

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

Klusivit Syrup

Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₃, Vitamin B₅, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D₃, Calcium, Iron, Magnesium, Phosphorus, Zinc
Sugar free
Contains sweetener: Sucralose 2,00 mg/ml

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

Category: D.34.12 Multiple Substance formulation

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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

Klusivit Syrup is available without a doctor's prescription, for you to maintain your child's health. Nevertheless, you still need to use Klusivit Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Klusivit Syrup with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What Klusivit Syrup is and what it is used for

Klusivit Syrup is a multivitamin and mineral health supplement for children, and it assists in them meeting their daily nutritional needs as a factor in the maintenance of good health. Each vitamin and mineral in Klusivit Syrup plays a vital role in the support of overall health. The table below shows a brief summary of these functions.

VITAMIN / MINERAL	FUNCTION
Vitamin A	Contributes to the maintenance of eyesight, skin, membranes and immune function. Contributes to the development and maintenance of night vision. Contributes to the development and maintenance of bones and teeth.
Vitamin B ₁ ; Vitamin B ₃	Helps to metabolise carbohydrates, fats and proteins. Contributes to normal growth.
Vitamin B ₂ ; Vitamin B ₅ ; Vitamin B ₆	Helps to metabolise carbohydrates, fats and proteins. Contributes to tissue formation.
Vitamin B ₁₂	Helps to metabolise carbohydrates, fats and proteins. Contributes to normal red blood cell formation.
Vitamin C	Helps to metabolise fats and proteins. Helps in the development and maintenance of bones cartilage, teeth and gums. Helps in connective tissue formation and wound healing. An antioxidant for the maintenance of good health.
Vitamin D ₃	Helps in the development and maintenance of bones and teeth. Helps in the absorption and use of calcium and phosphorus
Calcium	Contributes to the development and maintenance of bones and teeth.
Iron	Helps to form red blood cells and helps in their proper function.
Magnesium	Helps to metabolise carbohydrates, fats and proteins. Contributes to the development and maintenance of bones and teeth. Contributes to tissue formation. Contributes to the maintenance of normal muscle function.
Phosphorus	Helps to metabolise carbohydrates, fats and proteins. Contributes to the development and maintenance of normal bones and teeth.
Zinc	Helps in connective tissue formation. Helps to maintain healthy skin. Helps the body to metabolise carbohydrates, fats and proteins. Helps to maintain immune function.

2. What you need to know before you use Klusivit Syrup

Do not give Klusivit Syrup if any of the following conditions are present:

- Hypersensitivity (allergy) to any of the ingredients of Klusivit Syrup (listed in section 6).
- Hypercalciuria (excess calcium in the urine) or hypercalcaemia (excess blood calcium levels).
- Iron-storage or iron-absorption diseases such as haemochromatosis.
- Existing gastrointestinal diseases such as inflammatory bowel disease, intestinal strictures or diverticulae.
- Renal (kidney) or hepatic (liver) insufficiency.
- Hypercalcaemia.
- Calcium associated kidney stones.
- Heart disease.
- High levels of vitamin D in the body or simultaneous intake of products containing vitamin D.

Warnings and precautions

Take special care with Klusivit Syrup:

- Vitamin B₃ should be given with caution in children with peptic ulcers.
- Klusivit Syrup should not be given to a child with anaemia resulting from a suspected vitamin B₁₂ deficiency without first confirming the diagnosis.
- Klusivit Syrup contains vitamin D and should therefore be used with caution in infants, who may have increased sensitivity to its effects.
- Infants taking Klusivit Syrup must be closely monitored for hypercalcaemia or signs of vitamin D toxicity if they are breast-fed by mothers taking pharmacological doses of vitamin D.
- Klusivit Syrup contains vitamin A and is indicated for use in children; however, caution should be taken as there is an increased risk of hypervitaminosis A (too much vitamin A in the body) if Klusivit Syrup is given with synthetic retinoids such as acitretin, isotretinoin and tretinoin.

