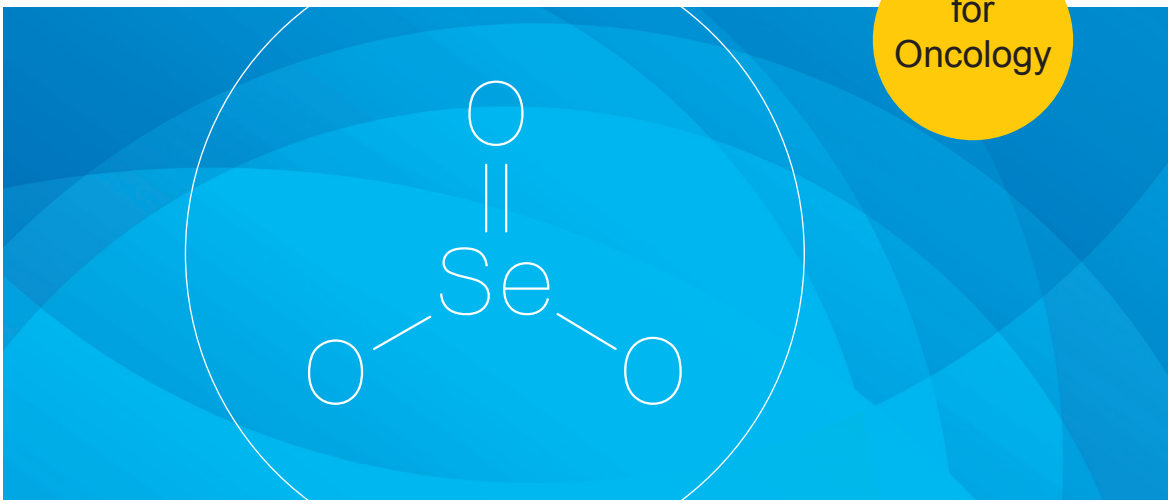
selenase® oral liquid

Replacement therapy
to reduce cancer treatment side effects

for
Oncology



cGMP quality standard made in Germany

Since 1984
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biosyn®

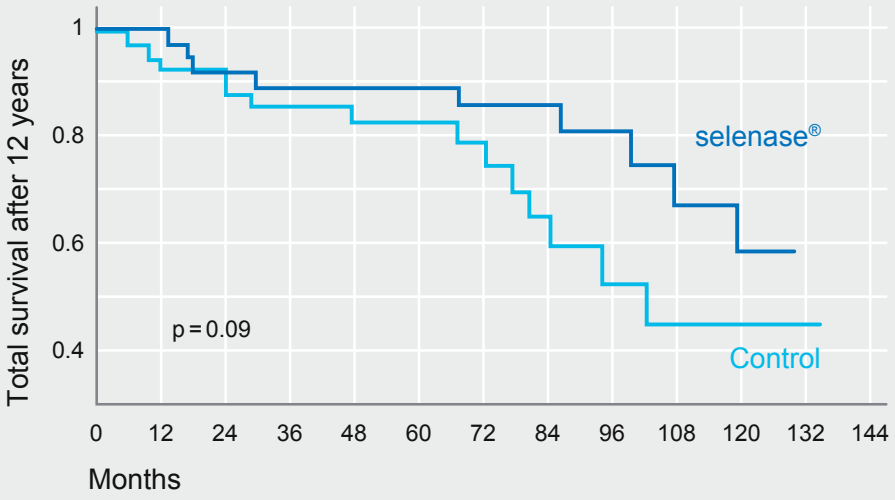
selenase® – improve patient wellness during cancer treatment by better control of side effects associated with radiation, chemotherapy, or surgery

Side effect reduction or prevention increases patient compliance and comfort. For many patients addressing a decrease in serum selenium levels which can occur during radiation, chemotherapy, or surgery, with adjunct selenium replacement may help avoid adverse clinical changes which may prompt therapy delays or interruption, or intervention.

