

# Complaint to TGA: Cabot Health Selenium Ultra Potent 60 Caps

## Acknowledgement:

This complaint was worked up by Monash University BMS3052 WAM Thurs 4pm Group 2-7; then edited and checked by Darci Bucheli and submitted by Assoc Prof Ken Harvey.

## Summary:

**We allege this is a 'high priority' complaint because the advertisement for this selenium supplement by Cabot Health (ABN 52 577 237 929) makes unfounded claims for effectiveness in HIV patients and links alleged selenium deficiency with the risk of neurological diseases (such as Alzheimer's) and cancer. In addition, there have been three previous complaints upheld by the TGACRP against Cabot Health.**

Selenium is an essential trace element that acts as a component of the enzyme glutathione peroxidase.

Cabot Health claim it is difficult to get adequate amounts of selenium from the diet. That this is due to the depletion of selenium in the soil, processing and mass production of foods and poor absorption of minerals due to intestinal inflammation. That studies have found a connection between selenium deficiency and increased incidence of viral infections, such as HIV. That people with chronic viral infections such as HIV, hepatitis or glandular fever have an increased requirement for selenium and are often deficient. That research suggests that those who consume a diet that is deficient in selenium, may have an increased risk of developing stomach, lung, skin, prostate and colon cancer.

We dispute the claim that selenium deficiency is common. We also argue that the claims that selenium deficiency will produce an increased incidence of viral infections such as HIV; neurological diseases such as Alzheimer's, and an increased risk of cancer will lead consumers to believe that they should take this supplement to reduce their risk of serious disease. These indications are not on the ARTG Public Summary. In addition, complementary medicines must not be advertised for serious disease.

Accordingly, we allege that advertisements for this product breach important provisions of the Therapeutic Goods Act 1989: 42DL(1)(a), (c), s.22(5) and the Therapeutic Goods Advertising Code 2015: s.5, 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(e) and 6(3).

## Claims:

1. "Unfortunately, it is difficult to get adequate amounts of selenium from the diet. This is due to the depletion of selenium in the soil, processing and mass production of foods and poor absorption of minerals due to intestinal inflammation."
2. "Studies have found a connection between selenium deficiency and increased incidence of viral infections, such as HIV." "Those with chronic viral infections such as HIV, hepatitis or glandular fever have an increased requirement for selenium and are often deficient."
3. "Research also suggests that those who consume a diet that is deficient in selenium, may have an increased risk of developing stomach, lung, skin, prostate and colon cancer." "Studies have shown that supplementing with selenium could be effective in reducing the risk of neurological diseases (such as Alzheimer's) and tumor formation."
4. "May be beneficial for those who want to slow down the ageing process."
5. "May be beneficial for those who have a history of stroke or cardiovascular disease."

# Complaint to TGA: Cabot Health Selenium Ultra Potent 60 Caps

**Advertisement type:** Internet

**Where did it appear:**

- <https://shop.cabothhealth.com.au/selenium-ultra-potent-60-caps>
- <https://www.chemistwarehouse.com.au/buy/77885/cabot-health-selenium-ultra-potent-60-capsules>
- <https://www.evelynfaye.com.au/selenium-ultra-potent.html>
- Etc.

**Date seen:** November 28, 2018

**Product:**

***Cabot Health Selenium Ultra Potent 60 Capsules; ARTG ID: 209209***

Sponsor: Health Direction Pty Ltd; Business name: Cabot Health; ABN 52 577 237 929