Other medicines and Klusivit Syrup

Always tell your healthcare provider if your child is taking any other medicine. (This includes all complementary or traditional medicines).

Klusivit Syrup may interact with the following medicines. Please check with your healthcare provider before giving your child this medicine, if your child is taking:

- Antibiotics such as tetracyclines and quinolones, as the magnesium in Klusivit Syrup may decrease the absorption of the antibiotics. If given together, the doses of Klusivit Syrup and the antibiotic should be separated by a number of hours;
- Thiazide diuretics, calcium or phosphates, as the vitamin D in Klusivit Syrup may result in a risk of hypercalcaemia;
- Retinoids such as acitretin, isotretinoin and tretinoin, as the vitamin A in Klusivit Syrup may contribute to hypervitaminosis A;
- Antiepileptic medicines such as phenytoin, carbamazepine and phenobarbital, as vitamin B₆ may interfere with their effectiveness;

- Levodopa, a medicine used in the treatment of Parkinsons disease, as vitamin B₆ may decrease the effectiveness of levodopa.

Klusivit Syrup with food and drink

Klusivit Syrup should be taken once daily after food. (See Section 3, How to give Klusivit Syrup).

Pregnancy, breastfeeding and fertility

Klusivit Syrup is indicated for use in children. Regardless of this, please take note of the following:

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 using this medicine.

3. How to give Klusivit Syrup

Do not share any medicines with any other person.

Always give Klusivit Syrup exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Children 1 to 13 years old: 5 ml once daily, after food, or as directed by a healthcare provider.

Shake the bottle well before use.

If you give more Klusivit Syrup than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to give Klusivit Syrup

If you forget to give a dose, give it as soon as you remember to, then go back to your regular dosage schedule.

Do not give a double dose to make up for any forgotten individual doses.

4. Possible side effects

Klusivit Syrup can have side effects.

Not all side effects reported for Klusivit Syrup are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking Klusivit Syrup, please consult your doctor or healthcare provider for advice.

If any of the following happens, stop giving your child Klusivit Syrup and tell your doctor immediately, or take the child to the casualty department at your nearest hospital:

- Swelling of the face, throat, lips or tongue,
- Rash or itching,
- Difficulty in breathing or swallowing.

These are all very serious side effects. If your child has any of these, he/she may have had a serious reaction to Klusivit Syrup. They may require urgent medical attention. Your child may also experience the following mild side effects:

- Headache,
- Stomach complaints such as diarrhoea, constipation, stomach pain or cramps,
- Nausea and vomiting,
- Yellow discoloration of urine,
- Darkening of stools.

Most of these reported side effects occur when your child takes more Klusivit Syrup than they should. It is therefore important that your child receives the correct Klusivit Syrup dosage. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If your child experiences side effects, talk to your doctor or pharmacist.

You can report side effects to info@afasiahealth.co.za.

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 Klusivit Syrup.

5. How to store Klusivit Syrup

Store all medicines out of reach of children.

Store in the original package in a cool place and out of direct sunlight, at or below 25°C. Do not refrigerate.

Do not use after the expiry date stated on the packaging.

Return all unused medicine to your pharmacist for safe and controlled disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Klusivit Syrup contains

Each 5 ml Klusivit Syrup contains the following active substances:

Vitamin A palmitate (Vitamin A)	1980 IU
Vitamin D ₃ 100 CWS (Vitamin D ₃)	200 IU
Vitamin B ₁₂ 0.1 % (Vitamin B ₁₂)	2,00 µg
Calcium lactate (Calcium)	300,00 mg
Phosphorus AAC 10 % (Phosphorus)	75,00 mg
Ferrous gluconate (Iron)	53,72 mg
providing Iron (elemental)	6,50 mg
Ascorbic acid BP (Vitamin C)	45,00 mg
Zinc lactate (Zinc)	27,27 mg
providing Zinc (elemental)	6,00 mg
Magnesium gluconate	19,90 mg
Nicotinamide (Vitamin B ₃)	10,00 mg
Thiamine (Vitamin B ₁)	5,00 mg
Riboflavin (Vitamin B ₂)	5,00 mg
Calcium D pantothenic acid (Vitamin B ₅)	5,00 mg
Pyridoxine HCL (Vitamin B ₆)	1,00 mg