Cancer therapy induced side effects are often the result of the therapies toxic effects on healthy cells.

selenase® form of selenium replacement reduces side effects by reducing cytotoxic impact on healthy cells while maintaining the desired oncologic therapeutic effect of radiation or chemotherapy on the target malignancy.

selenase® did not impair effectiveness of radiotherapy during treatment



Muecke R et al. Integr Cancer Ther. 2014 Nov; 13(6): 463-7. Multicenter, phase III trial comparing selenium supplementation with observation in gynecologic radiation oncology: follow-up analysis of the survival data 6 years after cessation of randomization.

Fig. 1

selenase® significantly reduced the incidence of diarrhea grade 2 or higher by 20 % (p = 0.04) in patients with cervical or uterine cancer undergoing radiotherapy. Long term follow-up at 12 years showed selenase® did NOT interfere with the effectiveness of radiotherapy.[1]

Sodium selenite (selenase®) replacement is safe and well tolerated

To determine sodium selenite efficacy during chemotherapy, 45 patients receiving carbonplatin / paclitaxel for gynecological malignancy were given 50 – 5,000 mcg sodium selenium pre therapy.[2] Baseline plasma selenium: 76 – 141 mcg/l. Adding selenium to chemotherapy was safe, well tolerated, and did NOT alter carboplatin pharmacokinetics.

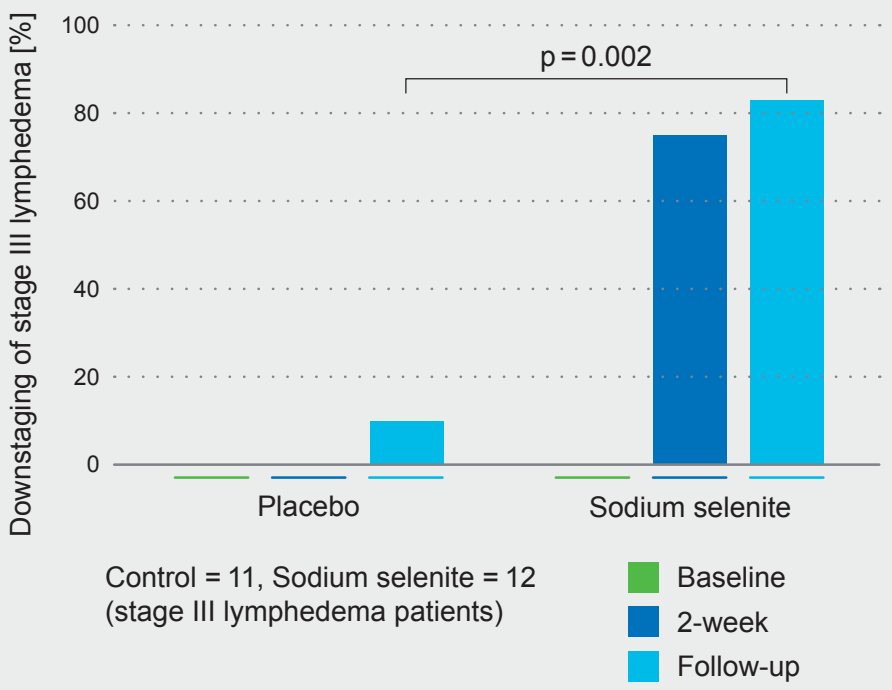
Sodium selenite (selenase®) reduces chemo resistance

Preclinical studies demonstrate that sodium selenite helps prevent the development of chemo resistance. In an open label trial of patients with therapy resistant tumors (71 % lung Ca)[3] I.V. sodium selenite was given five times a week after which one third of the patients responded to first line chemotherapy.

Sodium selenite (selenase®) decreases lymphedema

In patients with stage II – III breast cancer related lymphedema, a randomized, double blind, placebo controlled trial found 75 % of participants showed clinical stage improvement following two weeks of selenium replacement.[4] At 4 weeks post treatment follow-up 83 % showed stage improvement (III to II, $p = 0.02$).

