local health
Your Life / Your Choice

PREGNANCY MULTIVITAMIN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

LOCAL HEALTH PREGNANCY MULTIVITAMIN (capsules)

Vitamin A (as Vitamin A Acetate), Cholecalciferol (Vitamin D3), Calcium (as Calcium Carbonate), Ascorbic Acid (Vitamin C), Iron (as Ferrous Fumarate), Nicotinamide (Vitamin B3), Thiamine (Vitamin B1), Riboflavin (Vitamin B2), Pyridoxine (Vitamin B6), Potassium (as Di-Potassium Phosphate), Magnesium (as Magnesium Oxide), Folic Acid, Copper (as Copper Amino Acid Chelate 10%), Zinc (as Zinc Oxide), Manganese (as Manganese Amino Acid Chelate 10%), Molybdenum Amino Acid Chelate 0.2%, Iodine (as Potassium Iodide), Cyanocobalamin (Vitamin B12)

Sugar free.

COMPLEMENTARY MEDICINE: D.34.12 MULTIPLE SUBSTANCE FORMULATION
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

Read all of this insert carefully as it contains important information for you.
LOCAL HEALTH PREGNANCY MULTIVITAMIN is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH PREGNANCY MULTIVITAMIN carefully to get the best results from it.
- Keep this leaflet, you may need it again.
- Do not share LOCAL HEALTH PREGNANCY MULTIVITAMIN 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 PREGNANCY MULTIVITAMIN is and what it is used for.
- What you need to know before you use LOCAL HEALTH PREGNANCY MULTIVITAMIN
- How to use LOCAL HEALTH PREGNANCY MULTIVITAMIN
- Possible side effects.
- How to store LOCAL HEALTH PREGNANCY MULTIVITAMIN
- Contents of the pack and other information.

1.What LOCAL HEALTH PREGNANCY MULTIVITAMIN is and what it is used for.
LOCAL HEALTH PREGNANCY MULTIVITAMIN is a multivitamin and mineral health supplement that:
- Contributes to the maintenance of good health and immune function during pregnancy.

2. What you need to know before you use LOCAL HEALTH PREGNANCY MULTIVITAMIN.
Do not use LOCAL HEALTH PREGNANCY MULTIVITAMIN:
- If you are allergic or sensitive to any of the ingredients of LOCAL HEALTH PREGNANCY MULTIVITAMIN (listed in section 6).

Warnings and precautions
Take special care:
- If you have anaemia, liver or metabolism problems.

Children and adolescents
LOCAL HEALTH PREGNANCY MULTIVITAMIN is not suitable for individuals 18 years and younger. Consult with your healthcare practitioner before using.

Other medicine and LOCAL HEALTH PREGNANCY MULTIVITAMIN
Always tell your healthcare practitioner if you are 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 PREGNANCY MULTIVITAMIN may interact with the following medicine:
- Levodopa or penicillamine because their effectiveness may be decreased.

LOCAL HEALTH PREGNANCY MULTIVITAMIN 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 breast-feeding, please consult your doctor, pharmacist or healthcare practitioner before using LOCAL HEALTH PREGNANCY MULTIVITAMIN. Safety in pregnancy has not been established.

Driving and the use of machinery
LOCAL HEALTH PREGNANCY MULTIVITAMIN, no current 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 PREGNANCY MULTIVITAMIN does not adversely affect their performance.

3. How to use LOCAL HEALTH PREGNANCY MULTIVITAMIN.
Do not share medicines prescribed for you with any other person.
Always use LOCAL HEALTH PREGNANCY MULTIVITAMIN exactly as prescribed in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults 18 years and older
Take one capsule daily or as recommended by your healthcare practitioner. Do not exceed the recommended daily dosage.

If you take more LOCAL HEALTH PREGNANCY MULTIVITAMIN than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining capsules with you so the doctor will know what you have taken.

If you forget to take LOCAL HEALTH PREGNANCY MULTIVITAMIN
Do not take a double dose to make up for individual forgotten doses.

4. Possible side effects.
LOCAL HEALTH PREGNANCY MULTIVITAMIN can have side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects, while taking this medicine, please consult your doctor, pharmacist or other healthcare practitioner for advice.
Administration of high doses of Vit A can cause hypervitaminosis A, characterized by fatigue, headache, vertigo, changes in skin and mucous membranes, yellow-orange discoloration of skin, decreased tolerance to sunlight, dry and brittle nails and hair, cracking and bleeding lips, low grade fever, tenderness, pains in joints and bones, hypercalcemia, hyperglycaemia, intracranial hypertension, visual disturbances, increase in serum cholesterol and serum triglycerides concentrations, irritability and oedema. Long term use of Vit A in high doses (20 000IU) may cause hepatic injury and cirrhosis. Symptoms usually clear with withdrawal of Vit A.

