APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

SOLUVIT® NOVUM (lyophilized powder for solution for infusion)

Sugar free

Read all of this leaflet carefully before you are given SOLUVIT NOVUM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SOLUVIT NOVUM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What SOLUVIT NOVUM is and what it is used for

SOLUVIT NOVUM is a sterile concentrate which provides the body with water-soluble

multivitamins by the intravenous route, when the intake of nutrients or food is not possible, or it is not enough to supply the body's needs.

2. What you need to know before you are given SOLUVIT NOVUM

SOLUVIT NOVUM should not be administered to you:

- if you are hypersensitive (allergic) to folic acid, thiamine, methyl parahydroxybenzoate or any of the other ingredients of SOLUVIT NOVUM **(listed in section 6)**

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with SOLUVIT NOVUM:

- If you have an allergy to any other medicines
- If you take medicines for seizures (“fits”), such as phenytoin
- if you have anaemia (decrease in the total amount of red blood cells)
- if your vision is affected. The optic nerve may be affected in people receiving high doses of cyanocobalamin (also contained in SOLUVIT NOVUM)

SOLUVIT NOVUM contains 60,0 µg biotin per 10 mL vial. If you are about to undergo laboratory testing you must tell your doctor or the laboratory personnel that you are taking or have recently taken SOLUVIT NOVUM because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking SOLUVIT NOVUM before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin and affect the results of laboratory tests. Please inform your doctor or the laboratory personnel, if you are taking such products.

Other medicines and SOLUVIT NOVUM

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

This is especially important with the following medicines:

- Phenytoin (or other medicines used for seizures)
- Barbiturates (medicines used for sleeping problems)
- Levodopa (used for parkinsonism)

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

SOLUVIT NOVUM may be used during pregnancy or if you breastfeed your baby.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

SOLUVIT NOVUM may make some people feel dizzy. If this happens to you, do not drive or use tools or machines as SOLUVIT NOVUM could interfere with your ability to drive safely.

It is not always possible to predict to what extent SOLUVIT NOVUM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SOLUVIT NOVUM affects them.

SOLUVIT NOVUM contains glycine (amino acetic acid) and disodium edetate.

SOLUVIT NOVUM contains a preservative, methyl parahydroxybenzoate.

Before receiving SOLUVIT NOVUM, tell your doctor if you are allergic to any preservatives (listed in point 6 below).

3. How SOLUVIT NOVUM is given to you

Do not share medicines prescribed for you with any other person SOLUVIT NOVUM should be dissolved first and then diluted for single infusion only. SOLUVIT NOVUM is usually mixed in the bag of amino acids, glucose and/or fats, fat-soluble vitamins and given as a continuous infusion into a central vein. Your doctor will tell you how long your treatment with SOLUVIT NOVUM will last**.** If you have the impression that the effect of SOLUVIT NOVUM is too strong or too weak, tell your doctor or pharmacist**.** You will not be expected to give yourself SOLUVIT NOVUM. It will be given to you by a person who is qualified to do so.

If you receive more SOLUVIT NOVUM than you should

Since a healthcare provider will administer SOLUVIT NOVUM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage**.**

If you missed a dose of SOLUVIT NOVUM

You need not remember when to get your next dose; you will be cared for in hospital/clinic by a healthcare professional, who will ensure that you receive the correct amount of SOLUVIT NOVUM at the right time. Do not receive a double dose to make up for forgotten individual doses.

Since a health care provider will administer SOLUVIT NOVUM, it is unlikely that the dose will be missed.

4. Possible side effects

SOLUVIT NOVUM can have side effects. Not all side effects reported for SOLUVIT NOVUM are included in this leaflet. Should your general health worsen or if you experience any

untoward effects while taking SOLUVIT NOVUM, please consult your healthcare provider for advice.

If any of the following happens, stop using SOLUVIT NOVUM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SOLUVIT NOVUM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Skin rashes, flushing, redness, itching
- Headaches
- Dizziness
- Agitation

These are all serious side effects. You may need urgent medical attention. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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

By reporting side effects, you can help provide more information on the safety of SOLUVIT NOVUM.

