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VITAMIN C GUMMIES FOR KIDS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS (chewable gummies)
Ascorbic acid (Vitamin C)

Contains sugar (930 mg sucrose, and 600 mg glucose syrup per gummy).

Complementary Medicine: D.34.11 Vitamins
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this insert carefully as it contains important information for you.
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS carefully to get the best results from it.
- Keep this leaflet, you may need it again.
- Do not share LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet
- What LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is and what it is used for.
- What you need to know before you give your child LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
- How to give your child LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
- Possible side effects.
- How to store LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
- Contents of the pack and other information.

1.What LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is and what it is used for
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is a vitamin that:
- Contributes to the maintenance of good health and immune function in children.

2. What you need to know before you use LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS
Do not give LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS:
- If your child is hypersensitive (allergic) to the active ingredients or any of the other ingredients of LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS (listed in section 6).

Warnings and precautions
Take special care:
- If your child has anaemia, liver or metabolism problems.
- Vitamin supplements should not replace a balanced diet.

Children and adolescents
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is suitable for children 3 years and older. Consult with your healthcare practitioner before using.

Other medicine and LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS
Always tell your healthcare practitioner if your child is taking any other medicine. This includes complementary or traditional medicines. Not all possible interactions with other medicine may be included in this leaflet. Consult with your healthcare practitioner prior to use. LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS has no known interaction with other medicine if taken at recommended daily dosage:

LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS with food and drink
No known interaction with food and drinks. See Section 3.

Pregnancy, breastfeeding and fertility:
If you are pregnant, planning to become pregnant, or are breastfeeding please consult your doctor, pharmacist or healthcare practitioner before using LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS. Safety in pregnancy has not been established.

Driving and the use of machinery
No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS does not adversely affect their performance.

3. How to use LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
Do not share your child's medicines with any other person.
Always give LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS exactly as prescribed in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.
Children 3 years and older:
Give one to two gummies daily or as recommended by your healthcare practitioner.
Do not exceed the recommended daily dosage.

4. Possible side effects.
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS can have side effects.
Not all side effects reported for LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS are included in this leaflet.
Should your child's general health worsen or if your child experiences any untoward effects while taking LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS please consult your doctor, pharmacist or other healthcare practitioner for advice.

If any of the following happens, stop giving LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS to your child and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are very serious side effects. If your child has them, he/she may have had a serious reaction to LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS. Your child may need urgent medical attention or hospitalisation.
Tell your doctor if you notice any of the following:
- abdominal pain,
- dyspepsia (indigestion),
- bloating,
- diarrhoea,
- rash,
- fatigue,
- headache,
- vertigo.

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

Reporting of side effects:
If you are experiencing side effects, inform your doctor or pharmacist. You can also report your side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Form"** found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side-effects you can help provide more information on the safety of LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.

5. How to store LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
- Store at or below 25 °C in a dry place away from moisture and direct sunlight.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original packaging until required for use.
- Do not use after expiry date on the label.
- Return all unused LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS 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 LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS contains

Each gummy contains:
Ascorbic Acid (Vitamin C) 100 mg

The other ingredients are sugar, glucose syrup, water, pectin, colourant and flavouring.
Contains sugar: 930 mg sucrose, and 600 mg glucose syrup per gummy.

Presentation and identification of LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS
Orange, bear-shaped chewable gummies with an orange flavour, packed into a clear PET 250 ml container with a white child-proof screw-cap lid.
Pack size: 60 gummies.

Holder of certificate of Registration
Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685.
Careline: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in
October 2024

Registration number
Will be allocated by SAHPRA upon registration.

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VITAMIN C GUMMIES FOR KIDS

PASIËNTINLIGTINGSBLAD

SKEDULERINGS STATUS: S0

LOCAL HEALTH VITAMIN C GUMMIE FOR KIDS (koubare gummies)
Askorbiensuur (Vitamien C)

Bevat suiker (930 mg sukrose, en 600 mg glukose stroop per gummy).