If any of the following happens, stop using LOCAL HEALTH PREGNANCY MULTIVITAMIN 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 you have them, you may have a serious reaction to LOCAL HEALTH PREGNANCY MULTIVITAMIN. You may need urgent medical attention or hospitalization.
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 PREGNANCY MULTIVITAMIN.

5. How to store LOCAL HEALTH PREGNANCY MULTIVITAMIN.
- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after expiry date on the label.
- Return all unused LOCAL HEALTH PREGNANCY MULTIVITAMIN 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.

Each capsule contains:	
Calcium (as Calcium Carbonate)	230 mg
Ascorbic Acid (Vitamin C)	50 mg
Iron (as Ferrous Fumarate)	20 mg
Nicotinamide (Vitamin B3)	10 mg
Thiamine (Vitamin B1)	3 mg
Riboflavin (Vitamin B2)	2 mg
Pyridoxine (Vitamin B6)	1 mg
Potassium (as Di-Potassium Phosphate)	840 µg
Vitamin A (as Vitamin A Acetate)	800 µg (2666 IU)
Magnesium (as Magnesium Oxide)	500 µg
Folic Acid	500 µg
Copper (as Copper Amino Acid Chelate 10%)	150 µg
Zinc (as Zinc Oxide)	85 µg
Manganese (as Manganese Amino Acid Chelate 10%)	50 µg
Molybdenum Amino Acid Chelate 0.2%	25 µg
Cholecalciferol (Vitamin D3)	10 µg (400 IU)
Iodine (as Potassium Iodide)	10 µg
Cyanocobalamin (Vitamin B12)	2 µg

The other ingredients are Bovine gelatine capsule, Microcrystalline Cellulose, Magnesium stearate.

Sugar free

Presentation and identification of LOCAL HEALTH PREGNANCY MULTIVITAMIN
White, size 00, bovine gelatine capsules packed into a white PET 175 ml container with a white screw-cap lid.
Pack size: 30 capsules.

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.

local health
Your Life / Your Choice

PREGNANCY MULTIVITAMIN

PASIENT INFORMASIE BROSJURE

SKEDULERINGS STATUS: S0

LOCAL HEALTH PREGNANCY MULTIVITAMIN (kapsules)

Vitamien A (as Vitamien A Asetaat), Cholekalciferol (Vitamien D3), Kalsium (as Kalsiumkarbonaat), Askorbiensuur (Vitamien C), Yster (as Ysterfumaraat), Nikotinamied (Vitamien B3), Tiamien (Vitamien B1), Riboflavien (Vitamien B2), Piridoksien (Vitamien B6), Kalium (as Di-Kaliumfosfaat), Magnesium (as Magnesiumoksied), Foliensuur, Koper (as Aminosuurchelaat 10%), Sink (as Sinkoksied), Mangaan (as Mangaan Aminosuurchelaat 10%), Molibdeen Aminosuurchelaat 0.2%, Jodium (as Kaliumjodied), Sianokobalamien (Vitamien B12)

Suikervry.

KOMPLEMENTÊRE MEDISYNE: D.34.12 MEERVOUDIGE BESTANDDEEL FORMULASIE
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of voorkom nie.

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

Wat is in hierdie pamflet
- Wat LOCAL HEALTH PREGNANCY MULTIVITAMIN is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy LOCAL HEALTH PREGNANCY MULTIVITAMIN gebruik.
- Hoe om LOCAL HEALTH PREGNANCY MULTIVITAMIN te gebruik.
- Moontlike newe-effekte.
- Hoe om LOCAL HEALTH PREGNANCY MULTIVITAMIN te bêre.
- Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH PREGNANCY MULTIVITAMIN is en waarvoor dit gebruik word.
LOCAL HEALTH PREGNANCY MULTIVITAMIN is 'n multivitamien- en mineraalgesondheidsaanvulling wat ginseng bevat en:
- Dra by tot die instandhouding van goeie gesondheid en immuunfunksie tydens swangerskap.

2. Wat jy moet weet voordat jy LOCAL HEALTH PREGNANCY MULTIVITAMIN gebruik.
Moet nie LOCAL HEALTH PREGNANCY MULTIVITAMIN neem:
- As jy allergies of sensitief is vir enige van die bestanddele van LOCAL HEALTH PREGNANCY MULTIVITAMIN (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg:
- As jy bloedarmoede, lewer- of metabolismeprobleme het.