You should also report side effects to the Holder of Certificate of Registration, **Fresenius Kabi South Africa (Pty) Limited.**

The contact details for our national reporting system are:

Email: safety.fksa@fresenius-kabi.com

Tel: +27 11 545 0000

Emergency: 0860 203 900

5. How to store SOLUVIT NOVUM

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Your healthcare professional will check that the SOLUVIT NOVUM is not past its expiry date stated on the label and carton before giving you the injection.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOLUVIT NOVUM contains

Each 10 mL contains:

Thiamine mononitrate corresponding to thiamine HCl	3,2 mg
Sodium riboflavin phosphate corresponding to riboflavin	3,6 mg
Nicotinamide	40,0 mg
Pyridoxine hydrochloride corresponding to pyridoxine	4,0 mg
Sodium pantothenate corresponding to pantothenic acid	15,0 mg
Sodium ascorbate corresponding to ascorbic acid	100,0 mg
Biotin	60,0 µg
Folic acid	0,4 mg
Cyanocobalamin	5,0 µg
The other ingredients are:	
Methyl parahydroxybenzoate (as preservative)	0,005 % *m/v*

Glycine	300 mg
Disodium edetate	0,5 mg

What SOLUVIT NOVUM looks like and contents of the pack

A lyophilised, sterile, yellow powder

1 x 10 mL vial

10 x 10 mL vials

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House extension 7

Midrand

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1685

Telephone number: (011) 545 0000

This leaflet was last revised on

04 May 2021

Registration number

U/22.1.4/200

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

S3

SOLUVIT® NOVUM (gevriesdroogde poeier vir oplossing vir infusie)

Suikervry

Lees die hele inligtingsblad deeglik deur voordat SOLUVIT NOVUM aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- SOLUVIT NOVUM is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad

1. Wat is SOLUVIT NOVUM en waarvoor word dit gebruik
2. Wat jy moet weet voordat SOLUVIT NOVUM aan jou gegee word
3. Hoe SOLUVIT NOVUM aan jou gegee word
4. Moontlike newe-effekte
5. Hoe om SOLUVIT NOVUM te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is SOLUVIT NOVUM en waarvoor word dit gebruik

SOLUVIT NOVUM is 'n steriele konsentraat wat wateroplosbare multivitamiene intraveneus

aan die liggaam lewer wanneer die inname van voedingstowwe of voedsel nie moontlik of nie voldoende is om aan die liggaam se behoeftes te voldoen nie.

2. Wat jy moet weet voordat SOLUVIT NOVUM aan jou gegee word

SOLUVIT NOVUM moet nie aan jou toegedien word nie:

- indien jy hipersensitief (allergies) is vir foliensuur, tiamien, metielparahidroksibensoaat of enige van die ander bestanddele van SOLUVIT NOVUM (gelys in afdeling 6)

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat jy ingespuit word:

Spesiale sorg moet gedra word met SOLUVIT NOVUM:

- Indien jy allergies is vir enige ander medisyne
- Indien jy medisyne neem vir epileptiese aanvalle ("stuipe"), soos fenitoïen
- as jy anemie het (afname in die totale hoeveelheid rooibloedselle)
- indien jou sig aangetas is. By mense wat hoë dosisse sianokobalamien (ook bevat in SOLUVIT NOVUM) ontvang, kan die optiese senuwee aangetas word.

SOLUVIT NOVUM bevat 60,0 µg biotien per 10 mL flessie. Indien jy op die punt staan om laboratoriumtoetse te ondergaan, moet jy jou dokter of die laboratoriumpersoneel inlig dat jy SOLUVIT NOVUM neem of onlangs geneem het, aangesien biotien die resultate van sulke toetse kan beïnvloed. Afhangende van die toets, kan die resultate valslik verhoog of valslik verlaag wees as gevolg van biotien. Jou dokter kan jou vra om op te hou om SOLUVIT NOVUM te neem voordat laboratoriumtoetse uitgevoer word. Jy moet ook in ag neem dat ander produkte wat jy dalk neem, soos multivitamienpreparate of aanvullings vir hare, vel en naels, biotien kan bevat en die resultate van laboratoriumtoetse kan beïnvloed. Lig asseblief jou dokter of die laboratoriumpersoneel in as jy sulke produkte gebruik.

Ander medisyne en SOLUVIT NOVUM

Lig altyd jou gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Dit is veral belangrik vir die volgende medisyne:

- Fenitoïen (of ander medisyne gebruik vir aanvalle)
- Barbiturate (medisyne gebruik vir slaapprobleme)
- Levodopa (gebruik vir parkinsonisme)

Swangerskap en borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne ontvang.

SOLUVIT NOVUM kan tydens swangerskap of as jy jou baba borsvoed, gebruik word.

Bestuur en die gebruik van masjinerie

Moenie bestuur of masjiene gebruik as jy enige newe-effekte ervaar wat jou vermoë om dit te doen, kan verminder nie.

SOLUVIT NOVUM kan sommige mense duiselig maak. Indien dit met jou gebeur, moenie bestuur of gereedskap of masjinerie gebruik nie omdat SOLUVIT NOVUM jou vermoë om veilig te bestuur kan beïnvloed.

Dit is nie altyd moontlik om te voorspel tot hoe 'n mate SOLUVIT NOVUM die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is tot hoe 'n mate SOLUVIT NOVUM hulle aantas nie.

