia® does not contain any of reported allergic substances, according to the European regulation CE/2003/89.

NeOpuntia® is not derived from animal, and the production process does not include any animal substances. A proof of this guarantee : NeOpuntia® is approved by the Vegetarian Society (worldwide recognised Vegetarian Organisation in UK – www.vegsoc.org).

12-Is there any contra-indication linked to the use of NeOpuntia® ?

Until now, no discomfort, nor any interaction with medicines was observed. We did not neither identified any interaction / synergy between NeOpuntia® and other active compounds.

Nevertheless, precautionary measures are always beneficial. Even though we did not show any significative interaction with liposoluble vitamins, we advise not to take liposoluble active compounds alongside with NeOpuntia®.

We would also advise that anyone suffering from pathology needing serious medical treatment (such as heart disease, blood parameter disorder, or cancer...), should consult its doctor before starting any weight management program, should it be based on dietary supplement or on drugs.

13-NeOpuntia® and hepatic steatosis (fat retention in liver)

In the case of benign hepatic steatosis (which does not need any medicinal treatment), to consume NeOpuntia® can induce a beneficial effect, because it is thought to reduce fat assimilation.

If medicinal treatment is necessary, we would always **recommend to take advice of a doctor**, to ensure lack of interactions with other family of molecules.

14-Analysis Methods

Lipophilic properties (butter / oil / mayonnaise)

Analysis method for NeOpuntia® lipophilic properties is strictly confidential and property of BIO SERAE Laboratoires SA.

Cellulose / hemicellulos (% RM)

You can click on the following links to access to detailed analysis methods :

Determination of fiber and lignin .pdf

Determination of plant cell wall constituent .pdf

Total Dietary Fiber Assay Kit .pdf

15-Nutritional facts

These figures are for indicative purpose only, they are not guaranteed.

Description	Result
Total Proteins (N x 6.25)	3.6 +/- 1.7 %
Different Glucides analyzed	34.4 % (batch 0506811)
Ash	20.6 +/- 3.2 %
Lipids	1.1 % (batch 0506811)
Total fibres	36.7% (batch 0506811)
Nutritional Value (Parameters analyzed on batch number 0506811):	
Calories/ 100g	159
Kjoules/100g	665

16-Fat-Soluble Vitamin interaction with NeOpuntia®

Based on the conducted studies, NeOpuntia® does not bind in a selective way to fat-soluble vitamins A and E either *in vitro* or *in vivo*.

Due to the effect of its fiber and its method of working, NeOpuntia® collects some of the bile acids and makes them unavailable for digestion of lipids by pancreatic lipase.

Complete method of testing :

- Food grade sunflower oil.
- E Vitamin : sunflower oil was guaranteed near to the Advised Nutritional Contribution for 20g of oil (approx. 60 mg/100g).
- A Vitamin : addition of trans-retinol to obtain a value comparable to the Advised Nutritional contribution for 20g of oil (approx. 4 mg/100g)
- Fat binding test : conducted with / without NeOpuntia®. 20g of oil mixed with 25 g of acidified water & 600 mg of NeOpuntia® / or without.
- After incubation in digestion conditions, collection of the supernatant oil, and analysis by external laboratory.
- Comparison between concentration of A and E vitamins after the test, with/without NeOpuntia® : No significant difference was observed between trial & control for A and E vitamins.

17-Glycemic index when taking NeOpuntia®

For the moment, BIO SERAE only conducted pilot *in vitro* tests to measure the influence of NeOpuntia® on Glycemic index. It is currently one of our main subject of interest. We plan to conduct soon a more complete study about this matter.

18-Hydrophobic interactions between NeOpuntia® and Fat

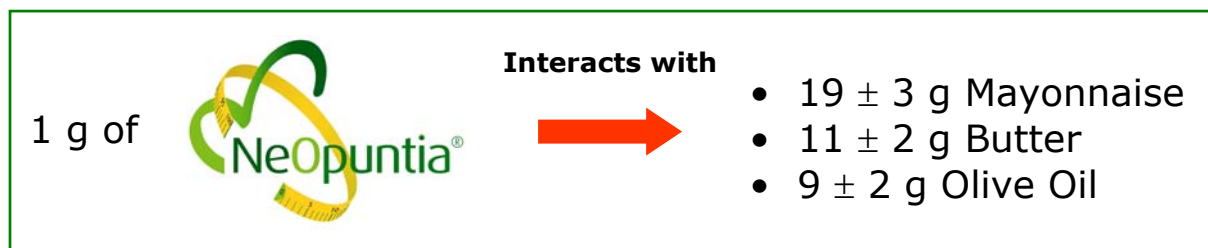
A study conducted by Dr. Vilarem (Science University of Toulouse – FRANCE), showed the hydrophobic properties of NeOpuntia®.

