

PROFESSIONAL INFORMATION

Complementary Medicine: Combination Product

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH IMMUNE FIZZY effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:	
<i>Echinacea purpurea</i> L. (Echinacea) [root, as 375 mg of a 4:1 extract]	1500 mg
Ascorbic Acid (Vitamin C)	333 mg
Quercetin	150 mg
[as 153,06 mg <i>Styphnolobium japonicum</i> L. extract standardised to 98% quercetin]	
<i>Pelargonium sidoides</i> (African Geranium) [root, 4 – 25:1 extract standardised to 60 ppm Umckalin, providing 80 – 500 mg dried herb equivalent]	20 mg
Zinc Gluconate	42 mg
Providing Zinc (elemental)	5 mg
Vitamin A (as Vitamin A Acetate)	1476 IU (440 µg)
Selenium Glycinate	750 µg
Providing Selenium (elemental)	15 µg
Cholecalciferol (Vitamin D3)	333 IU (8,3 µg)

Contains sugar: 200 mg isomalt and 400 mg sorbitol per effervescent tablet.

Contains sweetener: 17 mg sucralose per effervescent tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.

Flat, round, bevelled-edged yellow effervescent tablets with a citrus flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH IMMUNE FIZZY supports the immune system during colds, flu and during times of intense physical stress, contributes to normal immune response to seasonal allergens, and assists in the reduction of tiredness and fatigue.

4.2 Posology and method of administration

Adults 18 years and older: Take one effervescent tablet, dissolved in a glass of water, three times daily with food.

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 for use

- Patients with a progressive systemic disease such as tuberculosis, collagenosis, multiple sclerosis, AIDS and/or HIV infections.
- Patients with an autoimmune disorder.
- Patients taking medications to suppress the immune system.

4.5 Interaction with other medicines and other forms of interaction

- Consult a healthcare practitioner prior to use if you are taking any other medicine (including complementary or traditional medicines).
- Echinacea has immunostimulant activity which may interfere with immunosuppressant therapy.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

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 IMMUNE FIZZY does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: gastrointestinal upset, diarrhoea, abdominal pain, nausea, vomiting, heartburn, constipation.

Dermatological disorders

Frequent: rash.

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. Healthcare 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.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product.

5.1 Pharmacodynamic properties

LOCAL HEALTH IMMUNE FIZZY supports the immune system during colds, flu and during times of intense physical stress, contributes to normal immune response to seasonal allergens, and assists in the reduction of tiredness and fatigue.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH IMMUNE FIZZY.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous
Sodium bicarbonate
Isomalt
Sorbitol
Flavouring
Polyethylene glycol
Polyvinylpyrrolidone
Crospovidone
Sucralose
Colourant

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.

6.5 Nature and contents of container

Plastic tubes of 10 effervescent tablets, with a desiccant cap, packed into an outer carton. Pack size: 20 effervescent tablets.

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.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**

S0

LOCAL HEALTH IMMUNE FIZZY (effervescent tablets)

Each effervescent tablet contains:	
<i>Echinacea purpurea</i> L. (Echinacea)	1500 mg
[root, as 375 mg of a 4:1 extract]	
Ascorbic Acid (Vitamin C)	333 mg
Quercetin	150 mg
[as 153,06 mg <i>Styphnolobium japonicum</i> L. extract standardised to 98% quercetin]	
<i>Pelargonium sidoides</i> (African Geranium)	20 mg
[root, 4 – 25:1 extract standardised to 60 ppm Umckalin, providing 80 – 500 mg dried herb equivalent]	
Zinc Gluconate	42 mg
Providing Zinc (elemental)	5 mg
Vitamin A (as Vitamin A Acetate)	1476 IU (440 µg)
Selenium Glycinate	750 µg
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Cholecalciferol (Vitamin D3)	333 IU (8,3 µg)

Contains sugar: 200 mg isomalt and 400 mg sorbitol per effervescent tablet.
Contains sweetener: 17 mg sucralose per effervescent tablet.

Complementary Medicine: Combination Product

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH IMMUNE FIZZY 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 IMMUNE FIZZY is and what it is used for.
2. What you need to know before you use LOCAL HEALTH IMMUNE FIZZY.
3. How to use LOCAL HEALTH IMMUNE FIZZY.
4. Possible side effects.
5. How to store LOCAL HEALTH IMMUNE FIZZY.
6. Contents of the pack and other information.

