

# Dosage information on selenium in oncology



## **selenase<sup>®</sup>**

- corrects selenium deficiency
- selenium deficiency – factor for a worse prognosis
- selenium deficiency influences the risk of short- and long-term side effects of cancer therapy

## Sodium selenite

- reduces side effects by protecting healthy cells
- selectively cytotoxic against tumor cells
- improves the body's ability to destroy tumor cells

we are  
research



## Dosage information on selenium in oncology\*

Prevention	without genetic predisposition	up to 200 µg Se/day <sup>[A, B]</sup>
	with genetic predisposition	up to 300 µg Se/day <sup>[C, D]</sup>
Therapy	before therapy**	up to 1,000 µg Se <sup>[E-G]</sup>
	on therapy-free days***	up to 500 µg Se/day <sup>[H]</sup>
After cancer therapy		up to 300 µg Se/day <sup>[I]</sup>

\* according to dosage, regimes as presented in trials

\*\* as therapy scheme<sup>[H, J]</sup>

\*\*\* regime of therapy and therapy-free days<sup>[H]</sup>

Created according to:

- [A] Yu SY et al. Biol Trace Elem Res. 1997 Jan; 56(1): 117-24. [Protective role of selenium against hepatitis B virus and primary liver cancer in Qidong.](#)
- [B] Duffield-Lillico AJ et al. BJU Int. 2003 May; 91(7): 608-12. [Selenium supplementation, baseline plasma selenium status and incidence of prostate cancer: an analysis of the complete treatment period of the Nutritional Prevention of Cancer Trial.](#)
- [C] Kowalska E et al. Cancer Epidemiol Biomarkers Prev. 2005 May; 14(5): 1302-6. [Increased rates of chromosome breakage in BRCA1 carriers are normalized by oral selenium supplementation.](#)
- [D] Dziaman T et al. Cancer Epidemiol Biomarkers Prev. 2009 Nov; 18(11): 2923-8. [Selenium supplementation reduced oxidative DNA damage in adnexectomized BRCA1 mutations carriers.](#)
- [E] Holzhauer P. Dtsch. Z. für Onkol. 2002; 34; 14-6. Kann durch die prophylaktische Gabe von Natriumselenit die Inzidenz und der Schweregrad der durch Vinorelbin induzierten lokalen Phlebitis beeinflusst werden?
- [F] Zimmermann T et al. Biol Trace Elem Res. 2005 Sep; 106(3): 193-203. [Reduction of postoperative lymphedema after oral tumor surgery with sodium selenite.](#)
- [G] Pakdaman A. Biol Trace Elem Res. 1998 Apr-May; 62(1-2): 1-6. [Symptomatic treatment of brain tumor patients with sodium selenite, oxygen, and other supportive measures.](#)
- [H] Muecke R et al. Int J Radiat Oncol Biol Phys. 2010 Nov 1; 78(3): 828-35. [Multicenter, phase 3 trial comparing selenium supplementation with observation in gynecologic radiation oncology.](#)
- [I] EFSA Panel on Dietetic Products, Nutrition and Allergies, 2014. EFSA Journal 2014; 12(10): 3846, 67 pp. [Scientific Opinion on Dietary Reference Values for selenium.](#)
- [J] Bruns F et al. Med Princ Pract. 2004 Jul-Aug; 13(4): 185-90. [Selenium in the treatment of head and neck lymphedema.](#)

Selenium to correct selenium deficiency	
Low selenium status	Selenium deficiency
< 100 µg/l selenium in serum < 120 µg/l selenium in whole blood	< 80 µg/l selenium in serum < 100 µg/l selenium in whole blood
until start of cancer therapy up to 200 µg selenium per day (tablet or drinking ampoules)	until start of cancer therapy up to 300 µg selenium per day (tablet)
Costs: approx. € 17 per month or approx. € 200 per year*	Costs: approx. € 50 per month or approx. € 600 per year*
* calculation based on the marketed dosage forms indicated in parentheses	
Created according to: <a href="#">Summary of product characteristics selenase®</a> , biosyn Arzneimittel GmbH, November 2017.	

