

ITTENSYS® ZINC AND VITAMIN C LOZENGES

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

ITTENSYS® ZINC AND VITAMIN C LOZENGES

Each lozenge contains: Ascorbic Acid (Vitamin C) 6,930 mg, Sodium Ascorbate 15,829 (Equivalent to Vitamin C 14,070 mg) Zinc gluconate 29,274 mg (Equivalent to elemental zinc 4,2 mg)

Contains sugar (1574,409 mg Sucrose and 847,758 mg liquid glucose per lozenge)

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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.

ITTENSYS® ZINC AND VITAMIN C LOZENGES is available without a doctor's prescription, for you or your child to maintain your health. Nevertheless, you still need to use ITTENSYS® ZINC AND VITAMIN C LOZENGES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ITTENSYS® ZINC AND VITAMIN C LOZENGES with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What ITTENSYS® ZINC AND VITAMIN C LOZENGES is and what it is used for.
2. What you need to know before you take ITTENSYS® ZINC AND VITAMIN C LOZENGES.
3. How to take ITTENSYS® ZINC AND VITAMIN C LOZENGES.
4. Possible side effects.
5. How to store ITTENSYS® ZINC AND VITAMIN C LOZENGES.
6. Contents of the pack and other information.

1. What ITTENSYS® ZINC AND VITAMIN C LOZENGES is and what it is used for

ITTENSYS® ZINC AND VITAMIN C LOZENGES are indicated to refresh the mouth and for the temporary relief of a (minor) sore throat.

Helps to maintain immune function and is an antioxidant for the maintenance of good health.

2. What you need to know before you take ITTENSYS® ZINC AND VITAMIN C LOZENGES

Do not take ITTENSYS® ZINC AND VITAMIN C LOZENGES

- If you or your child are hypersensitive (allergic) to vitamin C, zinc or to any of the other ingredients of ITTENSYS® ZINC AND VITAMIN C LOZENGES (listed in section 6).

Warnings and precautions

Take special care with ITTENSYS® ZINC AND VITAMIN C LOZENGES

- If you or your child's sore throat worsens or persists for more than 2 days, consult your healthcare provider.

Children

Not suitable for children under the age of 6 years.

Other medicines and ITTENSYS® ZINC AND VITAMIN C LOZENGES

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- Quinolone or tetracycline antibiotics (used to treat bacterial infections). These antibiotics should be taken 2 hours before, or 4 – 6 hours after ITTENSYS® ZINC AND VITAMIN C LOZENGES.

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 provider for advice before taking ITTENSYS® ZINC AND VITAMIN C LOZENGES.

Safety and efficacy of ITTENSYS® ZINC AND VITAMIN C LOZENGES during pregnancy and breastfeeding has not been established.

Driving and using machines

ITTENSYS® ZINC AND VITAMIN C LOZENGES may cause side effects like sleepiness which may affect your ability to drive and use machines. Do not drive a vehicle or operate machinery until you know how ITTENSYS® ZINC AND VITAMIN C LOZENGES affects you.

ITTENSYS® ZINC AND VITAMIN C LOZENGES contains sucrose and glucose

Each lozenge contains 1574,409 mg sucrose and 847,758 mg liquid glucose syrup. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using ITTENSYS® ZINC AND VITAMIN C LOZENGES. May be harmful to the teeth.

3. How to take ITTENSYS® ZINC AND VITAMIN C LOZENGES

Always take ITTENSYS® ZINC AND VITAMIN C LOZENGES exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

Adults and children older than 6 years:

Adults: Take 1 lozenge every 2 - 3 hours as needed. Maximum 6 lozenges per day.

Children: 6 years and above, take 1 lozenge every 4 - 6 hours as needed. Maximum 3 lozenges per day.

If you take more ITTENSYS® ZINC AND VITAMIN C LOZENGES than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the remainder of the ITTENSYS® ZINC AND VITAMIN C LOZENGES with you so the doctor will know what you have taken.

If you forget to take ITTENSYS® ZINC AND VITAMIN C LOZENGES

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ITTENSYS® ZINC AND VITAMIN C LOZENGES can have side effects. Not all side effects reported for ITTENSYS® ZINC AND VITAMIN C LOZENGES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ITTENSYS® ZINC AND VITAMIN C LOZENGES, please consult your healthcare provider for advice.

If any of the following happens, stop using ITTENSYS® ZINC AND VITAMIN C LOZENGES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ITTENSYS® ZINC AND VITAMIN C LOZENGES. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects may occur, but the frequency is not known:

- Headache, tiredness.
- Sleeplessness, sleepiness.
- Nausea (feeling sick), vomiting (being sick), diarrhoea (loose, watery stools), heartburn, stomach cramps.
- Redness of the face and skin (known as flushing).