1. What LOCAL HEALTH IMMUNE FIZZY is and what it is used for

LOCAL HEALTH IMMUNE FIZZY supports the immune system during colds, flu and during times of intense physical stress, contributes to normal immune response to seasonal allergens, and assists in the reduction of tiredness and fatigue.

2. What you need to know before you use LOCAL HEALTH IMMUNE FIZZY

Do not use LOCAL HEALTH IMMUNE FIZZY:

- If you are hypersensitive (allergic) to any of the ingredients listed in section 6.

Warnings and precautions

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

Consult a healthcare practitioner prior to use:

- If you have a progressive systemic disease such as tuberculosis, collagenosis, multiple sclerosis, AIDS and/ or HIV infection.
- If you have an autoimmune disorder.
- If you are taking medications to suppress the immune system.

Consult a healthcare practitioner if symptoms persist or worsen while you are using LOCAL HEALTH IMMUNE FIZZY.

Children and adolescents

LOCAL HEALTH IMMUNE FIZZY is not recommended for individuals below the age of 18 years.

Other medicines and LOCAL HEALTH IMMUNE FIZZY

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 if you are taking any other medication. LOCAL HEALTH IMMUNE FIZZY may interact with the following medication: immunosuppressant medications.

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 IMMUNE FIZZY.

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 IMMUNE FIZZY does not adversely affect their performance.

3. How to use LOCAL HEALTH IMMUNE FIZZY

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH IMMUNE FIZZY exactly as described 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 effervescent tablet, dissolved in a glass of water, three times daily with food, or as recommended by your healthcare practitioner.

Consult a healthcare practitioner if symptoms persist or worsen while you are using LOCAL HEALTH IMMUNE FIZZY.

4. Possible side effects

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

Frequent: gastrointestinal upset, diarrhoea, abdominal pain, nausea, vomiting, heartburn, constipation, rash.

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 IMMUNE FIZZY.

5. How to store LOCAL HEALTH IMMUNE FIZZY

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

6. Contents of the pack and other information

What LOCAL HEALTH IMMUNE FIZZY contains

Each effervescent tablet contains:	
<i>Echinacea purpurea</i> L. (Echinacea)	1500 mg
[root, as 375 mg of a 4:1 extract]	
Ascorbic Acid (Vitamin C)	333 mg
Quercetin	150 mg
[as 153,06 mg <i>Styphnolobium japonicum</i> L. extract standardised to 98% quercetin]	
<i>Pelargonium sidoides</i> (African Geranium)	20 mg
[root, 4 – 25:1 extract standardised to 60 ppm Umckalin, providing 80 – 500 mg dried herb equivalent]	
Zinc Gluconate	42 mg
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Vitamin A (as Vitamin A Acetate)	1476 IU (440 µg)
Selenium Glycinate	750 µg
Providing Selenium (elemental)	15 µg
Cholecalciferol (Vitamin D3)	333 IU (8,3 µg)

Other ingredients: citric acid anhydrous, sodium bicarbonate, isomalt, sorbitol, flavouring, polyethylene glycol, polyvinylpyrrolidone, crospovidone, sucralose, colourant.

Contains sugar: 200 mg isomalt and 400 mg sorbitol per effervescent tablet.

Contains sweetener: 17 mg sucralose per effervescent tablet.

Presentation and identification of LOCAL HEALTH IMMUNE FIZZY

Plastic tubes of 10 yellow effervescent tablets with a citrus flavour, with a desiccant cap, packed into an outer carton.

Pack size: 20 effervescent tablets.

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

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS**

S0

LOCAL HEALTH IMMUNE FIZZY (bruistablette)

Elke bruistablet bevat:	
<i>Echinacea purpurea</i> L. (Echinacea)	1500 mg
[wortel, as 375 mg van 'n 4:1 ekstrak]	
Askorbiesuur (Vitamiën C)	333 mg
Kwersitien	150 mg
[as 153,06 mg <i>Styphnolobium japonicum</i> L. ekstrak gestandaardiseer tot 98% kwersitien]	
<i>Pelargonium sidoides</i> (African Geranium)	20 mg
[wortel, 4 – 25:1 ekstrak gestandaardiseer tot 60 ppm Umckalin, wat 80 – 500 mg gedroogde kruie ekwivalent verskaf]	
Sinkglukonaat	42 mg
Verskaf Sink (elementale)	5 mg
Vitamiën A (as Vitamiën A Asetaat)	1476 IU (440 µg)
Seleniumglisinaat	750 µg
Verskaf Selenium (elementale)	15 µg
Cholekalsiferol (Vitamiën D3)	333 IU (8,3 µg)

Bevat suiker: 200 mg isomalt en 400 mg sorbitol per bruistablet.
Bevat versoeter: 17 mg sukralose per bruistablet.