Active ingredients: selenomethionine -150 mcg

ARTG Start Date 6/5/2013

***Permitted indications:***

- None

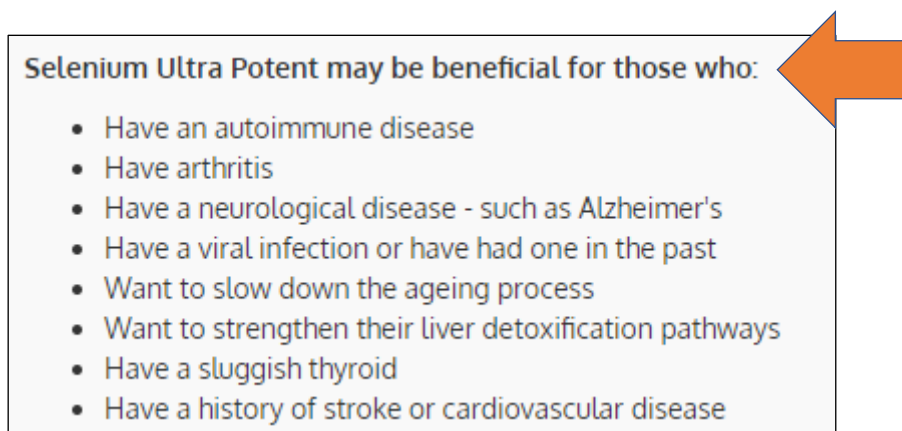
***Specific Indications:***

1. Selenium is a powerful antioxidant that helps to fight free radicals.
2. Selenium supports healthy immune system function.
3. Selenium has anti-inflammatory properties.

***Warnings required:***

1. This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
2. Keep out of reach of children (or words to that effect). **N.B. Not in advertisement.**
3. If symptoms persist consult your healthcare practitioner (or words to that effect).

**Screen shots:**



**Selenium Ultra Potent may be beneficial for those who:**

- Have an autoimmune disease
- Have arthritis
- Have a neurological disease - such as Alzheimer's
- Have a viral infection or have had one in the past
- Want to slow down the ageing process
- Want to strengthen their liver detoxification pathways
- Have a sluggish thyroid
- Have a history of stroke or cardiovascular disease

<https://shop.cabothhealth.com.au/selenium-ultra-potent-60-caps>

## Complaint to TGA: Cabot Health Selenium Ultra Potent 60 Caps

### SELENIUM ULTRA POTENT 60 CAPS

Ultra potent antioxidant



WAS AU \$23.50

**NOW AU \$18.80**

Sale Ends in 0 days 7 hours 31 mins 21 sec  
23:59 pm, 28 November 2018

IN STOCK

ON SALE

★★★★★ (1)

1

ADD TO CART



CALCULATE SHIPPING

Qty

Australia ▼

Post Code

Calculate



## SELENIUM ULTRA POTENT

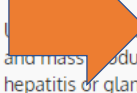
Our Selenium Ultra Potent capsules contain the therapeutic dose of the vitally important mineral selenium. Selenium is required for the production of glutathione - the most powerful antioxidant in the body. It is responsible for neutralising toxins, protecting cells from damage or mutation, strengthening the immune system and preventing viral replication. The organic form of selenium - selenomethionine has been used to improve absorption and utilisation by the body.

The benefits of selenium include:



**Immune system regulation:** Selenium acts as an antiviral agent and may assist the body in slowing down and preventing viral replication. Studies have found a connection between selenium deficiency and increased incidence of viral infections, such as HIV.


Selenium deficiency:



It is difficult to get adequate amounts of selenium from the diet. This is due to the depletion of selenium in the soil, processing and mass production of foods and poor absorption of minerals due to intestinal inflammation. Those with chronic viral infections such as HIV, hepatitis or glandular fever have an increased requirement for selenium, and are often deficient. Research also suggests that those who consume a diet that is deficient in selenium, may have an increased risk of developing stomach, lung, skin, prostate and colon cancer.

<https://shop.cabothealth.com.au/selenium-ultra-potent-60-caps>

## Complaint to TGA: Cabot Health Selenium Ultra Potent 60 Caps



### Cabot Health Selenium Ultra Potent 60 Capsules


Product ID: 77885

★★★★★ Write a review

# \$21.50

**SAVE \$2.00**  
Don't Pay RRP: \$23.50

QTY  
1 ▼

 **ADD TO CART**

#### General Information

Selenium Ultra Potent capsules contain the therapeutic dose of the vitally important mineral selenium. Selenium is required for the production of glutathione - the most powerful antioxidant in the body. It is responsible for neutralising toxins, protecting cells from damage and strengthening the immune system. The organic form of selenium - selenomethionine has been used to improve absorption and utilisation by the body.

#### Warnings

Selenium can be toxic in high doses. A daily dose of 150mcg of selenium for adults should not be exceeded.  
Keep out of reach of children.  
If symptoms persist consult your healthcare practitioner.

#### Common Uses

The benefits of selenium include:

**Immune system regulation:** Selenium is used to make selenoproteins which are involved in the activation and differentiation of immune cells.

**Strengthening detoxification pathways:** Glutathione is required by the liver and the kidneys for detoxification. Glutathione plays an important role in phase 2 liver detoxification which helps to convert toxins into water soluble compounds for excretion via sweat, urine and bowel movements. Selenium could be useful as part of a detox regime or after alcohol consumption.

