

SCHEDULING STATUS:^[S]

LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS (chewable gummies) Ascorbic acid (Vitamin C), Nicotinamide (as Vitamin B3), d-α-Tocopherol (Vitamin E), Pyridoxine (Vitamin B6), Calcium (as Tricalcium Phosphate), Zinc (as Zinc Citrate), Vitamin A (as Vitamin A Acetate), Magnesium (as Magnesium Citrate), Folic Acid, Riboflavin (Vitamin B2), Cholecalciferol (Vitamin D3), Copper (as Copper Amino Acid Chelate), Biotin (Vitamin H), Vitamin B12 (as Cyanocobalamin).

Contains sugar (1g sucrose, and 600mg glucose syrup per gummy).

Complementary Medicine: D.34.12 Multiple substance formulation

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 MULTIVITAMIN GUMMIES FOR KIDS is available without a doctor’s prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS carefully to get the best results from it.

- Keep this leaflet, you may need it again.
- Do not share LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS is and what it is used for.
- What you need to know before you give your child LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS
- How to give your child LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS
- Possible side effects.
- How to store LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS
- Contents of the pack and other information.

1.What LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS is and what it is used for

LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS is a multivitamin and mineral health supplement that:

- Contributes to the maintenance of good health, normal growth, and immune function in children.

2. What you need to know before you use LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS

Do not give LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS:

- if your child is hypersensitive (allergic) to the active ingredients or any of the other ingredients of LOCAL HEALTH MULTIVITAMIN GUMMIES (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 MULTIVITAMIN GUMMIES FOR KIDS is suitable for children 3 years and older. Consult with your healthcare practitioner before using.

Other medicine and LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS may interact with the following medicine:

- Levodopa or penicillamine because their effectiveness may be decreased.

LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS does not adversely affect their performance.

3. How to use LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS.

Do not share your child’s medicines with any other person.

Always give LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS can have side effects.

Not all side effects reported for LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS please consult your doctor, pharmacist or other healthcare practitioner for advice.

If any of the following happens, stop giving LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS.

5. How to store LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS contains

Each gummy contains:	
Ascorbic Acid (Vitamin C)	10 mg
Nicotinamide (Vitamin B3)	4 mg
d-α-Tocopherol (Vitamin E)	2 mg α-TE (3 IU)
Pyridoxine (Vitamin B6)	700µg
Calcium (as Tricalcium Phosphate)	300 µg
Zinc (as Zinc Citrate)	300 µg
Vitamin A (as Vitamin A Acetate)	220 µg (733 IU)
Magnesium (as Magnesium Citrate)	170 µg
Folic Acid	100 µg
Riboflavin (Vitamin B2)	30 µg
Cholecalciferol (Vitamin D3)	4 µg (160IU)
Copper (as Copper Amino Acid Chelate 10%)	3 µg
Biotin (Vitamin H)	1.70 µg
Cyanocobalamin (Vitamin B12)	0.80 µg

The other ingredients are sugar, glucose syrup, water, pectin, flavouring, and citric acid.

Contains sugar: 1g sucrose, and 600 mg glucose syrup per gummy.

Presentation and identification of LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS

Yellow, bear-shaped chewable gummies with a tropical flavour, packed into a clear PET 175 ml (30’s) and or 250 ml (60’s) container with a white child-proof screw-cap lid. Pack size: 30/60 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.

PASIËNTINLIGTINGSBLAD

SKEDULERINGS STATUS:^[S]

LOCAL HEALTH MULTIVITAMIN GUMMIE FOR KIDS (koubare gummies) Askorbiensuur (Vitamiën C), Nikotinamide (as Vitamiën B3), d-α-Tokoferol (Vitamiën E), Piriidoksien (Vitamiën B6), Kalsium (as Trikalسيومfosfaat), Sink (as Sinksitraat) Vitamiën A (as Vitamiën A Asetaat), Magnesium (as Magnesiumsitraat), Foliensuur, Riboflaviën (Vitamiën B2), Cholekalsiferol (Vitamiën D3), Koper (as Koper Aminosuurchelaat), Biotiën (Vitamiën H), Vitamin B12 (as Cyanocobalamin)

Bevat suiker (1g sukrose, en 600mg glukose stroop per gummy).

Komplementêre Medisyne: D.34.12 Meervooudige Bestanddeel Formulasie

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheids of beoogde gebruik nie.

Lees hierdie inligtingspamflet noukerig deur aangesien dit belangrike inligting bevat vir jou. LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS is beskikbaar sonder 'n dokter se voorskryf om jou gesondheid te handhaaf. Nietemin moet jy LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy jou kind LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS gee.
- Hoe om vir jou kind LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS te gee.
- Moontlike nuwe-effekte.
- Hoe om LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS te bêre.
- Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS is en waarvoor dit gebruik word.

LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS is 'n multivitamin- en mineraalgesondheidsaanvulling en:

- Dra by tot die instandhouding van goeie gesondheid, normale groei, en immuunfunksie by kinders.

2. Wat jy moet weet voordat jy LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS gebruik.

Moet nie LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS gee nie:

- As jou kind hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS (getys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg:

- As jou kind bloedarmoede, lewer- of metabolismeprobleme het.
- Vitamiënaanvullings behoort nie 'n gebalanseerde dieet te vervang nie.