We observed a high rate of esterification of NeOpuntia® in comparison with several samples of cellulose. The esterification rate is an indirect way of controlling hydrophobicity. This explains the high affinity between NeOfiber™ (non soluble polymer of NeOpuntia®) and the fats from the food.

These interactions are not pH dependant (as it is the case with chitosan) so NeOpuntia® works in the whole digestive track.

BIO SERAE research team is still working to find out more details about NeOpuntia® structure.

19-How much fat can interact with NeOpuntia® ?



In vitro test, according to BIO SERAE Laboratoires research.

20-Does NeOpuntia® interact with triglycerides ?

Yes, NeOpuntia® interacts with triglycerides. The *in vitro* TNO study and the pilot *in vivo* clinical trial were conducted by using fat from food (especially oil) and the natural fatty molecules are triglycerides before digestion; digestion producing fatty acids and glycerol from triglycerides.

21-Does NeOpuntia® interact with cholesterol ?

We have no evidence for now that NeOpuntia® binds specifically to cholesterol, but there is no reason of absence of binding in comparison with other fatty molecules from food.

22-NeOpuntia® comparing with Chitosan

NeOpuntia® can be considered as the Green Alternative to Chitosan ...

Why replacing Chitosan should be considered? Though Chitosan comes in various “flavors” and is well established as the fat binder of reference, its marine origin and the harsh extraction process it is subjected to, prevents it from being universally accepted.

One point more : NeOpuntia® is approved by the Vegetarian Society (Chitosan, with marine origin, is obviously not !)

NeOpuntia®'s mode of action is also different from Chitosan's. It is thought to interact with fat in the stomach and its activity is not pH or lipid type dependant.

A recent comparative study performed with the TNO gastric simulation model (NL – 2004) indicates that *"Branded Chitosan shown no effect on the bioaccessibility of fatty acids in contrast to NeOpuntia® that decreased by 28.3 %"*.

23-How to declare NeOpuntia® on the package?

NeOpuntia® is an international trademark, you are allowed to use it but you need to complete the ingredient description like this : "NeOpuntia® patented powder of *Opuntia Ficus Indica* leaves" with the botanical name.

The typography of NeOpuntia® MUST be respected on any packaging or advertising, as it is a trademarked denomination and should also be followed by the mention : "NeOpuntia® is a product of BIO SERAE Laboratoires SA"

To match with end consumer increasing awareness of NeOpuntia®, we would obviously advise to include the logo on your packaging. Do not hesitate to ask our marketing department (marketing@bioserae.com), which keeps at your disposal a complete set of logos, images and other diverse marketing and communication tools.

24-How to mention NeOpuntia® patent ?

The patent number is very important and should be declared as follow: **PCT/FR 02/01254**.

25-How to explain the mechanism of action of NeOpuntia® to our end consumers ?

We can describe the physical mechanism called lipophilic action thanks to our researches but we can only make hypothesis of the action inside the body. As far as we know after 5 years of studies, we can not yet prove organism influence of the NeOpuntia®, except fat excretion. A 3D animation is available to explain this hypothesis.

26-What claims can be made for a product containing NeOpuntia® ?

If your product contains the recommended dosage of NeOpuntia®, which ensures maximum efficiency, we can propose you the following descriptions:

- The lipophilic fiber
- A food grade cactus powder
- Lipo-affinity
- Cactus power

Remember as well to always add recommendation as such :

- Must be taken alongside with healthy and balanced diet
- Exercise yourself
- Eat lots of fruit and vegetables
- Drink a lot of water, etc. ...

We obviously recommend you to take advice of local legal authority regarding advertising and claims (for example “Bureau de Vérification de la Publicité” in France, or the FTC in the USA).

27-Can we say : scientifically proven ?

Although the R&D program of BIO SERAE is quite important since 5 years and will continue to grow for the coming years, we are not authorized to use the term “clinically proven”. **We prefer “clinically tested”.**

During the pilot-clinical study, the population tested was too small. Today, our goal is to increase the panel size.

The results of our different studies indicated that there is no evidence showing that the fat binding mechanism will help people to reduce weight, but it does not necessary means that the product itself does not have weight loss effect.

28-I experienced some fluidity and / or compressibility problems while processing NeOpuntia®, what can I do ?

BIO SERAE can offer you 2 other different grades of NeOpuntia® :

- NeOpuntia® Fluid – for better flowing
- NeOpuntia® Granulated – for easier direct compression

Do not hesitate to contact us for further information (sales@bioserae.com).

29-Where can I buy NeOpuntia® ?

NeOpuntia® is available into many finished products worldwide, mainly in pharmacy, parapharmacy, and on the Internet.

The best thing would be to contact our local exclusive distributor, which can inform you about the latest finished products available. See our list of distributor : www.bioserae.com/links.php .