SCHEDULING STATUS: S0

GUMMY VITES SELECT CRECHE PROTECT

Multiple Substance Formulation, Gummies

Vitamin C 125 mg, Zinc 5 mg, *Echinacea purpurea* (Echinacea extract) 2 mg

Contains sugar: Glucose 1,23 g and Sucrose 936 mg per gummy.

Category D: Complementary Medicine

Discipline Specific: 33.7 Combination Product

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

- Keep this leaflet. You may need to read it again.
- Do not share **Gummy Vites Select Creche Protect** 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 Select Creche Protect** is and what it is used for.
2. What you need to know before you take **Gummy Vites Select Creche Protect.**
3. How to take **Gummy Vites Select Creche Protect.**
4. Possible side effects.
5. How to store **Gummy Vites Select Creche Protect.**
6. Contents of the pack and other information.

1. What Gummy Vites Select Creche Protect is and what it is used for

- Helps to metabolise fats and proteins.
- Helps in the development and maintenance of bones, cartilage, teeth and gums.
- Helps in wound healing.
- An antioxidant for the maintenance of good health.
- A factor in the maintenance of good health.

- Contributes to the maintenance of immune function.
- Helps to maintain healthy skin.

2. What you need to know before you give your child Gummy Vites Select Creche Protect

Do not give your child Gummy Vites Select Creche Protect:

- 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 Select Creche Protect

- Always tell your healthcare provider if your child is taking any other medicine. (This includes all complementary or traditional medicines.)
- Echinacea, an ingredient in **Gummy Vites Select Creche Protect**, could interfere with medicines used to suppress the immune system. This is because echinacea helps boost immune activity, which may reduce the effectiveness of these medicines. Additionally, echinacea could make symptoms worse in people with certain autoimmune diseases, such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or pemphigus vulgaris, by increasing immune activity. It’s best to avoid using echinacea with these conditions or treatments unless advised by a doctor or healthcare provider.

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 Select Creche Protect**.
Safety in pregnancy, lactation and fertility has not been established.

Driving and using machines

It is not always possible to predict to what extent **Gummy Vites Select Creche Protect** 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 Select Creche Protect** affects them.

Gummy Vites Select Creche Protect contains:

- **Sucrose** 936 mg and **glucose** 1,23 g. 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 Select Creche Protect. 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 Gummy Vites Select Creche Protect

Do not share medicines prescribed for your child with any other person.

Always use **Gummy Vites Select Creche Protect** 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 3 years and older: Chew 1 gummy once daily before food.

Chew thoroughly before swallowing.

Do not exceed the recommended dosage.

Consult a health care professional for use beyond 8 weeks.

If you give your child more Gummy Vites Select Creche Protect 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 Select Creche Protect

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

4. Possible side effects

Gummy Vites Select Creche Protect can have side effects.

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

Gummy Vites Select Creche Protect is generally well tolerated.

If any of the following happens, stop giving your child **Gummy Vites Select Creche Protect** 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 Select Creche Protect**. 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 Select Creche Protect**.

5. How to store Gummy Vites Select Creche Protect

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 Select Creche Protect contains:

The active substances are:

Each 3 g bear shaped gummy contains:	
Ascorbic Acid (Vitamin C)	125 mg
Zinc (as Zinc citrate)	5 mg
Echinacea purpurea (L.) Moench (Echinacea) [flower]	2 mg

The other ingredients are Glucose syrup, natural orange flavour, paprika extract, pectin [E440], sodium ascorbate [E301], sugar , trisodium citrate [E331], water.

What Gummy Vites Select Creche Protect looks like and contents of the pack

Orange coloured and flavoured bear-shaped gummies.

A plastic bottle containing 60 gummies, fitted with a light green lid.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
Customer Care: 0860 ADCOCK/232625

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Registration number

To be allocated.

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SKEDULERINGSTATUS: S0

GUMMY VITES SELECT CRECHE PROTECT
Veelvoudige bestanddeel formulering, Gummies
Vitamien C 125 mg, Sink 5 mg, *Echinacea purpure* (*Echinacea* ekstrak) 2 mg
Bevat suiker: Glukose 1,23 g en Sukrose 936 mg per gummy.

Kategorie D: Komplementêre Medisyne
Dissipline-spesifiek: 33.7 Kombinasie Produk
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

Lees die hele biljet noukeurig deur, want dit bevat belangrike inligting vir u:
Gummy Vites Select Creche Protect is beskikbaar sonder 'n doktersvoorskrif, om u gesondheid te onderhou. Nogtans moet u **Gummy Vites Select Creche Protect** versigtig gebruik om die beste resultate daarvan te verkry**.**

- Hou hierdie inligtingstuk. U moet dit dalk weer lees.
- Moenie **Gummy Vites Select Creche Protect** met enige ander persoon deel nie.
- Raadpleeg u gesondheidsorgkundige of apteker indien u meer inligting of advies benodig.