The other ingredients are:

Sweetening agent: Sucralose 2,00 mg/ 5 ml

Flavouring agent: Cherry flavour

Preservatives: Potassium sorbate 0,2 % m/v; Sodium benzoate 0,2 % m/v

Others: Carboxymethyl cellulose

What Klusivit Syrup looks like and contents of the pack

Klusivit Syrup is a light yellow, cherry-flavoured syrup.

Klusivit Syrup is available in a 200 ml white plastic bottle, in a carton.

Holder of Certificate of Registration:

Grischo (Pty) Ltd

Unit A, 3 Williams Road, Bedfordview, 2007

info@afasiahealth.co.za

This leaflet was last revised in

Will be allocated by the SAHPRA upon registration.

Registration number

Will be allocated by the SAHPRA upon registration

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

Ongeskeduleer

Klusivit Stroop

Vitamiën A, Vitamiën B₁, Vitamiën B₂, Vitamiën B₃, Vitamiën B₅, Vitamiën B₆, Vitamiën B₁₂, Vitamiën C, Vitamiën D₃, Kalsium, Yster, Magnesium, Fosfor, Sink
Suikerverry
Bevat versoeter: Sukralose 2,00 mg/ml

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

Kategorie: D.34.12 Meervoudige Stofformulering

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

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

Klusivit Stroop is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou kind se gesondheid te handhaaf. Nietemin, moet jy Klusivit Stroop versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie Klusivit Stroop met enige ander persoon deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat Klusivit Stroop is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy Klusivit Stroop gebruik
3. Hoe om Klusivit Stroop te gebruik
4. Moontlike nuwe-effekte
5. Hoe om Klusivit Stroop te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat Klusivit Stroop is en waarvoor dit gebruik word

Klusivit Stroop is 'n multivitamiën- en mineraalgesondheidsaanvulling vir kinders, en dit help hulle om in hul daaglikse voedingsbehoefes te voorsien as 'n faktor in die handhawing van goeie gesondheid. Elke vitamien en mineraal in Klusivit Stroop speel 'n belangrike rol in die ondersteuning van algemene gesondheid. Die tabel hieronder toon 'n kort opsomming van hierdie funksies.

VITAMIE / MINERAAL	FUNKSIE
Vitamiën A	Dra by tot die handhawing van sig, vel, membrane en immuunfunksie. Dra by tot die ontwikkeling en instandhouding van nagvisie. Dra by tot die ontwikkeling en instandhouding van bene en tande.
Vitamiën B ₁ ; Vitamiën B ₃	Help om koolhidrate, vette en proteïene te metaboliseer. Dra by tot normale groei.
Vitamiën B ₂ ; Vitamiën B ₅ ; Vitamiën B ₆	Help om koolhidrate, vette en proteïene te metaboliseer. Dra by tot weefselvorming.
Vitamiën B ₁₂	Help om koolhidrate, vette en proteïene te metaboliseer. Dra by tot normale rooibloedsewering.
Vitamiën C	Help om vette en proteïene te metaboliseer. Help met die ontwikkeling en instandhouding van bene, kraakbeen, tande en tandvleis. Help met die vorming van bindweefsel en wondgenesing. 'n Antioksidant vir die handhawing van goeie gesondheid.
Vitamiën D ₃	Help met die ontwikkeling en instandhouding van bene en tande. Help met die opname en gebruik van kalsium en fosfor.
Kalsium	Dra by tot die ontwikkeling en instandhouding van bene en tande.
Yster	Help om rooibloedselle te vorm en help met hul behoorlike funksie.
Magnesium	Help om koolhidrate, vette en proteïene te metaboliseer. Dra by tot die ontwikkeling en instandhouding van bene en tande. Dra by tot weefselvorming. Dra by tot die handhawing van normale spierfunksie.
Fosfor	Help om koolhidrate, vette en proteïene te metaboliseer. Dra by tot die ontwikkeling en instandhouding van normale bene en tande.
Sink	Help met die vorming van bindweefsel. Help om gesonde vel te handhaaf. Help om koolhidrate, vette en proteïene te metaboliseer. Help om immuunfunksie te handhaaf.

