

PROFESSIONAL INFORMATION

D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH ZINC PLUS tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Zinc Gluconate	70 mg
Of which elemental Zinc	10 mg
Vitamin A (as Vitamin A Acetate)	5000 IU / 1500 µg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Round, concave white to off-white tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Zinc and vitamin A contribute to the normal development and maintenance of bones and teeth, the immune function, and to normal vision. Zinc contributes to the metabolism of vitamin A, and to the maintenance of normal hair, skin, and nails.

4.2 Posology and method of administration

Adults and children 9 years and older: one (1) tablet daily with a meal.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Patients taking retinoids should avoid concomitant use with vitamin A containing supplements.

4.4 Special warnings and precautions for use

- Type V hyperlipoproteinemia increases the risk of vitamin A hypervitaminosis when taking vitamin A containing supplements.
- Patients with liver disease can have an increased risk of hypervitaminosis and hepato toxicity when taking large doses of vitamin A.

4.5 Interaction with other medicines and other forms of interaction

- Retinoids taken in conjunction with vitamin A containing supplements could have additive toxic effects. Patients should avoid taking vitamin A supplements if they are taking retinoids.
- Doses exceeding 750 µg of vitamin A daily may induce a hypoprothrombinaemic response. Patients taking anticoagulants may be at increased risk of bleeding.
- Zinc may interfere with the effectiveness of antiretroviral drugs due to reduced absorption.
- Zinc may reduce absorption of ciprofloxacin.
- Zinc forms an insoluble complex with penicillamine, interfering with its absorption and activity. Patients should take zinc and penicillamine at least 2 hours apart.
- Zinc forms various complexes with antibiotics in the gut, affecting the absorption and effectiveness of antibiotics.
- Zinc may lower blood glucose levels and may have additive effects in patients using antidiabetic drugs.

4.6 Fertility, pregnancy and lactation

Vitamin A and zinc is likely safe when used within the recommended dosage.

4.7 Effects on ability to drive and use machines

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 ZINC PLUS does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal

Frequent: Gastrointestinal disturbances including abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, gastritis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. In addition, overdose over long periods of time may result in Hypervitaminosis A (chronic toxicity), and acute vitamin A intoxication may also occur with very high doses.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc is a mineral that contributes to the maintenance of immune function, the maintenance of normal vision, nails, bones and hair. Zinc contributes to the normal metabolism of vitamin A.

Vitamin A contributes to the maintenance and development of normal vision and night vision. It contributes to the normal function of the immune system, the development and maintenance of bones and teeth.

5.2 Pharmacokinetic properties

Absorption of **zinc** from the gastrointestinal tract is incomplete, and is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 % to 30%. Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, eye, and prostatic fluids. It is primarily excreted in the faeces, and regulation of faecal losses is important in zinc homeostasis. Small amounts are lost in urine and perspiration.

Vitamin A is readily absorbed from the gastrointestinal tract but absorption may be reduced in the presence of fat malabsorption, low protein intake, or impaired liver or

pancreatic function. Vitamin A esters are hydrolysed by pancreatic enzymes to retinol, which is then absorbed and re-esterified. Some retinol is stored in the liver. It is released from the liver bound to a retinol-binding protein in the blood. The retinol not stored in the liver undergoes glucuronide conjugation and subsequent oxidation to retinal and retinoic acid, these and other metabolites are excreted in urine and faeces. Vitamin A does not readily diffuse across the placenta, but is present in breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinylpyrrolidone, maize starch, purified water, silicon dioxide, micro cellulose, magnesium stearate.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

60 tablets in a white, PET plastic container and white screwcap lid.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CJ Distribution
23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@cjdsa.com
011 589 2729
www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

**PATIENT INFORMATION LEAFLET
SCHEDULING STATUS**

SO
LOCAL HEALTH ZINC PLUS (tablets)

Each tablet contains:

Zinc Gluconate	70 mg
Of which elemental Zinc	10 mg
Vitamin A (as Vitamin A Acetate)	5000 IU / 1500 µg

Sugar free

Complementary Medicine: Multiple Substance Formulation (Health Supplement)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

Read all of this leaflet carefully because it contains important information for you.

LOCAL HEALTH ZINC PLUS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH ZINC PLUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH ZINC PLUS with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH ZINC PLUS is and what it is used for.
2. What you need to know before you use LOCAL HEALTH ZINC PLUS.
3. How to use LOCAL HEALTH ZINC PLUS.
4. Possible side effects.
5. How to store LOCAL HEALTH ZINC PLUS.
6. Contents of the pack and other information.

1. What LOCAL HEALTH ZINC PLUS is and what it is used for

Zinc and vitamin A contribute to the normal development and maintenance of bones and teeth, the immune function, and to normal vision. Zinc contributes to the metabolism of vitamin A, and to the maintenance of normal hair, skin, and nails.

2. What you need to know before you use LOCAL HEALTH ZINC PLUS

Do not use LOCAL HEALTH ZINC PLUS:

- If you are allergic or sensitive to any of the ingredients listed in section 6.
- If you are taking retinoids.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH ZINC PLUS, especially if you have a medical condition.