Komplementêre Medisyne: D.34.11 Vitamiene
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie.

Lees hierdie inligtingspamflet noukerig deur aangesien dit belangrike inligting bevat vir jou.
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is beskikbaar sonder 'n dokter se voorskrif om jou gesondheid te handhaaf. Nietemin moet jy LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS steeds versigtig gebruik om die beste resultate te kry.
- Hou hierdie pamflet, jy mag dit weer nodig hê.
- Moet nie LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS met enige ander persoon deel nie.
- Vra jou gesondheidsorgpraktisyn of apteker indien jy meer inligting of advies benodig.

Wat is in hierdie inligtingsblad
- Wat LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy jou kind LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS gee.
- Hoe om vir jou kind LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS te gee.
- Moontlike newe-effekte.
- Hoe om LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS te bêre.
- Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is en waarvoor dit gebruik word.
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is 'n vitamien en:
- Dra by tot die instandhouding van goeie gesondheid en immuunfunksie by kinders.

2. Wat jy moet weet voordat jy LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS gebruik.
Moet nie LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS gee nie:
• As jou kind hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS (gelys in afdeling 6).
Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg:
- As jou kind bloedarmoede, lewer- of metabolismeprobleme het.
- Vitamienaanvullings behoort nie 'n gebalanseerde dieet te vervang nie.

Kinders en adolessente:
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is geskik vir kinders 3 jaar en ouer. Raadpleeg jou gesondheidsorgpraktisyn voor gebruik.

Ander medisyne en LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS:
Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne neem. Dit sluit komplementêre of tradisionele medisyne in. Nie alle moontlike interaksies met ander medisyne is in hierdie pamflet ingesluit nie. Raadpleeg jou gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH VITAMIN C GUMMIES VIR KINDERS het geen bekende interaksie met ander medisyne indien dit teen die aanbevole daaglikse dosis geneem word nie.

LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS met kos en drinkgoed
Geen bekende interaksie met kos en drinkgoed nie. Sien Afdeling 3.

Swangerskap, borsvoeding en vrugbaarheid
As jy swanger is, beplan om swanger te raak, of borsvoed, raadpleeg asseblief jou dokter, apteker of gesondheidsorgpraktisyn voordat jy LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS gebruik. Veiligheid tydens swangerskap is nie vasgestel nie.

Bestuur en gebruik van masjinerie
Geen studies oor die effekte op bestuur of die gebruik van masjinerie is uitgevoer nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS nie hul prestasie negatief beïnvloed nie.

3. Hoe om LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS te gebruik.
Moet nie jou kind se medisyne met ander persone deel nie.
Gebruik altyd LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS presies soos in hierdie pamflet voorgeskryf of soos jou gesondheidsorgpraktisyn jou aangesê het. Raadpleeg jou gesondheidsorgpraktisyn indien jy onseker is.
Kinders 3 jaar en ouer:
Gee een tot twee gummies daagliks of soos aangedui deur u gesondheidsorgpraktisyn.
Moenie die aanbevole daaglikse dosis oorskry nie.

4. Moontlike newe-effekte.
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS kan newe-effekte hê.
Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, is in hierdie pamflet ingesluit nie. As jou algemene gesondheid versleg of jy enige ongewensde effekte ervaar terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou dokter, apteker of gesondheidsorgpraktisyn vir advies.

Indien enige van die volgende gebeur, hou op om LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS te gebruik en lig onmiddellik jou dokter of apteker in, of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat sukkel met sluk of asemhaling kan veroorsaak;
- uitslag of jeuk;
- floutes.

Dit is baie ernstige newe-effekte. As jou kind hulle ervaar, kan hy/sy 'n ernstige reaksie op LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS hê. Jou kind mag dringende mediese aandag of hospitalisasie benodig:
Sê vir jou dokter as jy enige van die volgende by jou kind opmerk:
- buikpyn,
- dispepsie (indigestie),
- opgeblasenheid,
- diarree,
- uitslag,
- moegheid,
- hoofpyn,
- lighoofdigheid.

