selesyn®
100 Peroral Oral Solution

SAFELINE PHARMACEUTICALS

Skeduleringstatus S1

Lees hierdie inligtingsblad noukeurig deur, want dit bevat inligting wat belangrik is vir jou.

selesyn® 100 peroral is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n minder ernstige siekte kan behandel. Jy moet selesyn® 100 peroral nogtans versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
- Moenie selesyn® 100 peroral met enigiemand anders deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies verlang.
- Jy moet 'n dokter gaan sien indien jou simptome vererger of nie verbeter nie.

Wat is in hierdie inligtingsblad

1. Wat is selesyn® 100 peroral en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy selesyn® 100 peroral neem
3. Hoe om selesyn® 100 peroral te neem
4. Moontlike newe-effekte
5. Hoe om selesyn® 100 peroral te berg
6. Inhoud van die verpakking en ander inligting

1. Wat is selesyn® 100 peroral en waarvoor word dit gebruik

selesyn® 100 peroral bevat: 0,333 mg natriumselenietpentahidraat gelykstaande aan 100 µg seleen.

Elke 2 mL orale oplossing bevat 0,31 mmol natrium.

selesyn® 100 peroral behoort aan 'n groep mineraalaanvullings en verskaf 'n voedingsbron van seleen.

Seleen is 'n essensiële spoorelement.

'n Seleentekort wat klinies bewys is en waarvoor nie gekompenseer kan word met voedingsbronne nie.

- wanvoeding. (Tekorte in 'n persoon se inname van energie en/of voedingstowwe.)

2. Wat jy moet weet voordat jy selesyn® 100 peroral neem

Moenie selesyn® 100 peroral neem nie

- indien jy allergies (hipersensitief) vir natriumselenietpentahidraat of enige van die ander bestanddele van selesyn® 100 peroral is (gelys by Afdeling 6)
- indien jy selenose het (seleenvergiftiging).

Waarskuwings en voorsorgmaatreëls

selesyn® 100 peroral moenie met reduseermiddels (bv. vitamien C) gemeng word nie, aangesien elementêre seleen mag presipiteer. selesyn® 100 peroral en vitamien C kan egter agtereenvolgend toegedien word met 'n interval van ten minste 1 uur tussen die toedienings.

Ander medisynes en selesyn® 100 peroral

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem (dit sluit alle komplementêre of tradisionele medisynes in).

selesyn® 100 peroral moenie met vitamien C gemeng word nie, aangesien presipitasie van die elementêre seleen kan voorkom. selesyn® 100 peroral en vitamien C kan egter agtereenvolgend toegedien word met 'n interval van ten minste 1 uur tussen die toedienings.

Swangerskap en Borsvoeding

Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige voordat jy selesyn® 100 peroral neem.

Bestuur en gebruik van masjinerie

Dit het geen effek op jou vermoë om 'n voertuig te bestuur of masjiene te gebruik nie.

3. Hoe om selesyn® 100 peroral te neem

Die gebruiklike dosis selesyn® 100 peroral is 100 µg seleen daagliks (gelykstaande aan 1 ampul).

Duur van toediening

Jou dokter sal bepaal hoe lank jou terapie sal duur.

Metode van toediening:

Mondelikse oplossing

Om selesyn® 100 peroral toe te dien, skei een ampul van die res van die strook en maak dit oop deur die bopunt af te draai. Druk die hele inhoud van die ampul uit in jou mondholte. Alternatiewelik kan die hele volume in 'n glas water verdun word voordat dit gedrink word.

4. Moontlike newe-effekte

Indien selesyn® 100 peroral gegee word soos wat aangedui word, word geen newe-effekte verwag nie.

Nie alle newe-effekte wat vir selesyn® 100 peroral gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy selesyn® 100 peroral gebruik, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg.

Rapportering van newe-effekte

Praat met jou dokter of apteker as jy newe-effekte ervaar. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form". Dit is 'n vorm om ongunstige geneesmiddelreaksies te rapporteer. Hierdie vorm is aanlyn beskikbaar onder SAHPRA se publikasies: www.sahpra.org.za/Publications/Index/8.

Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van selesyn® 100 peroral te verskaf.

5. Hoe om selesyn® 100 peroral te berg

Bêre by of onder 25 °C.

Die inhoud van die oopgemaakte ampul moet onmiddellik gebruik word.

Hou buite bereik van kinders.