**Cell protection:** Selenium helps to neutralise free radicals and toxins in the body to prevent them from damaging cells. Selenium, along with glutathione, may assist in repairing damaged DNA.

**Reducing inflammation:** Free radicals cause oxidative stress in the body, which leads to inflammation. Selenium plays an important role in helping to neutralise these free radicals and may regulate the production of inflammatory chemicals and immune cells. Selenium can help to reduce systemic inflammation in the body.

**Cardiovascular health:** Due to selenium's involvement in reducing inflammation, neutralising free radicals and improving blood flow, it may offer protection to the cardiovascular system. Observational studies suggest a link between selenium deficiency and increased risk of cardiovascular disease.

Selenium Ultra Potent may be beneficial for those who:


- Want to slow down the ageing process
- Want to strengthen their liver detoxification pathways
- Have a history of stroke or cardiovascular disease

Selenium deficiency:  
Unfortunately, it is difficult to get adequate amounts of selenium from the diet. This is due to the depletion of selenium in the soil, processing and mass production of foods and poor absorption of minerals due to intestinal inflammation.

<https://www.chemistwarehouse.com.au/buy/77885/cabot-health-selenium-ultra-potent-60-capsules>

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Home > Cabot Health Selenium Ultra Potent



### Cabot Health Selenium Ultra Potent

An important mineral for neutralising toxins, protecting cells, and strengthening your immune system.

Availability: **In stock**

OPTION	RRP	OUR PRICE	QTY
60 VeggieCaps	<del>\$29.00</del>	<b>\$22.95</b>	- 0 +

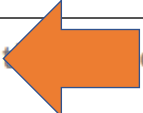
*or 4 interest free payments of \$5.74 after payA7 Learn more*

**SAVE \$6.05**

Email to a Friend

**DESCRIPTION**    **NUTRITIONAL INFORMATION**

Cabot Health (formerly known as Sandra Cabot's Health Formulations) Selenium Ultra Potent capsules contain a therapeutic dose of this vital and important mineral. Selenium is required for the production of glutathione- the most powerful antioxidant in the body. It is responsible for neutralising toxins, protecting cells from damage or mutation, strengthening the immune system and preventing viral replication. The organic form of selenium- selenomethionine has been used to improve absorption and utilisation by the body.

Cabot Health's Selenium Ultra Potent may be beneficial for :

- Have an autoimmune disease
- Have arthritis
- Have a neurological disease
- Have a viral infection or have had one in the past
- Want to slow down the ageing process
- Want to strengthen their liver detoxification pathways
- Have a sluggish thyroid
- Have a history of stroke or cardiovascular disease

<https://www.evelynfaye.com.au/selenium-ultra-potent.html>

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## Claims disputed and rationale:

1. *It is difficult to get adequate amounts of selenium from the diet.*

Selenium is found in a range of foods, the content of which varies with geographic sources of the food. In Australia and New Zealand, the main dietary sources of selenium are seafood, poultry and eggs and, to a lesser extent, other muscle meats.<sup>1</sup> The amount of selenium in food depends on the levels in soil that is used to grow crops, with availability depending on soil pH, redox potential, cation exchange capacity, and levels of Fe, sulphur, aluminum and carbon.<sup>2</sup>

Soil selenium availability varies in different areas, meaning that there is also variability in selenium deficiency in populations and sub-groups.<sup>3</sup> It is estimated that in Australia almost half of our selenium intake is provided by wheat.<sup>4</sup> Although it is thought that at least a billion people worldwide are deficient in selenium,<sup>5</sup> Australia is not considered an area with notably low selenium levels, these being parts of China, Siberia, central Africa, eastern Europe and New Zealand.<sup>6</sup>

A study of 834 South Australia residents found mean plasma selenium concentrations just exceeding the nutritional adequacy level in 288 residents.<sup>6</sup> A 20% decrease in mean whole blood selenium between 1977 and 1979 was also noted.<sup>6</sup> However, although levels are above the nutritional adequacy level, it is thought that many South Australians do not consume enough selenium to maximize selenoenzyme expression.<sup>6</sup> It has also been found that a number of Tasmanians possess low or marginal selenium intakes.<sup>7</sup> Despite this, research suggests that dietary sources of selenium (and other vitamins) are more effective and bioavailable than selenium present in supplements.<sup>7</sup>

Lyons et al., (2005) suggests that agronomic biofortification of wheat with selenium (applying selenium as selenite to the soil at seeding) is a viable option for increasing selenium levels in South Australians.<sup>8</sup> The addition of selenate to fertilizers has been occurring in Finland since 1984 and has been shown to be an effective way of increasing the population's selenium levels. Biofortification would offer a relatively easy to implement, effective and inexpensive way of increasing selenium levels when compared with supplementation.