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **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 ITTENSYS® ZINC AND VITAMIN C LOZENGES.

5. How to store ITTENSYS® ZINC AND VITAMIN C LOZENGES

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date stated on the container.
- Return all unused medicine 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 ITTENSYS® ZINC AND VITAMIN C LOZENGES contains

Each lozenge contains:

Ascorbic Acid (Vitamin C) 6,930 mg, Sodium Ascorbate 15,829 (Equivalent to Vitamin C 14,070 mg) Zinc gluconate 29,274 mg (Equivalent to elemental zinc 4,2 mg)

The other ingredients are Sucrose NF, Liquid Glucose BP, Anhydrous Citric acid BP, Flavour Orange oil sweet excellent, Colour beta Carotene, Colour Caramel NF, Purified Water BP.

What ITTENSYS® ZINC AND VITAMIN C LOZENGES look like and contents of the pack

Orange to opaque orange coloured, circular flat surface lozenges with occasional presence of air bubbles entrapped in the lozenge and rough edges. 12 lozenges are packed in a blister strip. 2 blister strips are packed in a cardboard carton.

Pack size: 24 lozenges.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa
Tel. no.: 011 848 3050

This leaflet was last revised in

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Registration number

Will be allocated by SAHPRA upon registration.

ITTENSY® ZINC AND VITAMIN C LOZENGES

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

ITTENSY® ZINC AND VITAMIN C LOZENGES

Elke suigtablet bevat: Askorbienzuur (Vitamiën C) 6,930 mg, Natriumaskorbaat 15,829 mg (Gelykstaande aan 14,070 mg Vitamiën C), Sinkglukonaat 29,274 mg (Gelykstaande aan elementele Sink 4,2 mg).

Bevat suiker (1574,409 mg sukrose en 847,758 mg vloeibare glukose per suigtablet)

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

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

Lees hierdie hele inligtingsblad aandagtig deur wat dit bevat inligting wat belangrik is vir jou.

ITTENSY® ZINC AND VITAMIN C LOZENGES is beskikbaar sonder 'n dokter se voorskrif sodat jy jou of jou kind se gesondheid in stand kan hou. Jy moet ITTENSY® ZINC AND VITAMIN C LOZENGES nietemin steeds versigtig gebruik om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie ITTENSY® ZINC AND VITAMIN C LOZENGES met 'n ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.

Wat is in hierdie inligtingsblad

1. Wat is ITTENSY® ZINC AND VITAMIN C LOZENGES en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy ITTENSY® ZINC AND VITAMIN C LOZENGES neem.
3. Hoe om ITTENSY® ZINC AND VITAMIN C LOZENGES te neem.
4. Moontlike nuwe-effekte.
5. Hoe om ITTENSY® ZINC AND VITAMIN C LOZENGES te bewaar.
6. Inhoud van die pak en ander inligting.

1. Wat is ITTENSY® ZINC AND VITAMIN C LOZENGES en waarvoor word dit gebruik

ITTENSY® ZINC AND VITAMIN C LOZENGES is aangedui om die mond te verfris en vir die tydelike verligting van 'n (geringe) seer keel. Help om immuunfunksie te handhaaf en is 'n antioksidant vir die handhawing van goeie gesondheid.

2. Wat jy moet weet voordat jy ITTENSY® ZINC AND VITAMIN C LOZENGES neem

Moenie ITTENSY® ZINC AND VITAMIN C LOZENGES neem nie

- Indien jy of jou kind hipersensitief (allergies) is vir vitamien C, sink of vir enige van die ander bestanddele van ITTENSY® ZINC AND VITAMIN C LOZENGES (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met ITTENSY® ZINC AND VITAMIN C LOZENGES

- Indien jou of jou kind se keelseer vererger of vir langer as 2 dae aanhou, kontak jou gesondheidsorgverskaffer.

Kinders

Nie geskik vir kinders jonger as 6 jaar nie.

Ander medisyne en ITTENSY® ZINC AND VITAMIN C LOZENGES

Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel jou dokter of apteker indien jy tans die volgende neem:

- Kinoloon of tetrasiklien antibiotika (gebruik om bakteriële infeksies te behandel). Hierdie antibiotika moet 2 ure voor, of 4 – 6 ure na ITTENSY® ZINC AND VITAMIN C LOZENGES geneem word.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy ITTENSY® ZINC AND VITAMIN C LOZENGES neem.

