

Package leaflet: Information for the patient

SELENIUM 10 micrograms/ml concentrate for solution for infusion

Selenium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of this medicine product is SELENIUM 10 micrograms/ml concentrate for solution for infusion but will be referred as SELENIUM throughout the whole leaflet.

What is in this leaflet

1. What SELENIUM is and what it is used for
2. What you need to know before you use SELENIUM
3. How to use SELENIUM
4. Possible side effects
5. How to store SELENIUM
6. Contents of the pack and other information

1. What SELENIUM is and what it is used for

SELENIUM contains the active substance sodium selenite. It belongs to a group of mineral supplements and provides a nutritional source of selenium. Selenium is an essential trace element that ensures your metabolism functions efficiently.

SELENIUM is used to:

- Prevent selenium deficiency in patients receiving parenteral nutrition (artificial feeding through a vein).
- Treat selenium deficiency that cannot be compensated by intake from food alone.

SELENIUM can be used in adults and in children.

Selenium is a trace element. It means your body needs only very small quantity of this nutriment. Selenium is essential for some of your organs (thyroid gland, liver, muscles), and your defence against risk of infection (immune system). Selenium also enhances the protection of your cell membranes against potential attack from diseases. Any selenium deficiency in your body might induce weakness of these organs or systems which could lead to tiredness, shortness of breath, muscular discomfort, abnormalities in nails or hair.

2. What you need to know before you use SELENIUM

Do not use SELENIUM:

- if you are allergic to selenium compounds.

Warnings and precautions

This medicine should not be injected without prior dilution.

Your doctor will use SELENIUM with caution if you are being administered nutrition through a vein (parenteral nutrition) and need to be given other medicines at the same time. This will help avoid undesirable reactions.

SELENIUM should not be administered at the same time as ascorbic acid (vitamin C). When these two substances are mixed, selenium can no longer be used by the body as a nutrition source.

Other medicines and SELENIUM

Tell to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy:

The use of SELENIUM is not recommended during pregnancy, unless considered essential.

Breast-feeding:

Selenium is excreted in human milk, but at therapeutic doses of selenium no effects on the breastfed newborns/infants are anticipated. Selenium can be used during breast-feeding.

Fertility:

There are no data on fertility from the use of selenium in humans. Selenium did not impair male fertility in rats, and effects of selenium on female fertility in rodents were only observed at very high doses (see section 5.3). Overall, doses used to correct selenium deficiency are not expected to exert adverse effects on fertility.

SELENIUM contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml vial, that is to say essentially 'sodium-free'.

3. How to use SELENIUM

This medicine will always be administered to you by a healthcare professional.

Your doctor will determine the dose of SELENIUM based on your needs. Samples of your blood will be taken during treatment. Your doctor will monitor the level of selenium in your blood to ensure it does not exceed the recommended level.

The recommended dose is:

- Adults:
 - o To supplement total parenteral nutrition: 60 to 100 micrograms daily.
 - o Other situation with proven selenium deficiency: 100 micrograms up to a maximum of 400 micrograms daily. Treatment will be given until selenium levels are normal.

- Paediatric population:
 - o To supplement total parenteral nutrition:
 - Infants: 2 micrograms/kg/day and infants with low birth weight: 2 to 3 micrograms/kg/day.
 - Children: 2 micrograms/kg/day, up to a maximum of 30 micrograms daily.
 - Adolescents: no data are available
 - o Other situation with proven selenium deficiency: No data are available

Method of administration

SELENIUM will be diluted before it is given to you as a slow infusion.

Duration of administration

The treatment duration will be determined by your doctor.

If you use more SELENIUM than you should

Symptoms of acute (short-term) overdose are garlicky breath, tiredness, vomiting, diarrhoea and abdominal pain. In case of chronic (long-term) overdose, skin and hair and nails can be affected with changes in nail and hair growth and may lead to peripheral polyneuropathies (a nerve disorder that can result in numbness or tingling).

In case of acute overdose by ingestion of large amount of selenium, treatment includes stomach pumping (gastric lavage) and forced diuresis. In case of extreme overdose (1,000 – 10,000x), elimination of selenite by dialysis can be tried. There is no specific antidote.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

There are no known side-effects in case of proper use.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SELENIUM

After dilution, chemical and physical in-use stability has been demonstrated for 48 h at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label. The expiry date refers to the last day of that month.

There are no specific storage conditions for this medicine.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SELENIUM contains

- The active substance is selenium. Each vial of 10 ml contains 100 micrograms of selenium as sodium selenite (219 micrograms). Each ml of solution contains 10 micrograms of selenium as sodium selenite (21.9 micrograms).
- The other ingredient is water for injection.

What SELENIUM looks like and contents of the pack

SELENIUM is a clear, colourless solution for infusion in glass vial.

Pack of 10 vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Laboratoire AGUETTANT
1, rue Alexander Fleming
69007 LYON
France

Manufacturer
Laboratoire AGUETTANT
1, rue Alexander Fleming
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France

DELPHARM Tours
Rue Paul Langevin
37170 CHAMBRAY LES TOURS
France

This leaflet was last revised in.

The following information is intended for healthcare professionals only:

This is an extract from the Summary of Product Characteristics to assist in the administration of Selenium Sterile concentrate. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the Summary of Product Characteristics of the product.

Incompatibilities:

Selenium is generally incompatible with high concentration of ascorbic acid (reduction of selenite to elemental selenium which is not soluble and unavailable as a nutritional source of selenium).

SELENIUM 10 micrograms/ml, concentrate for solution for infusion cannot be mixed with medicines other than sodium chloride 0.9%, glucose 5%, solution for parenteral nutrition or solution of trace elements.

Each ml of concentrate should be diluted in at least 5 ml of solution for infusion.