Sodium selenite downstaged lymphedema in selenium replete patients*



*selenium in whole blood > 140 mcg/l

Modified after: Han HW, et al. Nutrients. 2019 May 7;11(5). pii: E1021. Sodium Selenite Alleviates Breast Cancer-Related Lymphedema Independent of Antioxidant Defense System.

Fig. 2

Why sodium selenite (selenase®)?

Selenium is an essential trace element. Selenium deficiency as identified in serum levels can adversely impact immune mechanisms, affect hepatic enzymatic activity. In patients undergoing oncology treatments, maintaining adequate selenium levels can mitigate the cytotoxic effects of cancer therapy.

Sodium selenite is highly water soluble making it applicable in oral selenium solutions. Sodium selenite (selenase®) is directly and efficiently incorporated into human metabolism.

In contrast: selenomethionine, the primary form of selenium found in food which has high bioavailability, is less efficiently assimilated into selenoproteins. Selenium replacement using selenomthionine supplements can be problematic.

Methionine rich foods can impair selenomethionine absorption. Selenomethionine may also accumulate to abnormal levels since it is less well excreted than the sodium selenite form of selenium which is either rapidly used for selenoproteins synthesis or excreted.

Advantages of sodium selenite [5-7]

	Sodium selenite (selenase®)	Seleno-methionine [A]
Dietary occurrence	Drinking water, food	Main form in food
Absorption in the gastrointestinal tract	Passive	Active
Impaired absorption due to methionine-rich food [B]	No	Yes
Uptake in the selenium metabolism	Controlled	Uncontrolled
Incorporation in selenoproteins	Completely	Partially
Incorporation in “wrong” proteins	No	Yes [C]
Accumulation in the human body	No [D]	Yes
Increase of selenium level considerable above recommended reference values	No [D]	Yes
Excreted through the body	Completely	Partially

[A] Main form in selenium yeast
[B] Meat, fish, dairy products, soybeans
[C] Instead of the amino acid methionine
[D] With a daily intake up to 300 microgram selenium

Safety – Not all forms of selenium are equivalent

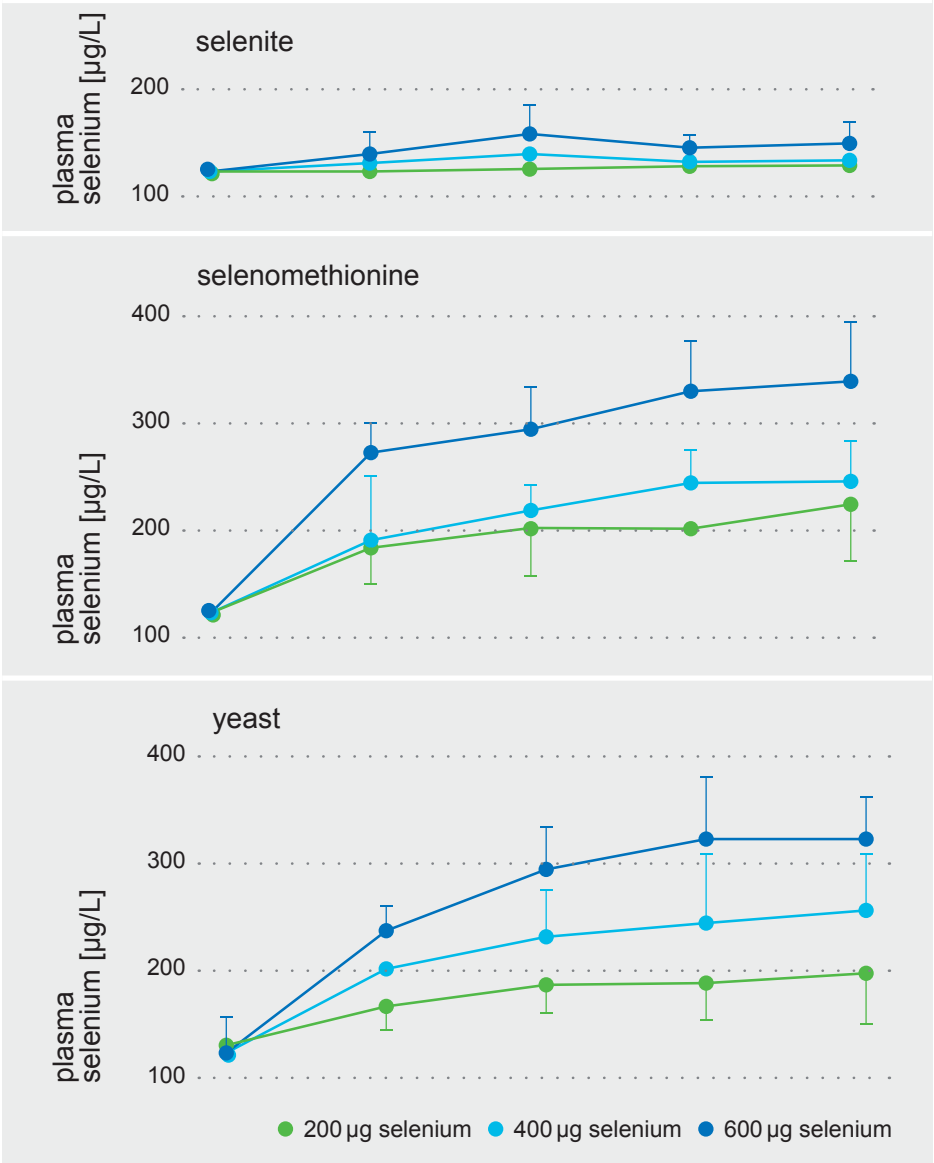
While maintaining normal selenium serum levels during treatment has demonstrated efficacy for reducing therapeutic side effects, selecting the appropriate form of medical selenium replacement is important.