2. Wat jy moet weet voordat jy Klusivit Stroop gebruik

Moenie Klusivit Stroop gee as enige van die volgende toestande teenwoordig is nie:

- Hipersensitiwiteit (allergie) vir enige van die bestanddele van Klusivit Stroop (gelys in afdeling 6).
- Hiperkalsiurie (oortollige kalsium in die urine) of hiperkalsemie (oortollige kalsiumvlakke in die bloed).
- Ysterberging of ysterabsorpsie siektes soos hemochromatose.
- Bestaande gastrointestinale siektes soos inflammatoriese dermsiekte, demstrikte of divertikulae.
- Nier of lewer ontoereikendheid.
- Hiperkalsemie.
- Kalsiumgeassosieerde nierstene.
- Hartsiekte.
- Hoë vlakke van vitamien D in die liggaam of gelyktydige inname van produkte wat vitamien D bevat.

Waaskuwings en voorsorgmaatreëls

Wees veral versigtig met Klusivit Stroop:

- Vitamiën B₃ moet met omsigtigheid gegee word by kinders met maagsere.
- Klusivit Stroop moet nie aan 'n kind met anemie as gevolg van 'n vermoedelike vitamien B₁₂-tekort gegee word sonder om eers die diagnose te bevestig nie.
- Klusivit Stroop bevat vitamien D en moet dus met omsigtigheid gebruik word by babas, wat moontlik verhoogde sensitiwiteit vir die effekte daarvan kan hê.
- Babas wat Klusivit Stroop neem, moet fyn gemonitor word vir hiperkalsemie of tekens van vitamien D-toksiteit as hulle geborsvoed word deur moeders wat farmakologiese dosisse vitamien D neem.
- Klusivit Stroop bevat vitamien A en is aangedui vir gebruik by kinders; versigtigheid moet egte gedra word aangesien daar 'n verhoogde risiko van hipervitaminose A (te veel vitamien A in die liggaam) is as Klusivit Stroop saam met sintetiese retinoïede soos asitretien, isotretinoïen en tretinoïen gegee word.

Ander medisyne en Klusivit Stroop

Sê altyd vir jou gesondheidsorgverskaffer indien jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Klusivit Stroop kan interaksie hê met die volgende medisyne. Raadpleeg asseblief jou gesondheidsorgverskaffer voordat jy hierdie medisyne aan jou kind gee, indien jou kind die volgende neem:

- Antibiotika soos tetrasiklene en kinolone, aangesien die magnesium in Klusivit Stroop die absorpsie van die antibiotika kan verminder. As dit saam gegee word, moet die dosisse Klusivit Stroop en die antibiotika met 'n aantal ure geskei word;
- Tiasieddiuretika, kalsium of fosfate, aangesien die vitamien D in Klusivit Stroop 'n risiko van hiperkalsemie kan veroorsaak;
- Retinoïede soos asitretien, isotretinoïen en tretinoïen, aangesien die vitamien A in Klusivit Stroop tot hipervitaminose A kan bydra.
- Anti-epileptiese medisyne soos fenitoien, karbamasepien en fenobarbital, aangesien vitamien B₆ met hul doeltreffendheid kan inmeng;
- Levodopa, 'n medisyne wat gebruik word in die behandeling van Parkinson se siekte, aangesien vitamien B₆ die doeltreffendheid van levodopa kan verminder.

Klusivit Stroop met voedsel en drank

Klusivit Stroop moet een keer per dag na ete geneem word. (Sien afdeling 3, Hoe om Klusivit Stroop te gee).

