Kora Corporation Ltd. t/a Kora Healthcare
20 Harcourt Street
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Ireland

PACKAGE LEAFLET: INFORMATION FOR THE USER

Selenase® 100 micrograms, solution for injection (50 micrograms/ml)
100 microgram selenium per 2 ml solution for injection

Selenase® 500 micrograms, solution for injection (50 micrograms/ml)
500 microgram selenium per 10 ml solution for injection

Active substance: Sodium selenite pentahydrate

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT SELENASE® SOLUTION FOR INJECTION IS AND WHAT IT IS USED FOR

Selenase® solution for injection is a medicinal product which belongs to the group of the mineral supplements. Sodium selenite pentahydrate, the active substance in your solution for injection, provides a source of selenium, which is an essential trace element in nutrition to ensure that your metabolism functions efficiently.

Your doctor will have recommended this medicine because tests to measure the selenium levels in your blood have shown that you have a selenium deficiency, which cannot be corrected by selenium intake from food sources.

2. BEFORE YOU USE SELENASE® SOLUTION FOR INJECTION

Do not use Selenase® solution for injection
- if you are allergic (hypersensitive) to sodium selenite pentahydrate or any of the other ingredients of Selenase® solution for injection.
- if you have a selenosis (selenium poisoning).

Take special care with Selenase® solution for injection
There are no special warnings or precautions for the use of Selenase® solution for injection.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It must be ensured that the solution is not mixed with reducing substances (e.g. vitamin C).

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy:
There are no data from the use of Selenase® solution for injection in pregnant women. No adverse effect of sodium selenite on the pregnancy or the unborn child is expected, provided that it is used in case of proven selenium deficiency.

Breast-feeding:
Selenium is excreted into the breast milk. But doses correcting selenium deficiency in breast-feeding women are not expected to exert adverse effects on the breast-feeded infant.

Driving and using machines
There is no effect on the ability to drive and use machines.

Important information about some of the ingredients of Selenase® solution for injection
Selenase® solution for injection contains less than 1 mmol sodium (23 mg) per ml, therefore it is essentially “sodium free”.

3. HOW TO USE SELENASE® SOLUTION FOR INJECTION

Always use medicinal products exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Selenase® solution for injection is for single use only.

The usual daily dose is:
100 – 200 micrograms selenium (equivalent to 1 to 2 ampoules Selenase® 100 micrograms, solution for injection or 2 – 4 ml Selenase® 500 micrograms, solution for injection).

If the results from a blood test show that more selenium is required your doctor can increase the dose up to 500 micrograms selenium (equivalent to 5 ampoules Selenase®

100 micrograms, solution for injection or 1 injection vial Selenase® 500 micrograms, solution for injection).

Method of administration:
Selenase® solution for injection is always administered to you by a nurse or a doctor. Selenase® solution for injection is administered as an intramuscular (injection into the muscles) or intravenous (injection into a vein) injection.

Duration of treatment:
Samples of your blood will be taken from time to time and used to determine the levels of selenium in your blood in order to monitor the success of your treatment. As soon as your selenium levels will be normal your treatment with Selenase® solution for injection will be finished.

Dosage in children
If you are a child your doctor will prescribe you a dose of 2 µg/kg body weight per day at therapy onset and a maintenance dose of 1 µg/kg body weight per day. Samples of your blood will be taken from time to time and used to determine the levels of selenium in your blood in order to monitor the success of your treatment.

In the table below you can find the maximum daily doses for children for a longer time:

Age (years)	Tolerable Upper Intake Level (µg selenium/day)
1-3	60
4-6	90
7-10	130
11-14	200
15-17	250

Dosage in patients with renal or hepatic impairment:
Your doctor will not prescribe a different dose if you have renal or hepatic impairment.

If you use more Selenase® solution for injection than you should
If you use more Selenase® solution for injection than you should the following symptoms may occur:

- acute (short-term): odour of garlic on the breath, tiredness, nausea, diarrhoea and abdominal pain or
- chronic (long-term) what can affect the growth of nails and hair and may lead to peripheral polyneuropathy (a disorder of a nerve or nervous pathway that may be associated with numbness or tingling).

If you forget to use Selenase® solution for injection
Do not use a double dose to make up for a forgotten injection.

If you stop using Selenase® solution for injection
There are no special instructions, if you stop using Selenase® solution for injection.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Selenase® solution for injection can cause side effects, although not everybody gets them.

