SCHEDULING STATUS: S0

GUMMY VITES MULTIVITAMIN
Multiple Substance Formulation, Gummies
Vitamin C 15 mg, Vitamin B_3 6 mg, Vitamin B_5 3 mg, Vitamin B_6 1,1 mg,
Zinc 500 µg, Vitamin B_2 50 µg, Biotin 2,5 µg, Vitamin B_{12} 1,25 µg,
Vitamin A 1100 IU, Vitamin D_3 250 IU & Vitamin E 5 IU, Magnesium 250 µg, Copper 5 µg
Contains sugar: 0,49 mg from elderberry concentrate and 0,2 mg from black carrot concentrate, Glucose 480 mg and Sucrose 1,36 g per gummy.

Category D: Complementary Medicine
Health Supplements: 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.
Gummy Vites Multivitamin is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take Gummy Vites Multivitamin carefully to get the best results from it.

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

What is in this leaflet

1. What Gummy Vites Multivitamin is and what it is used for.
2. What you need to know before you give your child/use Gummy Vites Multivitamin.
3. How to give your child/use Gummy Vites Multivitamin.
4. Possible side effects.
5. How to store Gummy Vites Multivitamin.
6. Contents of the pack and other information.

1. What Gummy Vites Multivitamin is and what it is used for

- Contributes to the maintenance of eyesight, skin, membranes and immune function.
- Contributes to development and maintenance of night vision.
- Contributes to the development and maintenance of bones, cartilage, teeth and

gums.

- A factor in the maintenance of good health.
- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to tissue formation.
- Multi-vitamin/mineral supplement.
- Helps in wound healing.
- Helps in the absorption and use of calcium and phosphorus.
- Helps to form red blood cells.
- Helps in connective tissue formation.
- Helps to maintain healthy skin.

2. What you need to know before you give your child Gummy Vites Multivitamin

Do not give your child Gummy Vites Multivitamin:

- If your child is hypersensitive (allergic) to any of the active ingredients or any of the other ingredients (listed in section 6).

Other medicines and Gummy Vites Multivitamin

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

Pregnancy, 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 taking Gummy Vites Multivitamin.
Safety in pregnancy and lactation has not been established.
There is no fertility data available.

Driving and using machines

It is not always possible to predict to what extent Gummy Vites Multivitamin may interfere with your child's daily activities. Ensure that your child does not engage in the above activities until you are aware of the measure to which Gummy Vites Multivitamin affects them.

Gummy Vites Multivitamin contains:

- **Sucrose** 1,36 g and **glucose** 480 mg. If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving him/her Gummy Vites Multivitamin. Sucrose and glucose may be harmful to the teeth.
- Less than 1 mmol **sodium** (23 mg) per gummy, that is to say essentially ''sodium-free''.

3. How to give your child/use Gummy Vites Multivitamin

Do not share medicines prescribed for your child with any other person.
Always give your child/use Gummy Vites Multivitamin exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:
Children aged 1- 3 years: Chew 1 gummy once daily after food.
Children 4 years and older: Chew 2 gummies once daily after food.
Chew thoroughly before swallowing.
Do not exceed the recommended dosage.

If you give your child more Gummy Vites Multivitamin than you should

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

If you forget to give your child Gummy Vites Multivitamin

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

4. Possible side effects

Gummy Vites Multivitamin can have side effects.

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

Gummy Vites Multivitamin is generally well tolerated.

If any of the following happens, stop giving your child Gummy Vites Multivitamin and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching and/or hives or fainting.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to Gummy Vites Multivitamin. Your child may need urgent medical attention or hospitalisation.

If you notice any side effects not mentioned in this leaflet, please inform your child's doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side affects you can help provide more information on the safety of Gummy Vites Multivitamin.

5. How to store Gummy Vites Multivitamin

Store all medicines out of reach of children.