Swangerskap, borsvoeding en vrugbaarheid

Klusivit Stroop word aangedui vir gebruik by kinders. Ongeag hiervan, neem asseblief kennis van die volgende:

As jy swanger is of borsvoed, dink jy dat jy swanger is of van plan is om 'n baba te hê, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

3. Hoe om Klusivit Stroop te gee

Moet nie jou medisyne met enige ander persoon deel nie.

Gee Klusivit Stroop altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Kinders van 1 tot 13 jaar oud: 5 ml een keer per dag, na ete, of soos aangedui deur 'n gesondheidsorgverskaffer.

Skud die bottel goed voor gebruik.

As jy meer Klusivit Stroop gee as wat jy moet

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om Klusivit Stroop te gee

As jy vergeet om 'n dosis te gee, gee dit sodra jy dit onthou, gaan dan terug na jou gewone dosisskedule.

Moet nie 'n dubbele dosis gee om vir die vergete dosis op te maak nie.

4. Moontlike nuwe-effekte

Klusivit Stroop kan nuwe- effekte hê.

Nie alle nuwe-effekte wat vir Klusivit Stroop gerapporteer is, word in hierdie inligtingsblad ingesluit nie. As jou kind se algemene gesondheid verswak of jou kind enige onvoorwaardelike gevolge ervaar terwyl hulle Klusivit Stroop neem, raadpleeg jou dokter of gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om jou kind Klusivit Stroop te gee en onmiddellik vir jou dokter vertel, of neem die kind na die ongevalle-afdeling in jou naaste hospitaal:

- Swelling van die gesig, keel, lippe of tong,
- Uitslag of jeuk
- Moeilikhed met asemhaal of sluk.

Dit is alles baie ernstige nuwe-effekte. As jou kind enige van hierdie ervaar, het hy/sy moontlik 'n ernstige reaksie op Klusivit Stroop gehad. Dit kan dringend mediese hulp benodig.

Jou kind kan ook die volgende ligte nuwe-effekte ervaar:

- Hoofpyn
- Maagklagtes soos diarree, hardlyghed, maagpyn of krampe,
- Naarheid en braking,
- Geel verkleuring van urine,
- Verdonkering van stoelgange.

Die meeste van hierdie gemelde nuwe-effekte kom voor wanneer jou kind meer Klusivit Stroop neem as wat hulle moet. Dit is dus belangrik dat jou kind die regte Klusivit Stroop dosis ontvang.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van nuwe-effekte

Indien jou kind nuwe-effekte ondervind, bespreek dit met jou dokter of apteker.

Jy kan nuwe-effekte by info@afasiahealth.co.za rapporteer.

Jy kan ook nuwe-effekte aan SAHPRA rapporteer deur die "6.04 Adverse Drug Reaction Reporting Form" te gebruik, wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van Klusivit Stroop te verskaf.

5. Hoe om Klusivit Stroop te bêre

Bêre alle medisyne buite die bereik van kinders.

Bêre in die oorspronklike verpakking op 'n koel plek en uit direkte sonlig, teen of benede 25°C. Moet nie verkoel nie.

Moet nie gebruik na die vervaldatum wat op die verpakking vermeld word nie.

Neem alle ongebruikte medisyne terug na jou apteker vir veilige en beheerde wegdoening.

Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat Klusivit Stroop bevat

Elke 5 ml Klusivit Stroop bevat die volgende aktiewe bestanddele:

Vitamiën A palmitate (Vitamiën A)	1980 IU
Vitamiën D ₃ 100 CWS (Vitamiën D ₃)	200 IU
Vitamiën B ₁₂ 0.1 % (Vitamiën B ₁₂)	2,00 µg
Kalsiumlaktate (Kalsium)	300,00 mg
Fosfor AAC 10 % (Fosfor)	75,00 mg
Ferrous gluconaat (Yster)	53,72 mg
verskaf Yster (elementêr)	6,50 mg
Askorbiensuur BP (Vitamiën C)	45,00 mg
Sinklaktate (Sink)	27,27 mg
verskaf Sink (elementêr)	6,00 mg
Magnesiumglukonaat	19,90 mg
Nikotinamied (Vitamiën B ₃)	10,00 mg
Tiamien (Vitamiën B ₁)	5,00 mg
Riboflavien (Vitamiën B ₂)	5,00 mg
Kalsium D pantoteensuur (Vitamiën B ₅)	5,00 mg
Piridoksien HCl (Vitamiën B ₆)	1,00 mg