Although there have been limited studies suggesting low selenium levels in some areas of Australia, this does not indicate that selenium is difficult to obtain from a healthy, balanced diet,<sup>9</sup> and even so, alternative strategies like biofortification could provide a more viable solution than supplementation with products like Cabot Health Selenium Ultra Potent. This also demonstrates that the product is not necessary to receive the required intake and not superior

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<sup>1</sup> <https://www.nrv.gov.au/nutrients/selenium>

<sup>2</sup> <https://www.frontiersin.org/articles/10.3389/fpls.2018.00730/full#B27>

<sup>3</sup> <https://www.frontiersin.org/articles/10.3389/fpls.2018.00730/full#B27>

<sup>4</sup> <https://www.sciencedirect.com.ezproxy.lib.monash.edu.au/science/article/pii/S0946672X0500043X>

<sup>5</sup> <https://www.sciencedirect.com/science/article/pii/S0946672X0500043X?via%3Dihub>

<sup>6</sup> <https://www.mja.com.au/journal/2004/180/8/trends-selenium-status-south-australians>

<sup>7</sup> <https://www.ncbi.nlm.nih.gov/pubmed/21521546>

<sup>8</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16240676>

<sup>9</sup> <https://theconversation.com/what-are-antioxidants-and-are-they-truly-good-for-us-86062>

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to dietary selenium, with supplements in fact considered less bioavailable and effective than dietary sources.<sup>10</sup> Reports of disease caused by selenium deficiency are rare.<sup>11,12</sup>

***We allege this claim breaches the Therapeutic Good Advertising Code 2015, s.4(1)(b) and 4(2)(c)***

2. *Studies have found a connection between selenium deficiency and increased incidence of viral infections, such as HIV.” “Those with chronic viral infections such as HIV, hepatitis or glandular fever have an increased requirement for selenium and are often deficient*

Selenium deficiencies have been shown in HIV patients. Evidence to support the efficacy of selenium supplementation in preventing viral replication and reduce HIV disease burden has however varied in quality and outcome.

A Cochrane review, (Visser et al., 2017) assessed whether micronutrient supplements are effective and safe in reducing mortality and HIV-related morbidity of HIV-positive adults (excluding pregnant women), identifying randomized controlled trials (RCTs) that compared supplements containing single, dual or multiple micronutrients (vitamins A and D, zinc and selenium) with placebo, no treatment or other supplements.<sup>13</sup> They included 33 trials with a total of 10,325 participants with 9 of these trials directly relating to selenium.<sup>14</sup> Multiple micronutrient supplementation was found to have ‘little or no effect on mortality in adults living with HIV’, with routine supplementation for up to 2 years having little or no effect on the average mean CD4+ cell count or the average mean viral load.<sup>15</sup> In terms of single or dual micronutrient supplement trials, there were no significant changes in CD4 cell count or viral load observed.<sup>16</sup>

Despite the fact that the review itself is of very high quality with low bias due to multiple independent reviewers and strict study protocol, only 4 RCTs were assessed to determine whether selenium supplementation improved CD4+ T cell count, and these were considered low quality due to high risk of bias, small populations in 3 trials and 1 large population trial reporting no effect on CD4+ T cell count. It was concluded that selenium supplementation may have little or no effect on CD4+ count<sup>17</sup>, which does not support the claim.

Hurwitz et al (2008) conducted a 2-arm double-blind, randomized, placebo-controlled RCT which comprised a pretreatment phase followed by an 18-month treatment protocol where participants were either given 200 mcg of selenium consisting of high-selenium yeast or a placebo.<sup>18</sup> Serum supplementation was found to increase serum selenium, decrease viral load and increase CD4+ cells but this only occurred if selenium-treated subjects had a serum selenium increase greater than 26.1 mcg/L.<sup>19</sup> Although this is a positive result in support of the claim, evidence is considered low quality due to risk of bias. The dose tested in this study is also 50 mcg

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<sup>10</sup> <https://www-sciencedirect-com.ezproxy.lib.monash.edu.au/science/article/pii/S0946672X0500043X>

<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=selenium+deficiency+case+report>

<sup>12</sup> <https://www.rrh.org.au/journal/article/4350>

<sup>13</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5458097/>

<sup>14</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5458097/>

<sup>15</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5458097/>

<sup>16</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5458097/>

<sup>17</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5458097/>

<sup>18</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/411535>

<sup>19</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/411535>

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higher than the 150-mcg dose in Cabot Health Ultra Potent Selenium supplement meaning these positive effects should not be extrapolated to apply to the lower dose.