## Selenium deficiency in cancer patients

- Often reduced selenium status at diagnosis<sup>[11–16]</sup>
- Lower selenium status worsens prognosis<sup>[17,18]</sup>

## Selenium in cancer prevention

Low selenium status	Selenium deficiency
< 100 µg/l selenium in serum < 120 µg/l selenium in whole blood	< 80 µg/l selenium in serum < 100 µg/l selenium in whole blood
up to 100 µg selenium per day (tablet or drinking ampoules)	up to 200 µg selenium per day (tablet or drinking ampoules)
Costs: approx. € 26 per months or approx. € 300 per year*	Costs: approx. € 50 per months or approx. € 600 per year*

\* calculation based on the marketed dosage forms indicated in parentheses

Created according to:

Yu SY et al. Biol Trace Elem Res. 1997 Jan; 56(1): 117-24. [Protective role of selenium against hepatitis B virus and primary liver cancer in Qidong.](#)

Duffield-Lillico AJ et al. BJU Int. 2003 May; 91(7): 608-12. [Selenium supplementation, baseline plasma selenium status and incidence of prostate cancer: an analysis of the complete treatment period of the Nutritional Prevention of Cancer Trial.](#)

## Cancer prevention

- Selenium deficiency increases the risk of cancer<sup>[1,2]</sup>
- Different impact of the selenium status on different types of cancer<sup>[1]</sup>
- Suboptimal selenium supply in Europe increases colon cancer risk<sup>[3]</sup>
- Ten-fold increased risk of liver cancer at low selenoprotein P concentration<sup>[4]</sup>
- Preconditions and options for a preventive effect of selenium:
  - lower selenium status
  - administration of sodium selenite<sup>[5,48–50]</sup>
  - suitable dosage (not too low, not too high)

## Selenium in cancer prevention for patients with genetic predisposition

Low selenium status	Selenium deficiency
< 100 µg/l selenium in serum < 120 µg/l selenium in whole blood	< 80 µg/l selenium in serum < 100 µg/l selenium in whole blood
up to 200 µg selenium per day (tablet or drinking ampoules)	up to 300 µg selenium per day (tablet or drinking ampoules)
Costs: approx. € 17 per months or approx. € 200 per year*	Costs: approx. € 50 per months or approx. € 600 per year*

\* calculation based on the marketed dosage forms indicated in parentheses

Created according to:

Kowalska E et al. Cancer Epidemiol Biomarkers Prev. 2005 May; 14(5): 1302-6.

[Increased rates of chromosome breakage in BRCA1 carriers are normalized by oral selenium supplementation.](#)

Dziaman T et al. Cancer Epidemiol Biomarkers Prev. 2009 Nov; 18(11): 2923-8.

[Selenium supplementation reduced oxidative DNA damage in adnexectomized BRCA1 mutations carriers.](#)

## Cancer prevention with genetic predisposition

- Selenium reduces DNA damage<sup>[6]</sup>
- Selenium improves DNA repair mechanisms<sup>[7]</sup>
- Selenium supplementation improves DNA stability in cases of selenium deficiency<sup>[8]</sup>
- Highest DNA stability at selenium serum levels between 120–160 µg/l<sup>[8]</sup>
- Sodium selenite reduces the number of chromosomal breakages in women with BRCA1 mutation<sup>[9]</sup>
- Sodium selenite can reduce breast cancer risk with BRCA1 mutations<sup>[9, 10]</sup>

