SCHEDULING STATUS: S0

GUMMY VITES VITAMIN C

L-Ascorbic acid (Vitamin C) 60 mg, Gummies

Contains sugar: Glucose 240 mg and Sucrose 1,4 g per gummy.

Category D: Complementary Medicine

Health Supplements: 34.11 Vitamins

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 Vitamin C is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take Gummy Vites Vitamin C carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Gummy Vites Vitamin C 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 Vitamin C is and what it is used for.
2. What you need to know before you give your child/use Gummy Vites Vitamin C.
3. How to give your child/use Gummy Vites Vitamin C.
4. Possible side effects.
5. How to store Gummy Vites Vitamin C.
6. Contents of the pack and other information.

1. What Gummy Vites Vitamin C is and what it is used for

Gummy Vites Vitamin C contributes to:

- Iron absorption from food and helps to metabolise fats and proteins.
- Cell protection from free radical damage and helps to maintain the normal function of the immune system.
- Normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin, and teeth.
- Normal energy-yielding metabolism and helps protect cells from oxidative stress.
- Reduction of tiredness and fatigue, aids in the regeneration of the reduced form of Vitamin E and helps in connective tissue formation.

- Wound healing, act as an antioxidant for the maintenance of good health.
- Normal functioning of the nervous system
- Normal psychological function

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

Do not give your child Gummy Vites Vitamin C:

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

Other medicines and Gummy Vites Vitamin C

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 Vitamin C.
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 Vitamin C may interfere with your child's daily activities. Ensure that they do not engage in the above activities until you are aware of the measure to which Gummy Vites Vitamin C affects them.

Gummy Vites Vitamin C contains :

- **Sucrose** 1,4 g and **glucose** 240 mg per gummy. 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 Vitamin C. 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 Vitamin C

Do not share medicines prescribed for your child with any other person.
Always give your child/use Gummy Vites Vitamin C 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 to 2 gummies twice daily.

Children aged 4 years and older: Chew 2 to 3 gummies twice daily.

Maximum dosage: 8 Jelly bears per day.

Recommended for children over 12 months of age. Also suitable for adults.

Chew thoroughly before swallowing.

Do not exceed the recommended dosage.

If you give your child more Gummy Vites Vitamin C 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 Vitamin C

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

4. Possible side effects

Gummy Vites Vitamin C can have side effects.

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

Gummy Vites Vitamin C is generally well tolerated.

If any of the following happens, stop giving your child Gummy Vites Vitamin C 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 Vitamin C**.** 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 Vitamin C.

5. How to store Gummy Vites Vitamin C

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 unit 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 Vitamin C contains:

The active substance is:

Each gummy contains:	
L-Ascorbic acid (Vitamin C)	60 mg

The other ingredients are: Beta-carotene [E160a], burnt sugar, citric acid [E330], citrus pectin [E440], glucose syrup, orange flavour, Rose-hips extract (containing maltodextrin and silicon dioxide), sucrose, sucrose Syrup, trisodium citrate [E331] and water.

What Gummy Vites Vitamin C looks like and contents of the pack

Orange coloured and flavoured bear-shaped gummies.

A plastic bottle containing 60 or 120 gummies, fitted with an orange lid.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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01 October 2024

Registration number

To be allocated.

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SKEDULERINGSTATUS: S0

GUMMY VITES VITAMIN C

L-Askorbiensuur (Vitamien C) 60 mg, Gummies

Bevat suiker: Glukose 240 mg en Sukrose 1,4 g per gummy.