As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte:
As jy enige newe-effekte ervaar, lig asseblief jou dokter of apteker in. Jy kan ook jou newe-effekte aan SAHPRA rapporteer deur die **"6.04 Adverse Drug Reaction Form"** wat aanlyn beskikbaar is onder SAHPRA se publikasies: http://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS te verskaf.

5. Berging van LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
- Beskerm teen vog en bêre teen of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Moet nie gebruik na die vervaldatum op die etiket nie.
- Stuur alle ongebruikte LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting.
Wat LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS bevat

Elke gummy bevat:
Askorbiensuur (Vitamien C) 100 mg

Die ander bestanddele is suiker, glukose stroop, water, pektien, kleustof en geurmiddels.
Bevat suiker: 930 mg sukrose, en 600 mg glukose stroop per gummy.

Aanbiedings en identifikasie van LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS.
Oranje, beer-vormige koubare gummies met 'n lemoen geur, verpak in 'n deursigtige PET 250 ml houer met 'n wit kinderveilige skroefdop.
Verpakkingsgrootte: 60 gummies.

Houer van Registrasiesertifikaat:
Vervaardig vir: CJ Distribution, 23 Stagweg, Glen Austin, Johannesburg, Suid-Afrika, 1685.
Kliëntediens: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in
Oktober 2024

Registrasienommer:
Sal met registrasie deur SAHPRA toegeken word.

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VITAMIN C GUMMIES FOR KIDS

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: D.34.11 VITAMINS
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0
1.NAME OF THE MEDICINE
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS (chewable gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:
Ascorbic Acid (Vitamin C) 100 mg

CONTAINS SUGAR: 930 mg sucrose, and 600 mg glucose syrup per gummy. For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Chewable gummies.
Orange, bear-shaped chewable gummies with an orange flavour.
CONTAINS SUGAR: 930 mg sucrose, and 600 mg glucose syrup per gummy.

LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS contains colourant. Colour may vary from batch to batch.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
A vitamin supplement that contributes to the maintenance of good health and immune function in children.

4.2 Posology and method of administration
Posology
Children 3 years and older: Give one to two gummies daily or as recommended by your healthcare practitioner. Do not exceed the recommended daily dosage.
Method of administration
For oral use.

4.3 Contraindications
Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions to use
- If your child has anaemia, liver or metabolism problems.
- Vitamin supplements should not replace a balanced diet.

4.5 Interactions
Vitamin C
None known at recommended daily dosages.

4.6 Fertility, pregnancy and lactation
Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS studies on the ability to drive or use machinery have not been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS does not adversely affect their performance.

4.8 Undesirable effects
LOCAL HEALTH VITAMIN C GUMMIES FOR KIDS is generally well tolerated.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefits/risk balance of the medicine. healthcare practitioners are asked
to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/8.

4.9 Overdose
In the event of an overdose, undesirable effects listed in 4.8 can be precipitated or be of increased severity. Treatment is supportive and symptomatic. Should accidental overdose occur, discontinue use and consult a doctor or pharmacist.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
- **Ascorbic acid (Vitamin C):** Enhances immune function and acts as an antioxidant, aiding in collagen synthesis.

5.2 Pharmacokinetic properties
- **Ascorbic Acid (Vitamin C):** Rapidly absorbed in the small intestine, widely distributed, metabolized to oxalate, and excreted in urine.

6.1 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Sugar, glucose syrup, water, pectin, colourant and flavouring.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precaution for storage
Store at or below 25 °C. Store in the original packaging in order to protect from moisture.

6.5 Nature and contents of container
Clear 250 ml PET container with a white child-proof screw-cap lid.
(60 gummies)

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@cjdsa.com
010 589 2729
www.localhealth.co.za

8 REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION
Will be allocated by SAHPRA upon registration.