## Dosage information\* and costs of selenium in tumor surgery

To reduce surgery-related decrease of selenium status, oxidative stress and to improve the immune status\*

before surgery <sup>[A-C]</sup> (i.v. or drinking ampoules)	intra- or post-operative <sup>[A, C]</sup> (i.v.)	per day for 2 weeks <sup>[D]</sup> (i.v. or drinking ampoules)
1,000 µg selenium	1,000 µg selenium	up to 1,000 µg selenium <sup>[A, C]</sup>

Costs: approx. € 185\*\*

\* according to dosages, regimes as presented in trials

\*\* calculation based on the marketed dosage forms of selenase® indicated in parentheses

[A] Stoppe C et al. Crit Care Med. 2011 Aug; 39(8): 1879-85. [The intraoperative decrease of selenium is associated with the postoperative development of multiorgan dysfunction in cardiac surgical patients.](#)

[B] Stoppe C et al. Nutrition. 2013 Jan; 29(1): 158-65. [Selenium blood concentrations in patients undergoing elective cardiac surgery and receiving perioperative sodium selenite.](#)

[C] Zimmermann T et al. Biol Trace Elem Res. 2005 Sep; 106(3): 193-203. [Reduction of postoperative lymphedema after oral tumor surgery with sodium selenite.](#)

[D] [Summary of product characteristics selenase®](#), biosyn Arzneimittel GmbH, November 2017.

## Tumor surgery

- Surgical interventions lead to a significant decrease in selenium status<sup>[19,20]</sup>
- A small increase of the inflammation marker CRP already significantly reduces the selenium status<sup>[21]</sup>
- Negative impact of the surgery-induced systemic inflammatory response on the therapy success<sup>[22,23]</sup>
- Supra-nutritive dose of sodium selenite favors TH1 differentiation<sup>[24]</sup>
- Peri- and post-operative administration of selenase® improves selenium status<sup>[25]</sup>

## Dosage information\* and costs of selenium in lymphedema

### At increased risk of surgery-related lymphedema\*

before surgery <sup>[A]</sup> (i.v. or drinking ampoules)	intra- or post-operative <sup>[A]</sup> (i.v.)	per day for 3 weeks <sup>[A]</sup> (i.v. or drinking ampoules)
1,000 µg selenium	1,000 µg selenium	1,000 µg selenium

Costs: approx. €265\*\*

\* according to dosages, regimes as presented in trials

\*\* calculation based on the marketed dosage forms of selenase® indicated in parentheses

[A] Zimmermann T et al. Biol Trace Elem Res. 2005 Sep; 106(3): 193-203. [Reduction of postoperative lymphedema after oral tumor surgery with sodium selenite.](#)

## Surgery-related lymphedema

- Reduced volume of surgery-related lymphedema with simultaneous selenase® therapy<sup>[26]</sup>

## Lymphedema

- Especially affected: breast cancer patients and patients with head and neck tumors
- Only half of those affected obtain therapy<sup>[27]</sup>
- The selenium status decreases with increasing severity of lymphedema<sup>[28]</sup>
- Sodium selenite shows both biological as well as pharmacological effects<sup>[28]</sup>
- Selenium:
  - reduces lymphedema volume<sup>[26, 29]</sup>
  - raises the effectiveness of physical therapy<sup>[29]</sup>
  - reduces the risk of erysipelas<sup>[29, 30]</sup>
  - improves quality of life scores<sup>[35]</sup>
  - reduces side effects

## Dosage information\* and costs of selenium in lymphedema

### At increased risk of surgery-related lymphedema\*

before surgery <sup>[A]</sup> (i.v. or peroral)	intra- or post-operative <sup>[A]</sup> (i.v.)	for 3 weeks <sup>[A]</sup> (i.v. or peroral)
1,000 µg selenium	1,000 µg selenium	1,000 µg selenium per day
Costs: approx. € 265**		

### At radiotherapy-induced lymphedema\*

for 1 week <sup>[B]</sup> (i.v. or peroral)	for up to 6 weeks <sup>[C, D]</sup> (peroral)
1,000 µg selenium per day	500 µg selenium per day
Costs: approx. € 320**	