6. Inhoud van die verpakking en ander inligting

Wat selesyn® 100 peroral bevat

Die aktiewe bestanddeel is:
Natriumselenietpentahidraat

1 ampul met 2 mL orale oplossing bevat:
0,333 mg natriumselenietpentahidraat, gelykstaande aan 100 µg seleen.

Die ander bestanddele is:
Natriumchloried, soutsuur, water vir inspuitings.

Hoe selesyn® 100 peroral lyk en inhoud van die verpakking

Helder, kleurlose orale oplossing in ampulle wat gemaak is van deurskynende, kleurlose poliëtileen.

Oorspronklike verpakking van 20 ampulle met 2 mL oplossing.

Houer van Registrasiesertifikaat

Safeline Pharmaceuticals (Edms.) Bpk.
Rugbystraat 4845
Weltevredenpark, Suid-Afrika
Telefoon: 011 288 5360

Hierdie inligtingsblad is laas hersien

24 Mei 2022

Registrasienommer

A38/24/0441

Toegang tot die ooreenstemmende Professionele Inligting:

Safeline Pharmaceuticals webtuiste:
www.safeline.co.za

selesyn®
100 Peroral Oral Solution

SAFELINE PHARMACEUTICALS

Scheduling status S1

Read all of this leaflet carefully because it contains important information for you.

selesyn® 100 peroral is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use selesyn® 100 peroral carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share selesyn® 100 peroral with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What selesyn® 100 peroral is and what it is used for
2. What you need to know before you take selesyn® 100 peroral
3. How to take selesyn® 100 peroral
4. Possible side effects
5. How to store selesyn® 100 peroral
6. Contents of the pack and other information

1. What selesyn® 100 peroral is and what it is used for

selesyn® 100 peroral contains: 0,333 mg sodium selenite pentahydrate corresponding to 100 µg selenium.

Each 2 mL oral solution contains 0,31 mmol Sodium.

selesyn® 100 peroral belongs to a group of mineral supplements and provides a nutritional source of selenium.

Selenium is an essential trace element.

Clinically proven selenium deficiency that cannot be compensated by nutritional sources.

– malnutrition. (Deficiencies in a person's intake of energy and/or nutrients.)

2. What you need to know before you use selesyn® 100 peroral

Do not take selesyn® 100 peroral

– if you are allergic (hypersensitive) to sodium selenite pentahydrate or any of the other ingredients of selesyn® 100 peroral (Listed in Section 6)

– if you have a selenosis (selenium poisoning).

Warnings and precautions

selesyn® 100 peroral must not be mixed with reducing agents (e.g., vitamin C) since a precipitation of elementary selenium could occur. However, selesyn® 100 peroral and vitamin C may be administered consecutively with an interval of at least 1 hour between both administrations.

Other medicines and selesyn® 100 peroral

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

selesyn® 100 peroral must not be mixed with vitamin C since a precipitation of elementary selenium could occur. However, selesyn® 100 peroral and vitamin C may be administered consecutively with an interval of at least 1 hour between both administrations

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking selesyn® 100 peroral.

Driving and using machinery

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

3. How to take selesyn® 100 peroral

The usual daily dose of selesyn® 100 peroral is 100 µg selenium daily (equivalent to 1 ampoule).

Duration of administration

The duration of the therapy will be determined by your doctor.

Method of administration:

Oral Solution

To administer selesyn® 100 peroral, separate one ampoule from the rest of the bar and open it by turning the top off. Press the complete contents of the ampoule into oral cavity. Alternatively, the complete volume can be diluted in a glass of water prior to administration.

4. Possible side effects

If selesyn® 100 peroral is given as directed, side effects are not expected.

Not all side effects reported for selesyn® 100 peroral are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using selesyn® 100 peroral please consult your health care provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of selesyn® 100 peroral.

5. How to store selesyn® 100 peroral

Store at or below 25 °C.

The contents of the opened ampoule must be used immediately.

Keep out of reach of children.

6. Contents of the pack and other information

What selesyn® 100 peroral contains

The active substance is:
Sodium selenite pentahydrate

1 ampoule of 2 ml oral solution contains:
0,333 mg sodium selenite pentahydrate corresponding to 100 µg selenium.

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

What selesyn® 100 peroral looks like and contents of the pack

Clear, colourless oral solution in ampoules made of clear, colourless polyethylene.

Original pack of 20 ampoules of 2 ml solution

Holder of Certificate of Registration

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This leaflet was last revised in

24 May 2022

Registration number

A38/24/0441

Access to the corresponding Professional Information:

Safeline Pharmaceuticals Website:
www.safeline.co.za

Druck-Nr. Tx-22236 · November 2022