Komplementêre Medisyne: Kombinasieprodukt

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

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

LOCAL HEALTH IMMUNE FIZZY is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH IMMUNE FIZZY 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 IMMUNE FIZZY 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 IMMUNE FIZZY is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH IMMUNE FIZZY gebruik.
3. Hoe om LOCAL HEALTH IMMUNE FIZZY te gebruik.
4. Moontlike nuwe-effekte.
5. Hoe om LOCAL HEALTH IMMUNE FIZZY te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH IMMUNE FIZZY is en waarvoor dit gebruik word

LOCAL HEALTH IMMUNE FIZZY ondersteun die immuunstelsel tydens verkoue, griep en tydens tye van intensiewe fisiese stres, dra by tot normale immuunrespons op seisoenale allergene, en help met die vermindering van tamheid en moegheid.

2. Wat u moet weet voordat u LOCAL HEALTH IMMUNE FIZZY gebruik

Moet nie LOCAL HEALTH IMMUNE FIZZY neem nie:

- Indien u hipersensitief (allergies) is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

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

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u 'n progressiewe sistemiese siekte het, soos tuberkulose, kollagenose, veelvuldige sklerose, VIGS en/ of MIV-infeksie.
- Indien u 'n outo-immuun siekte het.
- Indien u medikasie gebruik om die immuunstelsel te onderdruk.

Raadpleeg 'n gesondheidsorgpraktisyn indien simptome voortduur of vererger terwyl u LOCAL HEALTH IMMUNE FIZZY gebruik.

Kinders en adolessente

LOCAL HEALTH IMMUNE FIZZY word nie aanbeveel vir individue onder die ouderdom van 18 jaar nie.

Die neem van LOCAL HEALTH IMMUNE FIZZY 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 indien u enige ander medikasie gebruik. LOCAL HEALTH IMMUNE FIZZY kan interaksie hê met die volgende medikasie: immuunonderdrukkers.

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 IMMUNE FIZZY 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 IMMUNE FIZZY nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH IMMUNE FIZZY 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 IMMUNE FIZZY presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes 18 jaar en ouer

Neem een bruistablet, opgelos in 'n glas water, drie keer per dag saam met kos, of soos aanbeveel deur u gesondheidsorgpraktisyn.

Raadpleeg 'n gesondheidsorgpraktisyn indien simptome voortduur of vererger terwyl u LOCAL HEALTH IMMUNE FIZZY gebruik.

4. Moontlike nuwe-effekte

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

Dikwels: gastroïntestinale ongemak, diarree, buikpyn, naarheid, braking, sooi-brand, hardlywigheid, veluitslag.

U siebief of 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 IMMUNE FIZZY.

5. Hoe om LOCAL HEALTH IMMUNE FIZZY te bêre

- Beskerm teen vog en bêre by of onder 25 °C.
- HOU BIJTE BEREIK VAN KINDERS.
- Stoor in die oorspronklike verpakking en hou die houer dig verseël.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH IMMUNE FIZZY na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH IMMUNE FIZZY in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH IMMUNE FIZZY bevat

Elke bruistablet bevat:	
<i>Echinacea purpurea</i> L. (Echinacea)	1500 mg
[wortel, as 375 mg van 'n 4:1 ekstrak]	
Askorbiesuur (Vitamiën C)	333 mg
Kwersitien	150 mg
[as 153,06 mg <i>Styphnolobium japonicum</i> L. ekstrak gestandaardiseer tot 98% kwersitien]	
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Sinkglukonaat	42 mg
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Seleniumglisinaat	750 µg
Verskaf Selenium (elementale)	15 µg
Cholekalsiferol (Vitamiën D3)	333 IU (8,3 µg)

Ander bestanddele: watervry sitroensuur, natriumbikarbonaat, isomalt, sorbitol, geurmiddel, poliëteenglikol, polivinilpirrolidone, crospovidone, sukralose, kleurstof.

Bevat suiker: 200 mg isomalt en 400 mg sorbitol per bruistablet.

Bevat versoeter: 17 mg sukralose per bruistablet.

Aanbieding en identifikasie van LOCAL HEALTH IMMUNE FIZZY

Plastiekbuis van 10 geel bruistablette met 'n sitrusgeur, met 'n droogmiddel deksel, verpak in a buitenste karton.

Verpakkingsgrootte: 20 bruistablette.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685

Sorglyn: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.