### At secondary lymphedema in breast cancer\*

for 1 week <sup>[B]</sup> (i.v. or peroral)	for 2 weeks <sup>[D]</sup> (peroral)
1,000 µg selenium per day	500 µg selenium per day
Costs: approx. € 160**	

\* according to dosages, regimes as presented in trials

\*\* calculation based on the marketed dosage forms of selenase<sup>®</sup> indicated in parentheses

[A] Zimmermann T et al. Biol Trace Elem Res. 2005 Sep; 106(3): 193-203. [Reduction of postoperative lymphedema after oral tumor surgery with sodium selenite.](#)

[B] Kasseroller RG et al. Am J Ther. 2000 Aug; 7(4): 273-9. [Treatment of secondary lymphedema of the arm with physical decongestive therapy and sodium selenite: a review.](#)

[C] Bruns F et al. Med Princ Pract. 2004 Jul-Aug; 13(4): 185-90. [Selenium in the treatment of head and neck lymphedema.](#)

[D] Micke O et al. Int J Radiat Oncol Biol Phys. 2003 May 1; 56(1): 40-9. [Selenium in the treatment of radiation-associated secondary lymphedema.](#)



## Dosage information\* and costs of selenium during radiotherapy

### To reduce radiotherapy-induced side effects\*

before radiation\*\* [A]  
(i.v. or drinking ampoules)

therapy days\*\* [B, C]  
(drinking ampoules)

up to 1,000 µg selenium

up to 500 µg selenium per day

Costs: approx. € 405

(calculation based on example of radiotherapy for 5 days/week for 6 weeks and on the marketed dosage forms of selenase® indicated in parentheses)

\* according to dosages, regimes as presented in trials

\*\* regime of therapy and therapy-free days

[A] Pakdaman A. Biol Trace Elem Res. 1998 Apr-May; 62(1-2): 1-6. [Symptomatic treatment of brain tumor patients with sodium selenite, oxygen, and other supportive measures.](#)

[B] Muecke R et al. Int J Radiat Oncol Biol Phys. 2010 Nov 1; 78(3): 828-35.

[Multicenter, phase 3 trial comparing selenium supplementation with observation in gynecologic radiation oncology.](#)

[C] Büntzel J et al. Anticancer Res. 2010 May; 30(5): 1783-6. [Selenium substitution during radiotherapy of solid tumours – laboratory data from two observation studies in gynaecological and head and neck cancer patients.](#)

## During radiotherapy

- Negative effect of radiotherapy on selenium status<sup>[32]</sup>
- Sodium selenite therapy reduces radiotherapy-induced adverse reactions<sup>[33]</sup>
- Phase III trial:<sup>[34, 35]</sup>
  - selenase® reduces radiotherapy-induced diarrhoea
  - selenase® significantly increases the selenium status
  - selenase® does not reduce its effectiveness during radiotherapy

## Sodium selenite during chemotherapy

### To reduce chemotherapy-induced side effects\*

before chemotherapy\*\*<sup>[A]</sup>  
(i.v. or drinking ampoules)

therapy-free days\*\*\*  
(drinking ampoules)

up to 1,000 µg selenium

up to 500 µg selenium per day

Costs: approx. €575

(calculation based on the example of chemotherapy 6 × every 21 days and on the marketed dosage forms of selenase® indicated in parentheses)

\* according to dosages, regimes as presented in trials

\*\* reduction of side effects

\*\*\* based on properties of sodium selenite<sup>[B]</sup>, results from radiotherapy<sup>[C]</sup> and current selenium status<sup>[D]</sup>

[A] Holzhauser P, Dtsch. Z. Für Onkol. 2002; 34; 14-6. Kann durch die prophylaktische Gabe von Natriumselenit die Inzidenz und der Schweregrad der durch Vinorelbin induzierten lokalen Phlebitis beeinflusst werden?