Die ander bestanddele is:

Versoetingsmiddel: Sukralose 2,00 mg/ 5 ml

Geurmiddel: Kersiegeur

Preserveermiddels: Kaliumsorbaat 0,2 % m/v; Natriumbensoaat 0,2 % m/v

Ander: Karboksimeetiel sellulose

Hoe Klusivit Stroop lyk en die inhoud van die verpakking

Klusivit Stroop is 'n liggeel, kersie-geurde stroop.

Klusivit Stroop is beskikbaar in 'n 200 ml wit plastiekbottel, verpak in 'n karton.

Houer van Registrasiesertifikaat

Grischo (Pty) Ltd

Unit A, 3 Williams Road, Bedfordview, 2007

info@afasiahealth.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur die SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur die SAHPRA toegeken word.

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

Klusivit Syrup

COMPOSITION

Each 5 ml contains:

Vitamin A palmitate (Vitamin A)	1980 IU
Vitamin D ₃ 100 CWS (Vitamin D ₃)	200 IU
Vitamin B ₁₂ 0.1 % (Vitamin B ₁₂)	2,00 µg
Calcium lactate (Calcium)	300,00 mg
Phosphorus AAC 10 % (Phosphorus)	75,00 mg
Ferrous gluconate (Iron)	53,72 mg
providing Iron (elemental)	6,50 mg
Ascorbic acid BP (Vitamin C)	45,00 mg
Zinc lactate (Zinc)	27,27 mg
providing Zinc (elemental)	6,00 mg
Magnesium gluconate	19,90 mg
Nicotinamide (Vitamin B ₃)	10,00 mg
Thiamine (Vitamin B ₁)	5,00 mg
Riboflavin (Vitamin B ₂)	5,00 mg
Calcium D pantothenic acid (Vitamin B ₅)	5,00 mg
Pyridoxine HCL (Vitamin B ₆)	1,00 mg

Other excipients: Sucralose 2,00 mg; cherry flavour; potassium sorbate 0,2 % m/v; sodium benzoate 0,2 % m/v; carboxymethyl cellulose.

Sugar free.

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine: Health Supplement

34.12 Multiple Substance formulation

PHARMACOLOGICAL ACTION

Each vitamin and mineral in Klusivit Syrup plays a vital role in the support of overall health.

The table below shows a brief summary of these functions.

VITAMIN / MINERAL	FUNCTION
Vitamin A	Contributes to the maintenance of eyesight, skin, membranes and immune function. Contributes to the development and maintenance of night vision. Contributes to the development and maintenance of bones and teeth.
Vitamin B ₁ ; Vitamin B ₃	Helps to metabolise carbohydrates, fats and proteins. Contributes to normal growth.
Vitamin B ₂ ; Vitamin B ₅ ; Vitamin B ₆	Helps to metabolise carbohydrates, fats and proteins. Contributes to tissue formation.
Vitamin B ₁₂	Helps to metabolise carbohydrates, fats and proteins. Contributes to normal red blood cell formation.
Vitamin C	Helps to metabolise fats and proteins. Helps in the development and maintenance of bones, cartilage, teeth and gums. Helps in connective tissue formation and wound healing. An antioxidant for the maintenance of good health.
Vitamin D ₃	Helps in the development and maintenance of bones and teeth. Helps in the absorption and use of calcium and phosphorous.
Calcium	Contributes to the development and maintenance of bones and teeth.
Iron	Helps to form red blood cells and helps in their proper function.
Magnesium	Helps to metabolise carbohydrates, fats and proteins. Contributes to the development and maintenance of bones and teeth. Contributes to tissue formation. Contributes to the maintenance of normal muscle function.
Phosphorus	Helps to metabolise carbohydrates, fats and proteins. Contributes to the development and maintenance of normal bones and teeth.
Zinc	Helps in connective tissue formation. Helps to maintain healthy skin. Helps the body to metabolise carbohydrates, fats and proteins. Helps to maintain immune function.

