SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

SELESYN 500 INJECTION

COMPOSITION

Each 10 ml vial contains sodium selenite pentahydrate equivalent to 500 µg of selenium
List of excipients:
Sodium chloride
Hydrochloric acid
Purified water

PHARMACOLOGICAL CLASSIFICATION

A 32.2 Other

PHARMACOLOGICAL ACTION

Pharmacodynamic Properties
Selenium is a trace element.
Selenium is excreted in the faeces, via the kidneys or the respiratory system depending on the administered dosage amount. Selenium is mainly excreted in the form of the trimethylselenium ion via the kidneys. The excretion path depends on the selenium status.
After intravenous administration the process of selenium excretion is divided into three phases.
The retention of selenium in the whole body decreases in three phases, with half-lives of 0,7-1,2 days in phase 1, 7-11 days in phase 2 and 96-144 days in phase 3.The selenium concentration decreases faster in the liver, heart and plasma than in the skeletal muscles or in the bones. An i.v. administered dose of sodium selenite 12 % is excreted within the first 24 hours. A further 40 % is eliminated with a biological half-life of 20 days. The half-life of the third phase is 115 days.
After administration of 82 µg selenium in the form of sodium selenite 18 % of the i.v. dose was excreted within the first 24 hours via the kidneys, together with metabolically exchanged physiological selenium.

INDICATIONS

Proven selenium deficiency in patients with sepsis in an intensive care unit that cannot be corrected by nutritional sources.
Selenium deficiencies may occur as a result of:
- states of maldigestion and malabsorption
- malnutrition

The selenium deficiency should be confirmed by low serum selenium levels.

CONTRA-INDICATIONS

Hypersensitivity to any of the excipients.
Selenosis

WARNINGS and SPECIAL PRECAUTIONS
One injection vial of 10 ml contains 1,55 mmol (33,70 mg) sodium. This has to be taken into consideration by patients on a controlled sodium (low sodium/low salt) diet.
Effects on ability to drive and use machines
No known restrictions.

INTERACTIONS

In parenteral administration as an additive to infusion solutions care must be taken to avoid any non-specific precipitations. The pH value must not fall below 7,0. The solution must not be mixed with reducing agents (e.g.) vitamin C since a precipitation of elementary selenium cannot be ruled out. Elementary selenium is insoluble in an aqueous medium and is therefore not bio available.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

The usual dose is 500 - 1000 µg selenium daily, preferably by bolus infusion over 0,5 -2 hours on the first day, followed by 24 hour continuous infusion on the subsequent days. SELESYN 500 is miscible with the following solutions: 5 % Dextrose in water, 20 % Dextrose in water, 0,9 % Sodium Chloride, 5 % Dextrose/0, 45 % Sodium Chloride and Ringer Lactate.
After dilution, the solution should be used immediately.
After mixing with SELESYN 500 all solutions should be checked for precipitation.

SIDE EFFECTS

None known to date if SELESYN 500 is administered according to prescription.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Manifestations of an acute overdose are garlic breath, fatigue, nausea, diarrhoea and abdominal pain. Chronic overdosing may affect the growth of nails and hair and may lead to peripheral polyneuropathy. Counter measures include gastric irrigation, forced diuresis or high doses of vitamin C.
In the event of extreme overdoses (1000 -10 000 times the normal dose) it should be attempted to eliminate the selenite by dialysis. The administration of dimercaprol is not advisable as it increases the toxicity of selenium.

IDENTIFICATION

Clear colourless solution free from visible particles.

PRESENTATION

SELESYN 500 INJECTION is available in a 10 ml clear, colourless, Type 1, glass vial.
Supplied in cartons containing 2 and 10 vials.

STORAGE INSTRUCTIONS

Store at or below 25 °C.
The contents of the opened vials must be used immediately. Any unused portion must be discarded after opening.
After dilution, the solution should be used immediately.
Do not refrigerate.
Keep out of reach of children.

REGISTRATION NUMBER

A38/32.2/0442

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Safeline Pharmaceuticals (Pty) Ltd
4845 Rugby Street
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DATE OF PUBLICATION OF THE PACKAGE INSERT

29 July 2016

SKEDULERINGSTATUS S4

EIENDOMSNAAM EN DOSEERVORM

SELESYN 500 INJECTION

SAMESTELLING

Elke 10 ml flessie bevat natriumselenietpentahidraat gelykstaande aan 500 µg selenium.
Lys van onaktiewe bestanddele:
Natriumchloried
Soutsuur
Gesuiwerde water