[B] Peyroche G et al. PLoS One. 2012; 7(5): e36343. [Sodium selenide toxicity is mediated by O2-dependent DNA breaks.](#)

[C] Muecke R et al. Int J Radiat Oncol Biol Phys. 2010 Nov 1; 78(3): 828-35. [Multicenter, phase 3 trial comparing selenium supplementation with observation in gynecologic radiation oncology.](#)

[D] [Summary of product characteristics selenase®](#), biosyn Arzneimittel GmbH, November 2017.

## During chemotherapy

- Sodium selenite is selectively cytotoxic for tumor cells<sup>[36]</sup>
- Nephroprotective effect of sodium selenite with platinum-based chemotherapeutics<sup>[37]</sup>
- Reduction of anthracycline-induced cardiac toxicity in case of selenium deficiency<sup>[38]</sup>
- Sodium selenite reduces vinorelbine-induced phlebitis<sup>[39]</sup>
- In combination with sodium selenite reduced side effects due to adjuvant hormone therapy in breast cancer patients<sup>[40]</sup>
- High-dose sodium selenite:
  - reduced infection rate<sup>[41]</sup>
  - cardioprotective effect<sup>[42]</sup>

## Dosage information\* and costs of selenium after cancer therapy

To improve the immune status<sup>[A]</sup>, for prophylaxis in case of lymphedema<sup>[B,C]</sup>, for elevated cardiotoxicity<sup>[D]</sup> and osteoporosis risk<sup>[E,F]</sup>

continuously

up to 300 µg selenium per day<sup>[G]</sup>

Costs: approx. € 17 per month or €200 per year  
(calculation based on the marketed dosage forms of selenase®)

### At secondary lymphedema in breast cancer\*

for 1 week<sup>[C]</sup>  
(i.v. or drinking ampoules)

for 2 weeks<sup>[H]</sup>  
(drinking ampoules)

1,000 µg selenium per day

500 µg selenium per day

Costs: approx. € 160  
(calculation based on the marketed dosage forms of selenase® indicated in parentheses)

\* according to dosages, regimes as presented in trials

- [A] Kiremidjian-Schumacher L et al. Biol Trace Elem Res. 2000 Feb; 73(2): 97-111. [Selenium and immunocompetence in patients with head and neck cancer.](#)
- [B] Zimmermann T et al. Biol Trace Elem Res. 2005 Sep; 106(3): 193-203. [Reduction of postoperative lymphedema after oral tumor surgery with sodium selenite.](#)
- [C] Kasseroller RG et al. Am J Ther. 2000 Aug; 7(4): 273-9. [Treatment of secondary lymphedema of the arm with physical decongestive therapy and sodium selenite: a review.](#)
- [D] Tacyildiz N et al. J Oncol. 2012; 2012: 651630. [Selenium in the prevention of anthracycline-induced cardiac toxicity in children with cancer.](#)
- [E] Hoeg A et al. J Clin Endocrinol Metab. 2012 Nov; 97(11): 4061-70. [Bone turnover and bone mineral density are independently related to selenium status in healthy euthyroid postmenopausal women.](#)
- [F] Beukhof CM et al. PLoS One. 2016 Apr 7; 11(4): e0152748. [Selenium Status Is Positively Associated with Bone Mineral Density in Healthy Aging European Men.](#)
- [G] [Summary of product characteristics selenase®](#), biosyn Arzneimittel GmbH, November 2017.
- [H] Micke O et al. Int J Radiat Oncol Biol Phys. 2003 May 1; 56(1): 40-9. [Selenium in the treatment of radiation-associated secondary lymphedema.](#)