Kinders en adolessente:
LOCAL HEALTH PREGNANCY MULTIVITAMIN is nie geskik vir individue 18 jaar en jonger nie. Raadpleeg jou gesondheidsorgpraktisyn voordat jy dit gebruik.

Ander medisyne en LOCAL HEALTH PREGNANCY MULTIVITAMIN
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 PREGNANCY MULTIVITAMIN kan interaksie hê met die volgende medisyne:.
- Levodopa of penisillamien omdat hul doeltreffendheid verminder kan word.

LOCAL HEALTH PREGNANCY MULTIVITAMIN 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 PREGNANCY MULTIVITAMIN 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 PREGNANCY MULTIVITAMIN nie hul prestasie negatief beïnvloed nie.

3. Hoe om LOCAL HEALTH PREGNANCY MULTIVITAMIN te gebruik.
Moet nie medisyne wat vir jou voorgeskryf is met ander persone deel nie. Moet nie die daaglikse aanbevole dosis oorskry nie. Gebruik altyd LOCAL HEALTH PREGNANCY MULTIVITAMIN presies soos in hierdie pamflet voorgeskryf of soos jou gesondheidsorgpraktisyn jou aangesê het. Raadpleeg jou gesondheidsorgpraktisyn indien jy onseker is.

Volwassenes ouer as 18 jaar
Neem 1 kapsule daagliks of soos aanbeveel deur u gesondheidsorgpraktisyn. Moenie die aanbevole daaglikse dosis oorskry nie.

As jy meer LOCAL HEALTH PREGNANCY MULTIVITAMIN neem as wat jy behoort
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. As geen van hulle beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum. Neem hierdie brosjure en die oorblywende kapsules saam sodat die dokter sal weet wat jy geneem het.

As jy vergeet om LOCAL HEALTH PREGNANCY MULTIVITAMIN te neem
Moet nie 'n dubbele dosis neem om vir individuele vergete dosisse in te haal nie.

4. Moontlike newe-effekte.
LOCAL HEALTH PREGNANCY MULTIVITAMIN kan newe-effekte hê.
Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.
Toediening van hoë dosisse Vitamien A kan hipervitaminose A veroorsaak, gekenmerk deur moegheid, hoofpyn, duiseligheid, veranderinge in die vel en slymvliese, geel-oranje verkleuring van die vel, verminderde verdraagsaamheid teenoor sonlig, droë en brose naels en hare, gebarste en bloeiende lippe, lae graad koors, teerheid, pyne in gewrigte en bene, hiperkalsemie, hiperglukemie, intrakraniale hipertensie, sigversteurings, verhoging in serum cholesterol en serum trigliseriedkonsentrasies, geïrriteerdheid en edeem. Langtermyn gebruik van Vitamien A in hoë dosisse (20 000IE) kan lewerbeskadiging en sirrose veroorsaak. Simptome verdwyn gewoonlik met die onttrekking van Vitamien A.

Indien jy enige van die volgende ervaar, hou op om LOCAL HEALTH PREGNANCY MULTIVITAMIN te neem en sê dadelik vir jou dokter of apteker, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
-swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
-uitslag of gejeuk;
-floute.
Hierdie is baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH PREGNANCY MULTIVITAMIN gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.
Sê vir jou dokter as jy enige van die volgende 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 PREGNANCY MULTIVITAMIN te verskaf..

5. Berging van LOCAL HEALTH PREGNANCY MULTIVITAMIN.
- 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 PREGNANCY MULTIVITAMIN terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting.

Elke kapsule bevat:	
Kalsium (as Kalsiumkarbonaat)	230 mg
Askorbiensuur (Vitamien C)	50 mg
Yster (as Ysterfumaraat)	20 mg
Nikotinamied (Vitamien B3)	10 mg
Tiamien (Vitamien B1)	3 mg
Riboflavien (Vitamien B2)	2 mg
Piridoksien (Vitamien B6)	1 mg
Kalium (as Di-Kaliumfosfaat)	840 µg
Vitamien A (as Vitamien A Asetaat)	800 µg (2666 IU)
Magnesium (as Magnesiumoksied)	500 µg
Foliensuur	500 µg
Koper (as Aminosuurchelaat 10%)	150 µg
Sink (as Sinkoksied)	85 µg
Mangaan (as Mangaan Aminosuurchelaat 10%)	50 µg
Molibdeen Aminosuurchelaat 0.2%	25 µg
Cholekalsiferol (Vitamien D3)	10 µg (400 IU)
Jodium (as Kaliumjodied)	10 µg
Sianokobalamien (Vitamien B12)	2 µg

Ander bestanddele: Beesgelatien kapsule, Mikrokrystallyne Sellulose, Magnesium Stearaat.