Frequency not known (cannot be estimated from the available data):
After intramuscular administration you may feel pain at the place, where your nurse or doctor has administered Selenase® solution for injection.

However, if you are given too much, the symptoms listed in the above section may be experienced.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SELENASE® SOLUTION FOR INJECTION

Keep out of the reach and sight of children.

The nurse or doctor will administer you this medicine immediately after opening the ampoules or the vials.

The nurse or doctor will not administer you this medicine if the ampoule or the vial is damaged or if the solution is cloudy.

This medicinal product does not require any special storage conditions.

Do not use Selenase® solution for injection after the expiry date which is stated on the label on the ampoule or the vial and on the carton after “EXP”. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Selenase® solution for injection contains
The active substance is:
Sodium selenite pentahydrate

The other ingredients are:
Sodium chloride, hydrochloric acid, water for injections

- Selenase® 100 micrograms, solution for injection:
  Each 2 ml injection ampoule contains 100 micrograms selenium in the form of 333 micrograms sodium selenite pentahydrate, corresponding to 50 micrograms/ml.

- Selenase® 500 micrograms, solution for injection:
  Each 10 ml injection vial contains 500 micrograms selenium in the form of 1,665 micrograms sodium selenite pentahydrate, corresponding to 50 micrograms/ml.

What Selenase® solution for injection looks like and contents of the pack

What Selenase® solution for injection looks like:
Selenase® solution for injection is a clear and colourless solution.

Contents of the pack:
- Selenase® 100 micrograms, solution for injection:
  Injection ampoules each containing 2 ml of injection solution are made of glass.
  Pack sizes: 5, 10 and 50.

- Selenase® 500 micrograms, solution for injection:
  Injection vials each containing 10 ml of solution for injection are made of clear, colourless glass closed with steel blue chlorobutyl rubber stopper, aluminium flip-off cap with natural coloured PP disc or closed with grey bromobutyl rubber stopper, aluminium flip-off cap with grey PP disc.
  Pack sizes: 2 and 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
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Ireland
Manufacturer:
biosyn Arzneimittel GmbH
Schorndorfer Strasse 32
70734 Fellbach
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

NL: selenase oplossing voor injectie 100 µg, oplossing voor injectie 50 µg/ml
selenase oplossing voor injectie 500 µg, oplossing voor injectie 50 µg/ml
CZ: selenase inječní roztok 500 µg, inječní roztok 50 µg/ml
HU: selesyn 100 microgramm, oldatos injekció
selesyn 500 microgramm, oldatos injekció
IE: selesyn 100 micrograms/2 ml solution for injection (50 micrograms/ml)
selesyn 500 micrograms/10 ml solution for injection (50 micrograms/ml)
IT: selesyn 100 mcg soluzione iniettabile
selesyn 500 mcg soluzione iniettabile
PT: selenase solução injectável 100 microgramas
selenase solução injectável 500 microgramas
SK: selenase inječný roztok 100 µg, inječný roztok 50 µg/ml
selenase inječný roztok 500 µg, inječný roztok 50 µg/ml
UK: selenase 100 micrograms, solution for injection (50 micrograms/ml)

selenase 500 micrograms, solution for injection (50 micrograms/ml)

This leaflet was last approved in 08/2023.

Further information for the medicinal staff

When preparing an infusion solution with Selenase® solution for injection as a supplement, it must be ensured that the pH value does not fall below 7.0 and that the solution is not mixed with reducing substances (e.g. vitamin C), as a precipitate of elemental selenium may possibly result. On grounds of safety, non-specific precipitation should be avoided after mixing infusion solutions with Selenase® solution for injection.

Elemental selenium is not soluble in an aqueous medium and has no biological availability.

When Selenase® solution for injection is administered as a supplement to general infusion solutions for total parenteral nutrition, a daily dose of 100 micrograms selenium (1 ampoule Selenase® 100 micrograms, solution for injection) must be ensured. There is no time limit to the administration of Selenase® solution for injection in a supplementary dose (100 micrograms selenium per day = 1 ampoule Selenase® 100 micrograms, solution for injection).

Selenium levels in the whole blood or serum should be determined in order to monitor the success of the therapy.

Selenase® solution for injection may be mixed with 0.9% NaCl.

This medicinal product does not require any special storage conditions.

The shelf-life of Selenase® solution for injection in the unopened ampoules or vials is 4 years.

Discard any unused contents.