# SCHEDULING STATUS: SO

# 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 °C. 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
<i>Echinacea purpurea</i> (Echinacea extract) [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

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#### **Registration number**

To be allocated.

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