Wat in hierdie biljet is

1. Wat **Gummy Vites Select Creche Protect** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **Gummy Vites Select Creche Protect** gebruik.
3. Hoe om **Gummy Vites Select Creche Protect** te gebruik.
4. Moontlike newe-effekte.
5. Hoe om **Gummy Vites Select Creche Protect** te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat Gummy Vites Select Creche Protect is en waarvoor dit gebruik word

- Help om vette en proteïene te metaboliseer
- Help met die ontwikkeling en instandhouding van bene, kraakbeen, tande en tandvleis
- Help met wondgenesing
- 'n Antioksidant vir die instandhouding van goeie gesondheid

- ‘n Faktor in die instandhouding van goeie gesondheid
- Dra by tot die instandhouding van immuunfunksie
- Help om gesonde vel in stand te hou

2. Wat u moet weet voordat u Gummy Vites Select Creche Protect aan u kind gee

Moenie Gummy Vites Select Creche Protect 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 Select Creche Protect

- Lig altyd u gesondheidsorgverskaffer in indien u kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
- *Echinacea*, 'n bestanddeel in **Gummy Vites Select Creche Protect**, kan inmeng met medisyne wat gebruik word om die immuunstelsel te onderdruk. Dit is omdat *echinacea* help om immuunaktiwiteit te bevorder, wat die doeltreffendheid van daardie medisyne kan verminder. Daarbenewens kan *echinacea* simptome vererger by mense met sekere outo-immuun siektes, soos veelvuldige sklerose (MS), sistemiese lupus eritematose (SLE), rumatoïede artritis (RA) of *pemphigus vulgaris*, deur immuunaktiwiteit te verhoog. Dit is beter om die gebruik van *echinacea* in hierdie toestande of saam met hierdie behandelings te vermy, tensy dit deur 'n dokter of gesondheidsorgverskaffer aangeraai word.

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 Select Creche Protect** neem.

Veiligheid tydens swangerskap, laktasie en vrugbaarheid is nie vasgestel nie.

Bestuur en hantering van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate **Gummy Vites Select Creche Protect** 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 Select Creche Protect** hulle beïnvloed nie.

Gummy Vites Select Creche Protect bevat:

- **Sukrose** 936 mg en **glukose** 1,23 g. Indien u dokter u ingelig het dat u kind 'n

onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u **Gummy Vites Select Creche Protect** aan hom/haar gee. Sukrose en glukose kan skadelik wees vir die tande.
- Minder as 1 mmol **natrium** (23 mg) per gummy, dit wil sê in wese "natriumvry".

3. Hoe om Gummy Vites Select Creche Protect aan u kind te gee

Moenie medisyne wat aan u kind voorgeskryf is, met enige ander persoon deel nie.
Gebruik altyd **Gummy Vites Select Creche Protect** 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 3 jaar en ouer: Kou 1 gummy een keer per dag voor voedsel.
Kou deeglik voordat dit gesluk word.
Moenie die aanbevole dosis oorskry nie.
Raadpleeg ‘n gesondheidsorgkundige vir gebruik vir langer as 8 weke.

Indien u meer Gummy Vites Select Creche Protect 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 Select Creche Protect 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 Select Creche Protect kan newe-effekte veroorsaak.

Nie alle newe-effekte wat vir **Gummy Vites Select Creche Protect** 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 Select Creche Protect** neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Gummy Vites Select Creche Protect word oor die algemeen goed verdra.

Indien enige van die volgende gebeur, hou op om **Gummy Vites Select Creche Protect** 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, 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 Select Creche Protect** 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 aanmeldingsplatform (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 Select Creche Protect** te verskaf.

5. Hoe om Gummy Vites Select Creche Protect 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 vir gebruik.
- 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 Select Creche Protect bevat:

Die aktiewe bestanddele is:

Elke 3 g beer-vormige gummy bevat:	
Askorbiensuur (Vitamien C)	125 mg
Sink (as Sinksitraat)	5 mg
Echinacea purpurea (L.) Moench (*Echinacea*) [blom]	2 mg

Die ander bestanddele is Glukosestroop, natuurlike lemoen-geursel, paprika ekstrak, pektien [E440], natriumaskorbaat [E301], suiker, trinatriumsitraat [E331], water.

Hoe Gummy Vites Select Creche Protect lyk en die inhoud van die verpakking

Oranje-gekleurde en lemoen-gegeurde beer-vormige gummies.

‘n Plastiek bottel wat 60 gummies bevat, toegemaak met ‘n liggroen prop.

Houer van Registrasiesertifikaat

Adcock Ingram Limited

New Road 1

Erand Gardens

Midrand

1685

Kliëntediens: 0860 ADCOCK/232625

Hierdie biljet is mees onlangs hersien op

22 Oktober 2024

Registrasienommer

Moet toegeken word.

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