Suikervry

Aanbiedings en identifikasie van LOCAL HEALTH PREGNANCY MULTIVITAMIN.
Wit, grootte 00, beesgelatien kapsules, verpak in 'n wit PET 175 ml houer met 'n wit skroefdop.
Verpakkingsgrootte: 30 kapsules.

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:
Sal met registrasie deur SAHPRA toegeken word

local health
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PREGANCY MULTIVITAMIN

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
S0

1.NAME OF THE MEDICINE
LOCAL HEALTH PREGNANCY MULTIVITAMIN (Capsules)
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:	
Calcium (as Calcium Carbonate)	230 mg
Ascorbic Acid (Vitamin C)	50 mg
Iron (as Ferrous Fumarate)	20 mg
Nicotinamide (Vitamin B3)	10 mg
Thiamine (Vitamin B1)	3 mg
Riboflavin (Vitamin B2)	2 mg
Pyridoxine (Vitamin B6)	1 mg
Potassium (as Di-Potassium phosphate)	840 µg
Vitamin A (as Vitamin A Acetate)	800 µg (2666 IU)
Magnesium (as Magnesium Oxide)	500 µg
Folic Acid	500 µg
Copper (as Copper Amino Acid Chelate 10%)	150 µg
Zinc (as Zinc Oxide)	85 µg
Manganese (as Manganese Amino Acid Chelate 10%)	50 µg
Molybdenum Amino Acid Chelate 0.2%	25 µg
Cholecalciferol (Vitamin D3)	10 µg (400 IU)
Iodine (as Potassium Iodide)	10 µg
Cyanocobalamin (Vitamin B12)	2 µg

Sugar free

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Capsules.
White, size 00, Bovine gelatine capsules containing an off-white to light brown coloured powder.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
LOCAL HEALTH PREGNANCY MULTIVITAMIN is a multivitamin and mineral health supplement that:
- Contributes to the maintenance of good health and immune function during pregnancy.

4.2 Posology and method of administration
Posology
Adults 18 years and older: Take 1 capsule 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. It is a supplement and is not intended for a specific vitamin deficiency.

4.4 Special warnings and precautions to use
Take special care:
- If you have anaemia, liver or metabolism problems.

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 malabsorption conditions.

Cyanocobalamin (Vitamin B12)
- Aminoglycosides, aminosalicylic acid, anticonvulsants, methyldopa, biguanides and chloramphenicol may reduce absorption of cyanocobalamin (Vitamin B12).

4.6 Fertility, pregnancy and lactation
If you are pregnant, planning to become pregnant, or are breast-feeding, please consult your doctor, pharmacist or healthcare practitioner before using LOCAL HEALTH PREGNANCY MULTIVITAMIN. Safety in pregnancy has not been established.

4.7 Effects on ability to drive and use machines
LOCAL HEALTH PREGNANCY MULTIVITAMIN 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 PREGNANCY MULTIVITAMIN does not adversely affect their performance.

4.8 Undesirable effects
Administration of high doses of Vit A can cause hypervitaminosis A, characterized by fatigue, headache, vertigo, changes in skin and mucous membranes, yellow-orange discoloration of skin, decreased tolerance to sunlight, dry and brittle nails and hair, cracking and bleeding lips, low grade fever, tenderness, pains in joints and bones, hypercalcemia, hyperglycaemia, intracranial hypertension, visual disturbances, increase in serum cholesterol and serum triglycerides concentrations, irritability and oedema. Long term use of Vit A in high doses (20 000IU) may cause hepatic injury and cirrhosis. Symptoms usually clear with withdrawal of Vit A.

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.