INDICATIONS

Klusivit Syrup is a multivitamin and mineral health supplement for children, and it assists in them meeting their daily nutritional needs as a factor in the maintenance of good health.

CONTRAINDICATIONS

Klusivit Syrup is contraindicated if the following conditions are present:

- Hypersensitivity (allergy) to any of the ingredients of Klusivit Syrup (listed in section 6).
- Hypercalciuria (excess calcium in the urine) or hypercalcaemia (excess blood calcium levels).
- Iron-storage or iron-absorption diseases such as haemochromatosis.
- Existing gastrointestinal diseases such as inflammatory bowel disease, intestinal strictures or diverticulae.
- Renal (kidney) or hepatic (liver) insufficiency.
- Hypercalcaemia.
- Calcium associated kidney stones.
- Heart disease.
- High levels of vitamin D in the body or simultaneous intake of products containing vitamin D.

WARNINGS AND SPECIAL PRECAUTIONS

Klusivit Syrup should be used with care in:

- Patients with peptic ulcers.
- Patients with anaemia resulting from a suspected vitamin B₁₂ deficiency without first confirming the diagnosis.
- Infants who may have increased sensitivity to the effects of vitamin D.
- Infants taking Klusivit Syrup, for hypercalcaemia or signs of vitamin D toxicity if they are breast-fed by mothers taking pharmacological doses of vitamin D.
- Instances where there is an increased risk of hypervitaminosis A (too much vitamin A in the body) if Klusivit Syrup is given with synthetic retinoids such as acitretin, isotretinoin and tretinoin.

This unregistered medicine has not

been evaluated by the SAHPRA for its quality, safety or intended use.

INTERACTIONS

Klusivit Syrup may interact with the following medicines. Caution is advised when used concurrently:

- Antibiotics such as tetracyclines and quinolones, as the magnesium in Klusivit Syrup may decrease the absorption of the antibiotics. If given together, the doses of Klusivit Syrup and the antibiotic should be separated by a number of hours;
- Thiazide diuretics, calcium or phosphates, as the vitamin D in Klusivit Syrup may result in a risk of hypercalcaemia;
- Retinoids such as acitretin, isotretinoin and tretinoin, as the vitamin A in Klusivit Syrup may contribute to hypervitaminosis A;
- Antiepileptic medicines such as phenytoin, carbamazepine and phenobarbital, as vitamin B₆ may interfere with their effectiveness;
- Levodopa, a medicine used in the treatment of Parkinson's disease, as vitamin B₆ may decrease the effectiveness of levodopa.

PREGNANCY AND LACTATION

Klusivit Syrup is indicated for use in children. Regardless of this, caution should be exercised during pregnancy or lactation, as the safety of Klusivit Syrup during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Children 1 to 13 years old: 5 ml once daily, after food, or as directed.

SIDE EFFECTS

Frequency unknown: Hypersensitivity reactions may include rash, itching; difficulty in breathing or swallowing; swelling of the face, tongue, lips or throat.

Common side effects may include headache; gastrointestinal effects such as nausea, vomiting, abdominal pain, diarrhoea or constipation; yellowing of urine; darkening of stools.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment is symptomatic and supportive.

IDENTIFICATION

A light yellow, cherry-flavoured syrup.

PRESENTATION

Klusivit Syrup is available in a 200 ml white plastic bottle, in a carton.

STORAGE INSTRUCTIONS

Store in the original package in a cool place and out of direct sunlight, at or below 25°C. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Grischo (Pty) Ltd

Unit A, 3 Williams Road, Bedfordview, 2007

CUSTOMER CARE

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

TBA

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