Not only does sodium selenite (selenase®) have specific metabolic advantages it is emphasized that there is NOT dosing equivalence between various selenium forms. Organic (generic) formulations based upon selenomethionine or selenium yeast may lead to abnormal, clinically undesirable serum levels and sequalae.

Selenium replacement with widely available OTC supplements is therefore not advised for patient safety and clinical efficacy.

Practitioners and patients should restrict selenium replacement to medical sodium selenite (selenase®) rather than generic selenium products which can prompt safety concerns.

Different effect of high-dosed selenium forms on adequate selenium status



Burk RF et al. Cancer Epidemiol Biomarkers Prev. 2006 Apr; 15(4): 804-10. Effects of chemical form of selenium on plasma biomarkers in a high-dose human supplementation trial.

Fig. 3

selenase® (sodium selenite) oral liquid is medical selenium

selenase® (medical selenium) is pharmaceutical grade and manufactured in compliance with strict German pharma regulation according to Arzneimittelzulassung nach § 21, Abs. 1 Arzneimittelgesetz (AMG). It is the identical selenium form used for selenium maintenance therapy including in the intensive care setting.

Directions for use

selenase® oral liquid is available in convenient bottles and ampules which can be diluted with water if necessary regardless is easy to swallow even for patients with dysphasia.

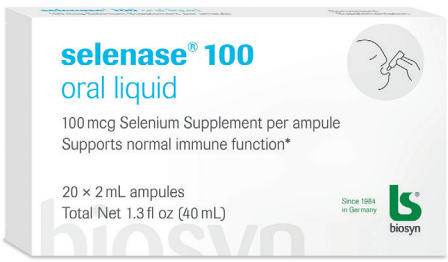
Suggested Dosage of selenase®	
Radiation and Chemotherapy	
Treatment day	1,000 µg selenase® / day
Therapy-free day	500 µg selenase® / day
Maintenance therapy	200 µg selenase® / day

Radiation and Chemotherapy: selenase® 500 µg – Amount per week

Treatment days per week	Amount on treatment days	Rest days per week	Amount on rest days	Total per week
1	2 bottles	6	6 bottles	8 bottles
2	4 bottles	5	5 bottles	9 bottles
3	6 bottles	4	4 bottles	10 bottles
4	8 bottles	3	3 bottles	11 bottles
5	10 bottles	2	2 bottles	12 bottles