Vitamin A
Administration of high doses of Vit A can cause hypervitaminosis A, characterized by fatigue, headache, vertigo, changes in skin and mucous membranes, yellow-orange discoloration of skin, decreased tolerance to sunlight, dry and brittle nails and hair, cracking and bleeding lips, low grade fever, tenderness, pains in joints and bones, hypercalcaemia, hyperglycaemia, intracranial hypertension, visual disturbances, increase in serum cholesterol and serum triglycerides concentrations, irritability and oedema. Long term use of Vit A in high doses (20 000IU) may cause hepatic injury and cirrhosis. Symptoms usually clear with withdrawal of Vit A.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
- **Vitamin A (as Vitamin A Acetate):** Supports normal vision, skin health, and immune system function.
- **Vitamin D3 (as Cholecalciferol):** Assists in calcium absorption and bone health maintenance.
- **Calcium (as Calcium Carbonate):** Contributes to the maintenance of bones and teeth.
- **Vitamin C (as Ascorbic acid):** Supports immune function and protects cells from oxidative stress.
- **Iron (as Ferrous Fumarate):** Aids in the formation of red blood cells and oxygen transport.
- **Vitamin B3 (as Nicotinamide):** Helps maintain normal skin and supports energy metabolism.
- **Vitamin B1 (as Thiamine):** Supports normal energy-yielding metabolism and nerve function.
- **Vitamin B2 (as Riboflavin):** Contributes to the maintenance of normal skin and vision.
- **Vitamin B6 (as Pyridoxine)**: Assists in protein metabolism and red blood cell formation.
- **Potassium (as Di-Potassium Phosphate)**: Supports normal muscle function and nerve communication.
- **Magnesium (as Magnesium Oxide):** Contributes to normal muscle and nerve function, and energy production.
- **Folic Acid:** Supports maternal tissue growth during pregnancy and normal blood formation.
- **Copper (as Copper AAC**): Aids in iron transport and contributes to normal skin pigmentation.
- **Zinc (as Zinc oxide):** Supports immune system function and maintenance of skin and nails.
- **Manganese (as Manganese AAC):** Contributes to normal bone formation and energy metabolism.
- **Molybdenum:** Helps the body process proteins and genetic material.
- **Iodine (as Potassium iodide):** Supports normal thyroid function and cognitive development.
- **Vitamin B12 (as Cyanocobalamin):** Contributes to normal red blood cell formation and neurological function.

5.2 Pharmacokinetic properties
- **Vitamin A (as Vitamin A Acetate)** Absorbed in the small intestine, stored in the liver, and metabolized to active forms like retinol and retinoic acid.
- **Vitamin D3 (as Cholecalciferol):** Absorbed in the intestines, converted in the liver to calcidiol, and further metabolized in the kidneys to the active form, calcitriol.
- **Calcium (as Calcium Carbonate):** Absorbed primarily in the small intestine with vitamin D enhancement, distributed to bones, and excreted in the urine.
- **Vitamin C (as Ascorbic acid):** Rapidly absorbed in the intestines, widely distributed to tissues, and excreted primarily in urine.
- **Iron (as Ferrous Fumarate):** Absorbed in the duodenum, binds to transferrin for transport, and stored in the liver or incorporated into hemoglobin.
- **Vitamin B3 (as Nicotinamide):** Well absorbed in the gastrointestinal tract, metabolized in the liver, and excreted in urine as inactive metabolites.
- **Vitamin B1 (as Thiamine):** Absorbed in the small intestine, phosphorylated in the liver to its active form, and excreted in urine.
- **Vitamin B2 (as Riboflavin):** Absorbed in the small intestine, converted to its active coenzyme forms, and excreted in urine.
- **Vitamin B6 (as Pyridoxine):** Absorbed in the intestines, converted to its active form in the liver, and excreted in urine.
- **Potassium (as Di-Potassium Phosphate):** Absorbed in the small intestine, distributed to intracellular fluid, and excreted primarily through the kidneys.
- **Magnesium (as Magnesium Oxide):** Absorbed in the small intestine, distributed to bones and cells, and excreted in urine and feces.
- **Folic Acid:** Absorbed in the small intestine, converted to its active form in the liver, and excreted in urine.
- **Copper (as Copper AAC):** Absorbed in the stomach and small intestine, bound to proteins for transport, and excreted through bile.
- **Zinc (as Zinc oxide):** Absorbed in the small intestine, distributed to muscles and bones, and excreted through feces.
- **Manganese (as Manganese AAC):** Absorbed in the small intestine, transported to the liver, and excreted mainly through bile.
- **Molybdenum:** Absorbed in the stomach and small intestine, distributed to tissues, and excreted in urine.
- **Iodine (as Potassium iodide):** Absorbed in the stomach and small intestine, concentrated in the thyroid gland, and excreted through urine.
- **Vitamin B12 (as Cyanocobalamin):** Absorbed in the ileum with the help of intrinsic factor, stored in the liver, and excreted in bile and urine.

6.1 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Capsule: Bovine gelatine
Capsule contents: Microcrystalline Cellulose, Magnesium stearate.

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.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container
White 175 ml PET container with white screwcap lid.
Pack size: 30 capsules

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
CJ Distribution, 23 Stag RD, 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.