Kora Corporation Ltd. t/a Kora Healthcare
20 Harcourt Street
Dublin 2, D02 H364
Ireland

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

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

Active substance: Sodium selenite pentahydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:
1. What Selenase® oral solution is and what it is used for
2. What you need to know before you use Selenase® oral solution
3. How to use Selenase® oral solution
4. Possible side effects
5. How to store Selenase® oral solution
6. Contents of the pack and other information

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

Selenase® oral solution is a medicinal product which belongs to the group of the mineral supplements. Sodium selenite pentahydrate, the active substance in your oral solution, 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. WHAT YOU NEED TO KNOW BEFORE YOU USE SELENASE® ORAL SOLUTION

Do not use Selenase® oral solution
- if you are allergic to sodium selenite pentahydrate or any of the other ingredients of this medicine (listed in section 6).
- if you have a selenosis (selenium poisoning).

Warnings and precautions
There are no special warnings or precautions for the use of Selenase® oral solution.
Talk to your doctor, pharmacist or nurse before using Selenase® oral solution.

Other medicines and Selenase® oral solution
Tell your doctor or pharmacist if you are taking/ using, have recently taken/ used or might take/ use any other medicines.

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

Selenase® oral solution and vitamin C should be administered at an interval of 4 hours.

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 or pharmacist for advice before taking this medicine.

Pregnancy:
There are no data from the use of Selenase® oral solution 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.

Fertility:
There are no data available regarding the effect on fertility.

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

3. HOW TO USE SELENASE® ORAL SOLUTION

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Selenase® oral solution is for single use only.

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

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, oral solution or 10 ml (2 x 5 ml) of Selenase® 500 micrograms, oral solution).

Use in children and adolescents
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.

For measuring your children's dose of less than 1 ml oral solution place approximately 5 ml oral solution in the measuring cup and draw up the needed volume with the enclosed pipette. For example if you have a 1-year-old child with 10 kg body weight the maintenance dose is 10 µg corresponding to 0.2 ml oral solution.

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:

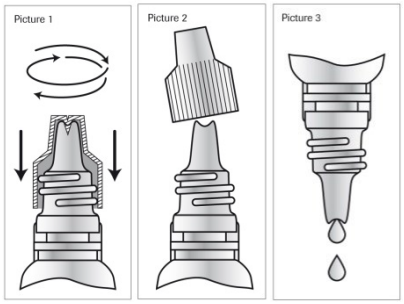
Age (years)	Tolerable Upper Intake Level (µg selenium/day)
1-3	60
4-6	90
7-10	130
11-14	200
15-17	250

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

Method of administration:
Selenase® oral solution is indicated for self-medication.

Selenase® 100 micrograms, oral solution:
Detach a single-dose ampoule from the remainder of the strip of ampoules and open the oral ampoule by twisting the top. Squeeze out the whole content of the ampoule into the mouth.

Selenase® 500 micrograms, oral solution:
You have to make the drinking bottle ready for use before use.



Picture 1:
Turn the screw cap first clockwise down in order to open the drinking bottle with the integrated spike of the screw cap.
Picture 2:
Then turn off the screw cap anti-clockwise.
Picture 3:
Please remove the required dose in milliliter which your doctor has prescribed you by carefully squeezing of the drinking bottle into the enclosed measuring cup with milliliter graduation. For example if you should take 500 micrograms selenium
please remove two times 5 ml (2 x 5 ml) from the drinking bottle. Then close the drinking bottle firmly.

Hold the liquid in the mouth for about 30 to 60 seconds before swallowing.

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® oral solution will be finished.

There is no time limit to the administration of Selenase® oral solution in a supplementary dose (100 micrograms selenium per day is equivalent to 1 ampoule).

If you use more Selenase® oral solution than you should
If you use more Selenase® oral solution 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® oral solution
Do not use a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

If Selenase® oral solution is given as directed, unwanted effects, so called side effects, have not been reported. 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® ORAL SOLUTION

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

Do not store Selenase® oral solution above 25 °C.

– Selenase® 100 micrograms, oral solution:
Use Selenase® 100 micrograms, oral solution immediately after opening the ampoules.

– Selenase® 500 micrograms, oral solution:
Use Selenase® 500 micrograms, oral solution immediately after opening of the drinking bottle.

Do not use this medicine if you notice the ampoule or the drinking bottle is damaged or if the solution is cloudy.

Discard any unused contents.

Do not use this medicine after the expiry date which is stated on the label on the ampoule or the drinking bottle and on the carton after “EXP”. The expiry date refers to the last day of that month.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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

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

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

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

What Selenase® oral solution looks like and contents of the pack
What Selenase® oral solution looks like:
Selenase® oral solution is a clear and colourless solution.

Contents of the pack:
- Selenase® 100 micrograms, oral solution:
  Ampoules each containing 2 ml of oral solution are made of plastic (LDPE)
  Pack sizes: 10, 20, 50, 60, 90 and 100.

- Selenase® 500 micrograms, oral solution:
  Drinking bottles of plastic (LDPE) with polypropylene screw cap each containing 10 ml of oral solution, a measuring cup and a dosing pipette.
  Pack sizes: 10, 20 and 50.

Not all pack sizes may be marketed.

Marketing Authorisation Holder**:**
Kora Corporation Ltd. t/a Kora Healthcare
20 Harcourt Street
Dublin 2, D02 H364
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 drank 100 µg, drank 50 µg/ml
selenase drank 500 µg, drank 50 µg/ml
HU: selesyn 100 microgramm, belsöleges oldat (oral solution)
selesyn 500 microgramm, belsöleges oldat (oral solution)
IE: selesyn 100 micrograms/2 ml, oral solution (50 micrograms/ml)
selesyn 500 micrograms/10 ml, oral solution (50 micrograms/ml)
IT: selesyn 100 mcg soluzione orale
selesyn 500 mcg soluzione orale
PT: selenase solução oral 100 microgramas
selenase solução oral 500 microgramas
SK: selenase perorálny roztok 100 µg, perorálny roztok 50 µg/ml
selenase perorálny roztok 500 µg, perorálny roztok 50 µg/ml
UK: selenase 100 micrograms, oral solution (50 micrograms/ml)
selenase 500 micrograms, oral solution (50 micrograms/ml)

This leaflet was last revised in 07/2024.