Kupka et al (2008) conducted a 2-arm randomized, double-blind, placebo-controlled RCT on a population of HIV-infected pregnant women at 12-27 weeks gestation where women were given either 200 mcg of daily selenium as selenomethionine or placebo as supplements until 6 months after delivery.<sup>20</sup> Selenium supplements given to the women did not have significant effects on HIV-1 viral load, CD4 cell counts, although marginally decreased low birth weight risk and marginally increased fetal death risk.<sup>21</sup> This study does not support the claim, and even so, tested a higher dose of selenium than in the product and tested pregnant women so cannot be relied on.

Baum et al (2013) conducted a 4-arm RCT on 878 HIV-infected participants whereby they were given either daily multivitamins (vitamins B, C and E), a 200 mcg dose of selenium alone, the multivitamins and selenium together or a placebo for 24 months.<sup>22</sup> Results of patients who were given selenium or multivitamin alone were not statistically significant when compared to the placebo for the study endpoints (primary endpoints were HIV disease progression and secondary endpoints were AIDS onset or death and HIV viral load.<sup>23</sup> However, multivitamin and selenium together were significantly better than the placebo with regard to study endpoints.<sup>24</sup> Although this result does appear to support the product advertisement claim, these observations were only made when selenium was used in conjunction with a multivitamin and additionally the dose was 50 mcg higher than the product dose.

Considering this key review and 3 RCTs, although there is some minimal evidence that selenium may be beneficial in increasing CD4 T cell count and decreasing viral load in HIV patients, this cannot be relied upon by Cabot Health in making this claim in their advertisement for Ultra Potent Selenium. This is because evidence comes from poor-quality studies or does not support the claim at all (Visser et al., 2017, Kupka et al., 2008), or the fact that studies test different extracts or target groups than the product. All RCTs examined tested a higher dose of selenium than what is present in the product, and Kupka et al., 2008 tested on pregnant women.

The claims that selenium deficiency will produce an increased incidence of viral infections such as HIV; neurological diseases such as Alzheimer's, and an increased risk of cancer will lead consumers to believe that they should take this supplement to reduce their risk of serious disease. These indications are not on the ARTG Public Summary. In addition, complementary medicines must not be advertised for serious disease.

Accordingly, we allege that advertisements for this product breach important provisions of the Therapeutic Goods Act 1989: 42DL(1)(a), (c), s.22(5) and the Therapeutic Goods Advertising Code 2015: s.5, 4(1)(a), (b), 4(2)(a), 4(2)(c), 4(2)(d), and 4(2)(e).

### 3. *May be beneficial for those who want to slow down the ageing process.*

We could find no good clinical studies to support this claim.<sup>25</sup>

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<sup>20</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2474659/>

<sup>21</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2474659/>

<sup>22</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4347896/>

<sup>23</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4347896/>

<sup>24</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4347896/>

<sup>25</sup> <https://www.ncbi.nlm.nih.gov/pubmed?term=selenium%20aging>



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***We allege this claim breaches the Therapeutic Good Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c).***

4. *May be beneficial for those who have a history of stroke or cardiovascular disease.*

A review by Benstoem et al (2015) concluded there is insufficient evidence to support protective effects of selenium therapy in cardiovascular prevention<sup>26</sup>. A systematic review and meta-analysis of randomized controlled trials on the effect of selenium supplementation on coronary heart disease by Ju et al (2017) concluded that selenium supplementation did not reduce mortality.<sup>27</sup>

***We allege this claim breaches the Therapeutic Good Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c).***

### Previous complaints:

A search for Cabot on the TGACRP revealed three previous upheld complaints for this sponsor.<sup>28</sup>

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29 November 2018

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<sup>26</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4446741/>

<sup>27</sup> <https://www.ncbi.nlm.nih.gov/pubmed/28965605>

<sup>28</sup> <http://www.tgacrp.com.au/complaint-register/?search=Cabot>