Veiligheid van ITTENSY® ZINC AND VITAMIN C LOZENGES tydens swangerskap of borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjiene

ITTENSY® ZINC AND VITAMIN C LOZENGES kan nuwe-effekte soos slaperigheid veroorsaak wat jou vermoë om 'n voertuig te bestuur en masjiene te gebruik kan affekteer. Moenie 'n voertuig bestuur of masjinerie hanteer totdat jy weet hoe ITTENSY® ZINC AND VITAMIN C LOZENGES jou beïnvloed nie.

ITTENSY® ZINC AND VITAMIN C LOZENGES bevat sukrose en glukose

Elke suigtablet bevat 1574,409 mg sukrose en 847,758 mg vloeibare glukose. Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sekere suikers is, raadpleeg jou dokter voordat jy ITTENSY® ZINC AND VITAMIN C LOZENGES neem. Kan skadelik wees vir tande.

3. Hoe om ITTENSY® ZINC AND VITAMIN C LOZENGES te neem

Neem ITTENSY® ZINC AND VITAMIN C LOZENGES altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou apteker vir jou aangewys het. Vra gerus jou apteker indien jy onseker is.

Volwassenes en kinders ouer as 6 jaar:

Volwassenes: Neem 1 suigtablet elke 2 - 3 ure soos benodig. Moenie meer as die maksimum van 6 suigtablette per dag neem nie. *Kinders:* 6 jaar en ouer: neem 1 suigtablet elke 4 - 6 ure soos benodig. Moenie meer as 'n maksimum van 3 suigtablette per dag neem nie.

Indien jy meer ITTENSY® ZINC AND VITAMIN C LOZENGES geneem het as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die oorblywende ITTENSY® ZINC AND VITAMIN C LOZENGES saam sodat die dokter kan sien wat jy gebruik het.

Indien jy vergeet om ITTENSY® ZINC AND VITAMIN C LOZENGES te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat oorgeslaan is nie.

4. Moontlike nuwe-effekte

ITTENSY® ZINC AND VITAMIN C LOZENGES kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir ITTENSY® ZINC AND VITAMIN C LOZENGES gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy ITTENSY® ZINC AND VITAMIN C LOZENGES neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om ITTENSY® ZINC AND VITAMIN C LOZENGES te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling.
- Uitslag of gejuuk.
- Floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op ITTENSY® ZINC AND VITAMIN C LOZENGES gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Die volgende nuwe-effekte mag voorkom, maar die frekwensie daarvan is onbekend:

- Hoofpyn, moegheid.
- Slapeloosheid, slaperigheid.
- Naarheid, braking, diarree (los, waterige stoelgange), sooibrand, maagkrampe.
- Rooiheid van die gesig en vel (bekend as blosing).

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die **voornamlik ongunstige geneesmiddelle-reaksies te rapporteer**, wat aantlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van ITTENSY® ZINC AND VITAMIN C LOZENGES te verskaf.

5. Hoe om ITTENSY® ZINC AND VITAMIN C LOZENGES te bewaar

- Bewaar teen of benede 25 °C.
- Bewaar alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die houer voorkom nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ITTENSY® ZINC AND VITAMIN C LOZENGES bevat

Elke suigtablet bevat:

Askorbienzuur (Vitamiën C) 6,930 mg, Natriumaskorbaat 15,829 mg (Gelykstaande aan 14,070 mg Vitamiën C), Sinkglukonaat 29,274 mg (Gelykstaande aan elementele Sink 4,2 mg).

Die ander bestanddele is Sukrose NF, Vloeibare Glukose BP, Watervrye Sitroensuur BP, Geur Lemoenolie soet uitstekend, Kleur beta Karoteen, Kleur Karamel NF, Gesuiwerde Water BP.

Hoe ITTENSY® ZINC AND VITAMIN C LOZENGES lyk en inhoud van die verpakking

Oranje tot ondeursigtige oranje gekleurde sirkelvormige suigtablet met 'n plat oppervlak en growwe kante, met lugborrels hier en daar vasgevang. 12 suigtablette word in 'n stulpstrok verpak. 2 stulpstrok word in 'n kartonhouer verpak. *Verpakkingsgrootte:* 24 suigtablette.

Houer van die registrasiesertifikaat

Biotech Laboratories (Edms.) Bpk.
Grondvloer, Blok K Wes, Central Park
400 16e Straat, Randjespark, Midrand, 1685
Suid-Afrika
Tel. 011 848 3050

Hierdie inligtingsblad is hersien in

September 2022.

Registrasienuommer

Sal met registrasie deur SAHPRA aangedui word.