Maintenance therapy: selenase® 100 µg – Amount per week

Per day amount	Total per week
2 ampules	14 ampules



About biosyn

biosyn Arzneimittel GmbH is a German pharmaceutical and biotechnology company.

biosyn, based in Fellbach, Germany, specializes in trace elements and is the recognized global leader for medical selenium replacement products. biosyn is also recognized for its unique manufacturing operations.

biosyn provides clinical products used across several areas including oncology, endocrinology, and intensive care applications. biosyn maintains an active research and development presence in the industry.

First cGMP-compliant manufacturing procedure for sodium selenite pentahydrate.
biosyn production facility in Fellbach, Germany


cGMP quality standard,
made in Germany

Literature

1. Muecke R, et al. Integr Cancer Ther. 2014 Nov;13(6):463-7. Multicenter, phase III trial comparing selenium supplementation with observation in gynecologic radiation oncology: follow-up analysis of the survival data 6 years after cessation of randomization.
2. Song M, et al. Gynecol Oncol. 2018 Sep;150(3):478-486. Phase I trial of selenium plus chemotherapy in gynecologic cancers.
3. Brodin O, et al. Nutrients. 2015 Jun 19;7(6):4978-94. Pharmacokinetics and Toxicity of Sodium Selenite in the Treatment of Patients with Carcinoma in a Phase I Clinical Trial: The SECAR Study.
4. Han HW, et al. Nutrients. 2019 May 7;11(5):1021. Sodium Selenite Alleviates Breast Cancer-Related Lymphedema Independent of Antioxidant Defense System.
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6. Suzuki KT. J Health Sci. 2005; 51: 107-14. Metabolomics of Selenium: Se Metabolites Based on Speciation Studies.
7. Thiry C, et al. Food Chem. 2012 Feb 15:130(4):767-784 Current knowledge in species-related bioavailability of selenium in food.
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Date of Information: 06/21

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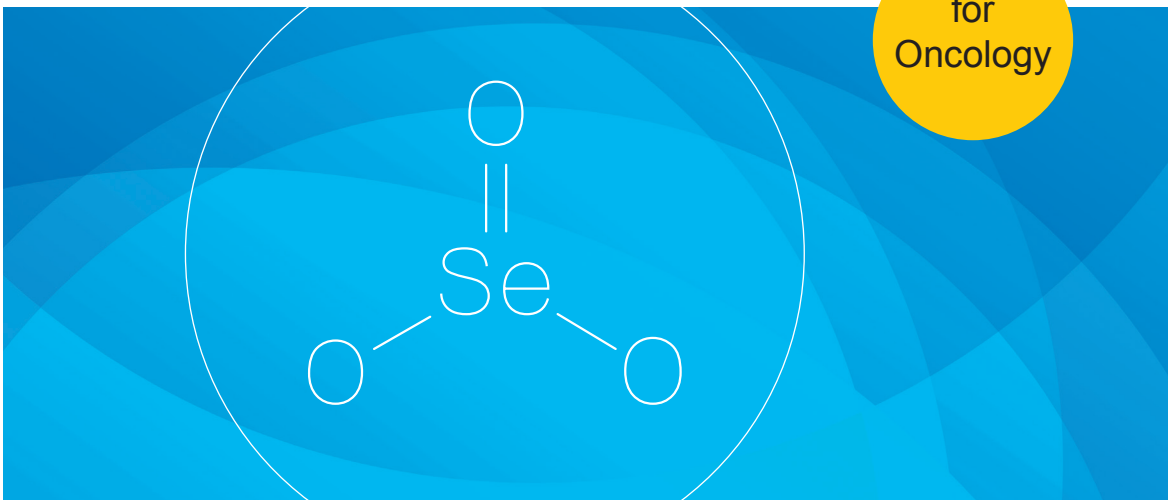

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