FARMAKOLOGIESE KLASSIFIKASIE

A 32.2 Ander

FARMAKOLOGIESE WERKING

Farmakodinamiese Eienskappe
Selenium is 'n spoorelement.
Selenium word in die feses, via die niere of die lugwegstelsel uitgeskei, afhangende van die dosis wat toegedien is. Selenium word hoofsaaklik deur die niere in die vorm van die trimetielselenium-ioon uitgeskei. Die roete van uitskeiding hang af van die selenium status.
Ná intraveneuse toediening word die proses van die uitskeiding van selenium verdeel in drie fases.
Die retensie van selenium in die hele liggaam neem in drie fases af, met halfleeftye van 0,7-1,2 dae in fase 1, 7-11 dae in fase 2 en 96-144 dae in fase 3. Die seleniumkonsentrasie daal vinniger in die lewer, hart en plasma as in die skeletspiere of -bene. Van 'n dosis natriumseleniet wat intraveneus toegedien is, word 12 % binne die eerste 24 uur uitgeskei. 'n Verdere 40 % word met 'n biologiese halfleeftyd van 20 dae geëlimineer. Die halfleeftyd van die derde fase is 115 dae.
Ná toediening van 82 µg selenium in die vorm van natriumseleniet, is 18 % van die intraveneuse dosis binne die eerste 24 uur via die niere uitgeskei, saam met metabolies-uitgeruilde fisiologiese selenium.

INDIKASIES

Bewese tekort aan selenium in pasiënte met sepsis in 'n intensiewesorgeenheid, wat nie met voedingsbronne reggestel kan word nie.
Seleniumtekorte mag voorkom as gevolg van:
- toestande van wanvertering en wanabsorpsie
- wanvoeding

Die seleniumtekort moet bevestig word met lae serumseleniumvlakke.

KONTRA-INDIKASIES

Hipersensitiwiteit vir enige van die eksipiënte.
Selenose.

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS

Een flessie 10 ml inspuiting bevat 1,55 mmol (33,70 mg) natrium. Dit moet in ag geneem word by pasiënte op 'n natriumbeperkte (lae natrium/lae sout) dieet.
Uitwerking op die vermoë om te bestuur en masjiene te gebruik
Geen beperking bekend nie.

INTERAKSIES

As 'n byvoeging tot infusie-oplossings by parenterale toedienings, moet sorg geneem word om enige niespesifieke presipitasies te vermy. Die pH-waarde moet nie laer as 7,0 daal nie. Die oplossing moet nie met reduseermiddels (bv. vitamien C) gemeng word nie, aangesien presipitasie van elementêre selenium nie uitgeskakel kan word nie. Elementêre selenium is onoplosbaar in 'n waterige medium en is gevolglik nie biobeskikbaar nie.

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS

Die gewone dosis is 500 - 1000 µg selenium daagliks, verkieslik deur 'n bolus infusie oor 0,5 – 2 uur op die eerste dag, gevolg deur 24 uur aaneenlopende infusie op daaropvolgende dae. SELESYN 500 kan met die volgende oplossings gemeng word: 5 % Dekstrose in water, 20 % Dekstrose in water, 0,9 % Natriumchloried, 5 % Dekstrose/0,45 % Natriumchloried en Ringer-oplossing met laktaat. Die oplossing moet onmiddellik na verdunning gebruik word. Ná vermenging met SELESYN 500 moet alle oplossings nagegaan word vir tekens van presipitasie.

NEWE-EFFEKTE

Huidiglik is geen newe-effekte bekend indien SELESYN 500 volgens voorskrif toegedien word nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Manifestasies van 'n akute oordosis is knoffelasem, vermoeidheid, naarheid, diarree en buikpyn. Chroniese oordosering mag die groei van hare en naels beïnvloed en kan lei tot perifere polineuropatie. Teenmaatreëls sluit gastriese spoeling, geforseerde diurese of hoë dosisse vitamien C in.
In die geval van uiterste oordosisse (1 000 – 10 000 keer die normale dosis) moet probeer word om die seleniet met dialise te elimineer. Dit is nie raadsaam om dimerkaprol toe te dien nie, want dit verhoog die toksisiteit van selenium.

IDENTIFIKASIE

Helder, kleurlose oplossing sonder enige sigbare deeltjies.

AANBIEDING

SELESYN 500 INJECTION is beskikbaar in 'n 10 ml helder, kleurlose, Tipe 1 glasflessie.
Dit word verskaf in kartonne met 2 en 10 flessies.

BEWARINGSINSTRUKSIES

Bêre by of onder 25 °C.
Die inhoud van oopgemaakte flessies moet onmiddellik gebruik word. Enige ongebruikte deel moet weggegooi word nadat dit oopgemaak is.
Die oplossing moet onmiddellik gebruik word na verdunning.
Moenie in die yskas bêre nie.
Hou buite bereik van kinders.

REGISTRASIENOMMER

A38/32.2/0442

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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