Use LOCAL HEALTH ZINC PLUS with caution and consult a healthcare practitioner before use:

- If you have hyperlipidemia or liver disease.

Children and adolescents

LOCAL HEALTH ZINC PLUS is not recommended for children below the age of 9 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH ZINC PLUS

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use. LOCAL HEALTH ZINC PLUS may interact with the following medications: retinoids, anticoagulants, antiretroviral drugs, ciprofloxacin, penicillamine, antibiotics, antidiabetes drugs.

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 practitioner for advice before using LOCAL HEALTH ZINC PLUS.

Driving and using 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 ZINC PLUS does not adversely affect their performance.

3. How to use LOCAL HEALTH ZINC PLUS

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH ZINC PLUS exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 9 years and older:

Take one (1) tablet daily with a meal, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH ZINC PLUS can have side effects. Not all side effects reported for LOCAL HEALTH ZINC PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH ZINC PLUS, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH ZINC PLUS and tell your doctor or pharmacist immediately, or go 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 had a serious reaction to LOCAL HEALTH ZINC PLUS. You may need urgent medical attention or hospitalisation.

- **Frequent:** gastrointestinal disturbances including abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, gastritis.

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

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting 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 ZINC PLUS.

5. How to store LOCAL HEALTH ZINC PLUS

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH ZINC PLUS to your pharmacist.
- Do not dispose of unused LOCAL HEALTH ZINC PLUS in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH ZINC PLUS contains

Each tablet contains:

Zinc Gluconate	70 mg
Of which elemental Zinc	10 mg
Vitamin A (as Vitamin A Acetate)	5000 IU / 1500 µg

Other ingredients: polyvinylpyrrolidone, maize starch, purified water, silicon dioxide, micro cellulose, magnesium stearate.

Sugar free

Presentation and identification of LOCAL HEALTH ZINC PLUS

60 round, concave white to off-white tablets packed into a white plastic container.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 011 589 2729; careline@cjdlsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

SO
LOCAL HEALTH ZINC PLUS (tablette)

Elke tablet bevat:

Sinkglukonaat	70 mg
Of which elementele Sink	10 mg
Vitamien A (as Vitamien A Asetaat)	5000 IU / 1500 µg

Suikervry

Komplementêre Medisyne: Meervoudige Bestanddeel Formulasie (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH ZINC PLUS is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH ZINC PLUS versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH ZINC PLUS met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH ZINC PLUS is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH ZINC PLUS gebruik.
3. Hoe om LOCAL HEALTH ZINC PLUS te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH ZINC PLUS.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH ZINC PLUS is en waarvoor dit gebruik word

Sink en vitamien A dra by tot die normale ontwikkeling en instandhouding van bene en tande, die immuunfunksie en tot normale sig. Sink dra by tot die metabolisme van vitamien A en tot die instandhouding van normale hare, vel en naels.

2. Wat u moet weet voordat u LOCAL HEALTH ZINC PLUS gebruik

Moet nie LOCAL HEALTH ZINC PLUS neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.
- Indien u retinoïede neem.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH ZINC PLUS gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH ZINC PLUS met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u hiperlipidemie of lewer siekte het.

Kinders en adolessente

LOCAL HEALTH ZINC PLUS word nie aanbeveel vir kinders jonger as 9 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH ZINC PLUS en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH ZINC PLUS kan interaksie hê met die volgende medisyne: retinoïede, antistomiddels, antiretrovirale-middels, ciprofloxacin, penisillamien, antibiotika, antidiabetes middels.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH ZINC PLUS gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH ZINC PLUS nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH ZINC PLUS te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH ZINC PLUS presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 9 jaar en ouer:

Neem een (1) tablet daaglik saam etes, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH ZINC PLUS kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH ZINC PLUS is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewensde reaksies ervaar tydens die gebruik van LOCAL HEALTH ZINC PLUS, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH ZINC PLUS en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH ZINC PLUS gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Dikwels:** gastroïntestinale verstourings insluitend buikpyn, dispepsie, naarheid, braking, diarree, gastriese irritasie, gastritis.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH ZINC PLUS.

5. Berging van LOCAL HEALTH ZINC PLUS

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BUIE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH ZINC PLUS na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH ZINC PLUS in afvoertype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH ZINC PLUS bevat

Elke tablet bevat:

Sinkglukonaat	70 mg
Of which elementele Sink	10 mg
Vitamien A (as Vitamien A Asetaat)	5000 IU / 1500 µg

Ander bestanddele: polivinilpirrolidoon, mieliestysel, gesuiwerde water, silikondioksied, mikrosellulose, magnesiumstearaat.

Suikervry

Aanbieding en identifikasie van LOCAL HEALTH ZINC PLUS

60 ronde, konkawe wit tot af-wit tablette verpak in 'n wit plastiekhouer.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 011 589 2729; careline@cjdlsa.com; www.localhealth.co.za

Hierdie pamflet is laas hiersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.