## After cancer therapy

- Long-term deterioration of the immune status after chemotherapy<sup>[43]</sup>
  - sodium selenite to improve the immune status<sup>[44]</sup>
- Long-term side effects<sup>[45]</sup>: lymphedema, cardiotoxicity, osteoporosis, second tumors
  - selenase<sup>®</sup> corrects selenium deficiency
  - improvement of lymphedema<sup>[29]</sup>
  - balanced selenium status to protect against increased cardiotoxicity<sup>[38]</sup> and risk of osteoporosis<sup>[46,47]</sup>

selenase<sup>®</sup>

corrects selenium deficiency

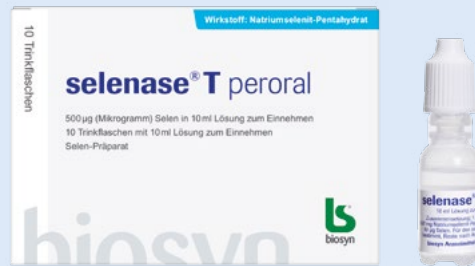
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## selenase<sup>®</sup> pharmaceuticals: prescription only

### selenase<sup>®</sup> T peroral

Oral solution  
500 µg selenium  
per drinking bottle



### selenase<sup>®</sup> 100 µg peroral

Oral solution  
100 µg selenium  
per drinking ampoule



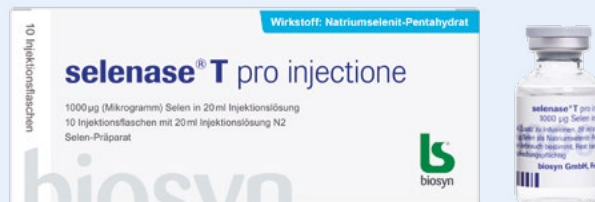
### selenase<sup>®</sup> 300 Mikrogramm Tabletten

Tablets  
300 µg selenium  
per tablet



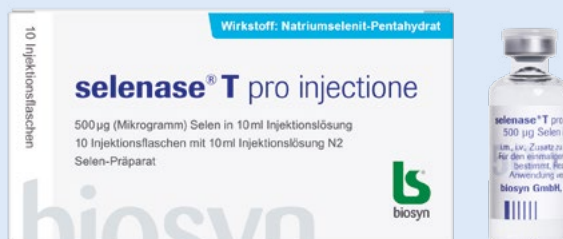
### selenase<sup>®</sup> T pro injectione

Injection solution  
1,000 µg selenium  
per injection bottle



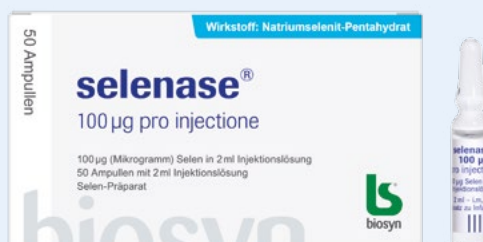
### selenase<sup>®</sup> T pro injectione

Injection solution  
500 µg selenium  
per injection bottle



### selenase<sup>®</sup> 100 µg pro injectione

Injection solution  
100 µg selenium  
per injection ampoule



Active ingredient: sodium selenite pentahydrate

# Information from biosyn Arzneimittel GmbH

## Brochures

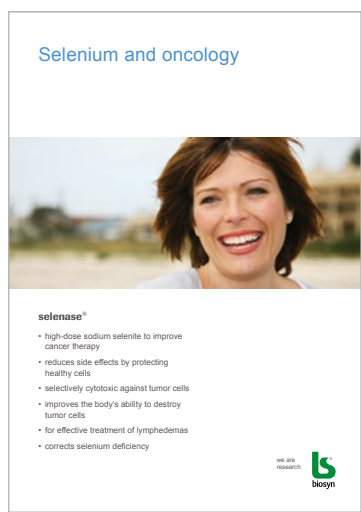
We gladly send you our detailed brochure “Selenium and oncology”.