- Store at or below 25 ºC. Protect from light.
- Keep the container tightly closed.
- Keep in the original container until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the packaging.
- 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 Gummy Vites Multivitamin contains:

The active substances are:

Each gummy contains:	
Ascorbic acid (Vitamin C)	15 mg
Niacinamide (Vitamin B_3)	6 mg
d-Pantothenic acid (Vitamin B_5)	3 mg
Pyridoxine HCl (Vitamin B_6)	1,1 mg
Zinc (as Zinc citrate)	500 µg
Riboflavin (Vitamin B_2)	50 µg
D-Biotin (Vitamin H)	2,5 µg
Cyanocobalamin (Vitamin B_{12})	1,25 µg
All-trans Retinyl Acetate (Vitamin A)	1100 IU

Cholecalciferol (Vitamin D_3)	250 IU
DL-alpha tocopheryl Acetate (Vitamin E)	5 IU
Magnesium (as Magnesium citrate)	250 µg
Copper (as Copper gluconate)	5 µg

The other ingredients are: Beta-carotene[E160a], black carrot concentrate, citric acid [E330], citrus pectin [E440], elderberry concentrate, glucose syrup, grape flavour, sucrose, sucrose syrup, trisodium citrate [E331] and water.

What Gummy Vites Multivitamin looks like and contents of the pack

Dark orange coloured, grape flavoured bear-shaped gummies.

A plastic bottle containing 60 or 120 gummies, fitted with a blue lid.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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adcock ingram

SKEDULERINGSTATUS: S0

GUMMY VITES MULTIVITAMIN

Veelvoudige bestanddeel formulering, Gummies

Vitamien C 15 mg, Vitamien B_3 6 mg, Vitamien B_5 3 mg, Vitamien B_6 1,1 mg, Sink 500 µg, Vitamien B_2 50 µg, Biotien 2,5 µg, Vitamien B_{12} 1,25 µg, Vitamien A 1100 IE, Vitamien D_3 250 IE & Vitamien E 5 IE, Magnesium 250 µg, Koper 5 µg

Bevat suiker: 0,49 mg vanaf vlierbessie-konsentraat en 0,2 mg vanaf swartwortel-konsentraat, Glukose 480 mg en Sukrose 1,36 g per gummy.

Kategorie D: Komplementêre medisyne

Gesondheidsaanvullings: 34.12 Veelvoudige bestanddeel formulering

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

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u.

Gummy Vites Multivitamin is beskikbaar sonder 'n doktersvoorskrif, vir u om u gesondheid te onderhou. Nietemin moet u steeds Gummy Vites Multivitamin versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie Gummy Vites Multivitamin met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat in hierdie biljet is

1. Wat Gummy Vites Multivitamin is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u Gummy Vites Multivitamin aan u kind gee/laat gebruik.
3. Hoe om Gummy Vites Multivitamin aan u kind te gee/laat gebruik.
4. Moontlike newe-effekte.
5. Hoe om Gummy Vites Multivitamin te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat Gummy Vites Multivitamin is en waarvoor dit gebruik word

- Dra by tot die instandhouding van sig, vel, membrane en immuunfunksie.
- Dra by tot die ontwikkeling en instandhouding van nagsig.
- Dra by tot die ontwikkeling en instandhouding van bene, kraakbeen, tande en

tandvleis.

- 'n Faktor in die handhawing van goeie gesondheid.
- Help om koolhidrate, vette en proteïene te metaboliseer.
- Dra by tot weefselvorming.
- Multi-vitamien/minerale aanvulling.
- Help met wondgenesing.
- Help met die opname en gebruik van kalsium en fosfor.
- Help om rooibloedselle te vorm.
- Help met bindweefselvorming.
- Help om 'n gesonde vel te handhaaf.

2. Wat u moet weet voordat u Gummy Vites Multivitamin aan u kind gee

Moenie Gummy Vites Multivitamin aan u kind gee nie:

- Indien u kind hipersensitief (allergies) is vir enige van die aktiewe bestanddele of enige van die ander bestanddele (gelys in afdeling 6).

Ander medisyne en Gummy Vites Multivitamin

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u Gummy Vites Multivitamin neem.

Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

Daar is geen vrugbaarheidsdata beskikbaar nie.

Bestuur en hantering van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate Gummy Vites Multivitamin met u kind se daaglikse aktiwiteite kan inmeng nie. Maak seker dat u kind nie aan bogenoemde aktiwiteite deelneem voordat u bewus is van die mate waartoe Gummy Vites Multivitamin hulle beïnvloed nie.

Gummy Vites Multivitamin bevat:

- **Sukrose** 1,36 g en **glukose** 480 mg. Indien u dokter u ingelig het dat u kind 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u Gummy Vites Multivitamin aan hom/haar gee. Sukrose en glukose kan skadelik vir die tande wees.
- Minder as 1 mmol **natrium** (23 mg) per gummy, dit wil sê in wese "natriumvry".