SOLUVIT NOVUM bevat glisien (amino-asynsuur) en dinatriumedetaat. SOLUVIT NOVUM bevat 'n preserveermiddel, metielparahidroksibensoaat.

Voordat jy SOLUVIT NOVUM ontvang, lig jou dokter in as jy allergies is vir enige preserveermiddels (gelys in punt 6 hieronder).

3. Hoe SOLUVIT NOVUM aan jou gegee word

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. SOLUVIT NOVUM moet eers opgelos en dan verdun word vir slegs 'n enkele infusie. SOLUVIT NOVUM word gewoonlik in 'n sakkie gemeng met aminosure, glukose en/of vette, vetoplosbare vitamiene en as 'n deurlopende infusie in 'n sentrale aar toegedien. Jou dokter sal jou inlig hoe lank jou behandeling met SOLUVIT NOVUM sal duur**.** Indien jy die indruk kry dat die effek van SOLUVIT NOVUM te sterk of te swak is, lig jou dokter of apteker in**.** Daar sal nie van jou verwag word om SOLUVIT NOVUM aan jouself toe te dien nie. Dit sal deur 'n gekwalifiseerde persoon aan jou gegee word.

Indien jy meer SOLUVIT NOVUM ontvang as wat jy moes

Aangesien 'n gesondheidsorgverskaffer SOLUVIT NOVUM sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel**.**

Indien 'n dosis SOLUVIT NOVUM oorgeslaan is

Jy hoef nie te onthou wanneer jy jou volgende dosis moet kry nie; jy sal in 'n hospitaal/kliniek deur 'n gesondheidsorgkundige versorg word, wat seker sal maak dat jy die regte hoeveelheid SOLUVIT NOVUM op die regte tyd ontvang. Moenie 'n dubbele dosis ontvang om te vergoed vir individuele dosisse wat oorgeslaan is nie.
Aangesien 'n gesondheidsorgverskaffer SOLUVIT NOVUM sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

SOLUVIT NOVUM kan newe-effekte hê. Nie alle newe-effekte wat vir SOLUVIT NOVUM

aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy SOLUVIT NOVUM ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, staak SOLUVIT NOVUM en sê dadelik vir jou dokter daarvan, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik maak om te sluk of asem te haal

Hierdie newe-effekte is almal baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige allergiese reaksie op SOLUVIT NOVUM hê. Jy kan moontlik dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy die volgende waarneem:

- Veluitslag, gloede, rooiheid, jeuking
- Hoofpyn
- Duiseligheid
- Onrustigheid

Hierdie newe-effekte is almal ernstig. Jy kan dringende mediese aandag benodig. Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, praat met jou dokter of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8 Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van

SOLUVIT NOVUM te verskaf.

Jy moet ook newe-effekte aanmeld by die registrasiehouer, **Fresenius Kabi South Africa (Pty) Limited.**

Die kontakbesonderhede vir ons nasionale aanmeldingstelsel:

Epos: safety.fksa@fresenius-kabi.com

Tel: +27 11 545 0000

Nood: 0860 203 900

5. Hoe om SOLUVIT NOVUM te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 25 °C. Beskerm teen lig.

Jou gesondheidsorgverskaffer sal voordat die inspuiting aan jou gegee word seker maak of SOLUVIT NOVUM nie reeds die vervaldatum wat op die etiket en karton aangebring is, bereik het nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat SOLUVIT NOVUM bevat

Elke 10 mL bevat:

Tiamienmononitraat wat ooreenstem met tiamien HCl	3,2 mg
Natriumriboflavienfosfaat wat ooreenstem met riboflavien	3,6 mg
Nikotienamied	40,0 mg
Piridoksienhidrochloried wat ooreenstem met piridoksien	4,0 mg
Natriumpantotenaat wat ooreenstem met pantoteensuur	15,0 mg
Natriumaskorbaat wat ooreenstem met askorbiensuur	100,0 mg
Biotien	60,0 µg

Foliensuur	0,4 mg
Sianokobalamien	5,0 µg
Die ander bestanddele is:	
Metielparahidroksibensoaat (as preserveermiddel)	0,005 % *m/v*
Glisien	300 mg
Dinatriumedetaat	0,5 mg

Hoe SOLUVIT NOVUM lyk en inhoud van die pakkie

'n Gevriesdroogde, steriele, geel poeier

1 x 10 mL flessie

10 x 10 mL flessies

Houer van die Registrasiesertifikaat

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Erf 7, Growthpoint Business Park

Tonettistraat 162

Halfway House uitbreiding 7

Midrand

Gauteng

1685

Telefoonnommer: (011) 545 0000

Hierdie inligtingsblad is voorheen hersien op

04 Mei 2021

Registrasienommer

U/22.1.4/200

Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.