Kinders en adolessente:

LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS is geskik vir kinders 3 jaar en ouer. Raadpleeg jou gesondheidsorgpraktisyn voor gebruik.

Ander medisyne en LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS kan interaksie hê met die volgende medisyne:

- Levodopa of penisillamien omdat hul doeltreffendheid verminder kan word.

LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN 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 MULTIVITAMIN GUMMIES FOR KIDS nie hul prestasie negatief beïnvloed nie.

3. Hoe om LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS te gebruik.

Moet nie jou kind se medisyne met ander persone deel nie.

Gebruik altyd LOCAL HEALTH MULTIVITAMIN 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:

Ge eën tot twee gummies daaglik of soos aanbeveel deur u gesondheidsorgpraktisyn. Moenie die aanbevole daaglikse dosis oorskry nie.

4. Moontlike nuwe-effekte.

LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir hierdie medisyne geraapporteer 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 MULTIVITAMIN GUMMIES FOR KIDS te gebruik en lig onmiddellik jou dokter in, of gaan na die ongewalle-afdeling van jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat sukkel met sluk of asemhaling kan veroorsaak;
- uitslag of jeuk;
- floues.

Dit is baie ernstige nuwe-effekte. As jou kind hulle ervaar, kan hy/sy 'n ernstige reaksie op LOCAL HEALTH MULTIVITAMIN 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 nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van nuwe-effekte

As jy enige nuwe-effekte ervaar, lig asseblief jou dokter of apteker in. Jy kan ook jou nuwe-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 nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van LOCAL HEALTH MULTIVITAMIN GUMMIE te verskaf.

5. Berging van LOCAL HEALTH MULTIVITAMIN 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 MULTIVITAMIN 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 MULTIVITMIN GUMMIES FOR KIDS bevat

Elke gummy bevat:	
Askorbiensuur (Vitamiën C)	10 mg
Nikotinamide (Vitamiën B3)	4 mg
d-α-Tokoferol (Vitamiën E)	2 mg α-TE (3 IU)
Piriidoksien (Vitamiën B6)	700µg
Kalsium (as Trikalسيومfosfaat)	300 µg
Sink (as Sinksitraat)	300 µg
Vitamiën A (as Vitamiën A Asetaat)	220 µg (733 IU)
Magnesium (as Magnesiumsitraat)	170 µg
Foliensuur	100 µg
Riboflaviën (Vitamiën B2)	30 µg
Cholekalsiferol (Vitamiën D3)	4 µg (160IU)
Koper (as Koper Aminosuurchelaat 10%)	3 µg
Biotin (Vitamiën H)	1.70 µg
Sianokobalamiën (Vitamiën B12)	0.80 µg

Die ander bestanddele is suiker, glukose stroop, water, pektien, geurmiddels, en sitroensuur.

Bevat suiker: 1g sukrose, en 600 mg glukose stroop per gummy.

Aanbieding en identifikasie van LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS.

Geel, beer-vormige koubare gummies met 'n tropiese geur, verpak in 'n deursigtige PET 175 ml (30’s) en/of 250 ml (60’s) houer met 'n wit kinderveilige skroefdoep. Verpakkingsgrootte: 30/60 gummies.

Houer van Registrasiesertifikaat:

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:

Sat met registrasie deur SAHPRA toegeken word.

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: D.34.12 MULTIPLE SUBSTANCE FORMULATION

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

^[S]

1.NAME OF THE MEDICINE

LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS (chewable gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:	
Ascorbic Acid (Vitamin C)	10 mg
Nicotinamide (Vitamin B3)	4 mg
d-α-Tocopherol (Vitamin E)	2 mg α-TE (3 IU)
Pyridoxine (Vitamin B6)	700µg
Calcium (as Tricalcium Phosphate)	300 µg
Zinc (as Zinc Citrate)	300 µg
Vitamin A (as Vitamin A Acetate)	220 µg (733 IU)
Magnesium (as Magnesium Citrate)	170 µg
Folic Acid	100 µg
Riboflavin (Vitamin B2)	30 µg
Cholecalciferol (Vitamin D3)	4 µg (160IU)
Copper (as Copper Amino Acid Chelate 10%)	3 µg
Biotin (Vitamin H)	1.70 µg
Cyanocobalamin (Vitamin B12)	0.80 µg

CONTAINS SUGAR: Contains sugar: 1g sucrose, and 600mg glucose syrup per gummy.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable gummies.

Yellow, bear-shaped chewable gummies with a tropical flavour.

Contains sugar: Contains sugar: 1g sucrose, and 600mg glucose syrup per gummy.

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LOCAL HEALTH MULTIVITAMIN GUMMIES FOR KIDS contains no colourant. Colour may vary from batch to batch.

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A multivitamin supplement and has the pharmacological action of each individual constituents of the formulation.

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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

Take special care:

- If your child has anaemia, liver or metabolism problems.
- Vitamin supplements should not replace a balanced diet.

4.5 Interactions

Pyridoxine

- Can reduce the effect of levodopa, but this effect will not occur if a dopa decarboxylase inhibitor is given in conjunction.
- Penicillamine may alter the metabolism of pyridoxine.

Vitamin A

- Cholestyramine, liquid paraffin and neomycin may reduce the absorption of Vit A in the GIT (gastro-intestinal tract).

- Absorption of Vit A can also be impaired by cholestatic jaundice and related fat malabs