3. Hoe om Gummy Vites Multivitamin aan u kind te gee/laat gebruik

Moenie medisyne wat aan u kind voorgeskryf is, met enige ander persoon deel nie.
Gebruik/gee altyd Gummy Vites Multivitamin aan u kind presies soos beskryf in hierdie biljet of soos u dokter of apteker of verpleegkundige u ingelig het. Raadpleeg u dokter of apteker of verpleegkundige indien u nie seker is nie.

Die algemene dosis is:
Kinders 1-3 jaar oud: Kou 1 gummy een keer per dag na voedsel.
Kinders 4 jaar en ouer: Kou 2 gummies een keer per dag na voedsel.
Kou deeglik voordat dit gesluk word.
Moenie die aanbevole dosis oorskry nie.

Indien u meer Gummy Vites Multivitamin aan u kind gee as wat u moes

In die geval van oordosering, raadpleeg u kind se dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om Gummy Vites Multivitamin aan u kind te gee

Moenie 'n dubbele dosis gee om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte

Gummy Vites Multivitamin kan newe-effekte hê.

Nie alle newe-effekte wat vir Gummy Vites Multivitamin aangemeld is, word in hierdie biljet gelys nie. Indien u kind se algemene gesondheid verswak of indien u kind enige ongewenste reaksies ervaar terwyl hy/sy Gummy Vites Multivitamin neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Gummy Vites Multivitamin word oor die algemeen goed verdra.

Indien enige van die volgende gebeur, hou op om Gummy Vites Multivitamin aan u kind te

gee en lig dadelik u dokter in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak, uitslag of jeukerigheid en/of galbulte of floute.

Hierdie is alles baie ernstige newe-effekte. Indien u kind dit ervaar, het hy/sy moontlik 'n ernstige allergiese reaksie op Gummy Vites Multivitamin gehad. U kind het dalk dringende mediese hulp of hospitalisasie nodig.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u kind se dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u enige newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte direk by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en elektroniese aanemldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van Gummy Vites Multivitamin te verskaf.

5. Hoe om Gummy Vites Multivitamin te bêre

Bêre alle medisyne buite bereik van kinders.

- Bêre teen of benede 25 ºC. Beskerm teen lig.
- Hou die houer dig toe.
- Hou in die oorspronklike houer totdat dit benodig word.
- Moenie in 'n badkamer bêre nie.
- Moenie gebruik ná die vervaldatum wat op die verpakking vermeld word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat Gummy Vites Multivitamin bevat:

Die aktiewe bestanddele is:

Elke gummy bevat:	
Askorbiensuur (Vitamien C)	15 mg
Niasinamied (Vitamien B_3)	6 mg
d-Pantoteensuur (Vitamien B_5)	3 mg
Piridoksien HCl (Vitamien B_6)	1,1 mg
Sink (as Sinksitraat)	500 µg
Riboflavien (Vitamien B_2)	50 µg
D-biotien (Vitamien H)	2,5 µg

Sianokobalamien (Vitamien B_{12})	1,25 µg
All-trans retinielasetaat (Vitamien A)	1100 IE
Cholekalsiferol (Vitamien D_3)	250 IE
DL-alfa-tokoferielasetaat (Vitamien E)	5 IE
Magnesium (as Magnesiumsitraat)	250 µg
Koper (as Koperglukonaat)	5 µg

Die ander bestanddele is: Beta-karoteen [E160a], swartwortel-konsentraat, sitroensuur [E330], sitruspektien [E440], vlierbessie-konsentraat, glukosestroop, druiwegeursel, sukrose, sukrosestroop, trinatriumsitraat [E331] en water.

Hoe Gummy Vites Multivitamin lyk en die inhoud van die verpakking

Donker oranje gekleurde, druiwe-gegeurde beervormige gummies.

'n Plastiekbottel wat 60 of 120 gummies bevat, toegemaak met 'n blou deksel.

Nie alle verpakkingsgroottes mag bemark word nie.

Houer van Registrasiesertifikaat

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Kliëntediens: 0860 ADCOCK/232625

Hierdie biljet is mees onlangs hersien op

4 Oktober 2024

Registrasienommer

Moet toegeken word.

PIL 311565 & 311547

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