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## Literature for medical experts



Selenium and oncology  
Folder for medical experts  
Format: A4, 172 pages

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## Further information

If you have specific questions on this topic, please call us at: +49(0)711 575 32 - 00

We would also be glad to provide you with dosage cards. Order by e-mail at: [information@biosyn.de](mailto:information@biosyn.de) (key words “dosage card onco” or “dosage card lymphedema”)

You can also find us on coliquio, the free medical network, with our Infocenter Selenium: [www.coliquio.de](http://www.coliquio.de)

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**selenase®. Active substance:** Selenium as sodium selenite pentahydrate. **selenase® 100 µg pro injectione, selenase® T pro injectione, selenase® 100 µg peroral, selenase® T peroral:** 50 µg selenium per ml. **selenase® 300 Mikrogramm Tabletten:** 300 µg selenium per tablet. **Indications:** selenase® 100 µg pro injectione, selenase® T pro injectione, selenase® 100 µg peroral, selenase® T peroral: Proven selenium deficiency that cannot be offset from food sources. Selenium deficiencies may occur as a result of states of maldigestion and malabsorption, as well as in malnutrition (e.g. due to complete parenteral nutrition). **selenase® 300 Mikrogramm Tabletten:** Adults: Treatment of clinically proven selenium deficiency that cannot be compensated by nutritional sources. **Composition:** selenase® 100 µg pro injectione: 1 ampoule of 2 ml solution for injection contains: 0.333 mg sodium selenite pentahydrate, corresponding to 100 µg (micrograms) selenium. **selenase® T pro injectione:** 1 injection vial of 10 ml/20 ml solution for injection contains: 1.67 mg/3.33 mg sodium selenite pentahydrate, corresponding to 500 µg/1,000 µg (micrograms) selenium. **selenase® 100 µg peroral:** 1 drinking ampoule of 2 ml oral solution contains: 0.333 mg sodium selenite pentahydrate, corresponding to 100 µg (micrograms) selenium. **selenase® T peroral:** 1 ml oral solution contains: 0.167 mg sodium selenite pentahydrate, corresponding to 50 µg (micrograms) selenium. Excipients: Sodium chloride, hydrochloric acid, water for injections. **selenase® 300 Mikrogramm Tabletten:** 1 tablet contains: 300 microgram selenium, corresponding to 0.999 mg sodium selenite pentahydrate. Excipients: Magnesium stearate (Ph. Eur., vegetable), maize starch, povidone K25, sucrose, talc. **Contra-indications:** Hypersensitivity to sodium selenite pentahydrate or to any of the excipients; Selenosis. **Side effects:** None known to date if the medicinal product is administered according to prescription. For selenase® 100 µg pro injectione, selenase® T pro injectione: **General disorders and administration site conditions:** Frequency not known (cannot be estimated from the available data); After intramuscular administration local pain at the site of administration has been reported. For selenase® 300 Mikrogramm Tabletten: None known to date when selenase® 300 Mikrogramm Tabletten are used as directed. **Interactions:** selenase® 300 Mikrogramm Tabletten must not be taken together with reducing agents (e.g. vitamin C). However, selenase® 300 Mikrogramm Tabletten and vitamin C may be administered consecutively with an interval of at least 1 hour between both administrations. **Form of administration, size of packages:** selenase® 100 µg pro injectione: 10 or 50 ampoules of 2 ml solution for injection. selenase® T pro injectione: 2 or 10 injection vials of 10 ml solution for injection, hospital-size pack 30 (3 × 10) or 50 (5 × 10) injection vials of 10 ml solution for injection, 2 or 10 injection vials of 20 ml solution for injection, hospital-size pack 30 (3 × 10) or 50 (5 × 10) injection vials of 20 ml solution for injection. selenase® 100 µg peroral: 20, 60, 90 or 100 ampoules of 2 ml oral solution. selenase® T peroral: 10 drinking bottles of 10 ml oral solution plus one measuring cup. selenase® 300 Mikrogramm Tabletten: 20, 50, 100 tablets. **Prescription only medicine.**

# Dosage information on selenium in oncology



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