Kategorie D: Komplementêre medisyne

Gesondheidsaanvullings: 34.11 Vitamiene

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 Vitamin C is beskikbaar sonder 'n doktersvoorskrif, om u gesondheid mee te handhaaf. Nietemin moet u steeds Gummy Vites Vitamin C versigtig neem om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie Gummy Vites Vitamin C 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 Vitamin C is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u Gummy Vites Vitamin C aan u kind gee/laat gebruik.
3. Hoe om Gummy Vites Vitamin C aan u kind te gee/te laat gebruik.
4. Moontlike newe-effekte.
5. Hoe om Gummy Vites Vitamin C te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat Gummy Vites Vitamin C is en waarvoor dit gebruik word

Gummy Vites Vitamin C dra by tot:

- Ysterabsorpsie vanuit voedsel en help om vette en proteïene te metaboliseer.
- Selbeskerming teen vry radikaal-skade en help om die normale funksie van die immuunstelsel te handhaaf.
- Normale kollageenvorming vir die normale funksie van bloedvate, bene, kraakbeen, tandvleis, vel en tande.
- Normale energie-opbrengs metabolisme en help om selle teen oksidatiewe stres te beskerm.
- Vermindering van moegheid en uitputting, help met die vernuwing van die verminderde

vorm van Vitamien E en help met bindweefselvorming.

- Wondgenesing, dien as 'n antioksidant vir die handhawing van goeie gesondheid.
- Normale funksionering van die senuweestelsel
- Normale psigologiese funksie

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

Moenie Gummy Vites Vitamin C aan u kind gee nie:

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

Ander medisyne en Gummy Vites Vitamin C

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 van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u Gummy Vites Vitamin C neem.

Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

Daar is geen vrugbaarheidsdata beskikbaar nie.

Bestuur en gebruik van masjinerie

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

Gummy Vites Vitamin C bevat:

- **Sukrose** 1,4 g en **glukose** 240 mg per gummy. Indien u dokter vir u gesê het dat u kind 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u Gummy Vites Vitamin C aan hom/haar gee.
- Minder as 1 mmol **natrium** (23 mg) per gummy, dit wil sê in wese "natriumvry'

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

Moenie medisyne wat aan u kind voorgeskryf is, met enige ander persoon deel nie.

Gebruik/gee Gummy Vites Vitamin C altyd 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 tot 2 gummies twee keer per dag.
Kinders 4 jaar en ouer: Kou 2 tot 3 gummies twee keer per dag.
Maksimum dosis: 8 gummies per dag.
Word aanbeveel vir kinders ouer as 12 maande. Ook geskik vir volwassenes.
Kou deeglik voor gesluk word.
Moenie die aanbevole dosis oorskry nie.

Indien u kind meer Gummy Vites Vitamin C ontvang as wat hy/sy 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 Vitamin C 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 Vitamin C kan newe-effekte hê.

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

Gummy Vites Vitamin C word oor die algemeen goed verdra.

Indien enige van die volgende gebeur, hou op om Gummy Vites Vitamin C aan u kind te gee en lig u dokter dadelik 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, veluitslag 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 Vitamin C 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 elektronies aanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind word. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van Gummy Vites Vitamin C.

5. Hoe om Gummy Vites Vitamin C 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 verpakkings-eenheid totdat dit benodig word vir gebruik.
- Moenie in 'n badkamer bêre nie.
- Moenie gebruik ná die vervaldatum wat op die verpakking aangedui 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 Vitamin C bevat:

Die aktiewe bestanddeel is:

Elke gummy bevat:	
L-askorbiensuur (Vitamien C)	60 mg

Die ander bestanddele is: Beta-karoteen [E160a], gebrande suiker, sitroensuur [E330], sitruspektien [E440], glukosestroop, lemoengeursel, roosbottelekstrak (wat maltodekstrien en silikondioksied bevat), sukrose, sukrosestroop, trinatriumsitraat [E331] en water.

Hoe Gummy Vites Vitamin C lyk en die inhoud van die verpakking

Oranjekleurige en lemoen-gegeurde beervormige gummies.

'n Plastiek-bottel wat 60 of 120 gummies bevat, toegemaak met 'n oranje deksel.

Nie alle verpakkingsgroottes mag bemark word nie.

Houer van Registrasiesertifikaat

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Hierdie biljet is mees onlangs hersien op

01 Oktober 2024

Registrasienommer

Moet toegeken word.

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