

ITTENSYS® GREEN TEA LOZENGES

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

50

ITTENSYS® GREEN TEA LOZENGES

Green tea extract (80 %) 40,0 mg (Equivalent to 30,0 mg caffeine)
Contains sugar (1591,850 mg sucrose and 857,150 mg liquid glucose syrup 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® GREEN TEA LOZENGES is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use ITTENSYS® GREEN TEA LOZENGES carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
 - Do not share ITTENSYS® GREEN TEA LOZENGES with any other person.
 - Ask your healthcare provider or pharmacist if you need more information or advice.
 - Do not use for longer than 12 weeks without consulting your healthcare provider.

What is in this leaflet

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

1. What ITTENSYS® GREEN TEA LOZENGES is and what it is used for

ITTENSYS® GREEN TEA LOZENGES contains caffeine which may temporarily assist to relieve fatigue, increase mental activity, and promote alertness and wakefulness.

2. What you need to know before you take ITTENSYS® GREEN TEA LOZENGES

Do not take ITTENSYS® GREEN TEA LOZENGES

- If you are hypersensitive (allergic) to caffeine, green tea or to any of the other ingredients of ITTENSYS® GREEN TEA LOZENGES (listed in section 6).

Warnings and precautions

Take special care with ITTENSYS® GREEN TEA LOZENGES:

- CONTAINS CAFFEINE. Each lozenge contains 30,0 mg caffeine. A cup of coffee contains approximately 80,0 mg of caffeine.
- If you have a bleeding disorder, ITTENSYS® GREEN TEA LOZENGES should be discontinued at least 2 weeks before surgical procedures.
- If you have heart problems or high blood pressure.
- If you have glaucoma (a condition causing increased pressure behind your eye).
- If you have any kidney problems or overactive bladder syndrome.
- Do not take ITTENSYS® GREEN TEA LOZENGES before bedtime, as it may result in sleep deprivation.
- If you have diabetes mellitus (high blood sugar) and you are taking medicines to control your blood sugar levels.
- If you have liver problems or if you develop symptoms of liver trouble such as yellowing of the skin or eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite. Stop using ITTENSYS® GREEN TEA LOZENGES and consult a healthcare provider immediately.
- If you have an iron deficiency (determined by a blood test).

Children

Not suitable for children under the age of 6 years.

Other medicines and ITTENSYS® GREEN TEA 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:

- Anticoagulant/antiplatelet medicines (used to thin your blood), or herbal supplements with blood thinning effects.
- Ephedrine and other stimulants, such as bitter orange extract, synephrine, octopamine and ephedra.
- Other caffeine-containing products.
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression).
- Lithium (used to stabilise your mood).
- Antidiabetic medicines (used to treat high blood sugar levels), or herbal supplements which can influence blood sugar levels.
- Diuretic medicines/water tablets (used to treat swelling).
- Hepatotoxic medicines (medicines that may damage your liver) such as:
 - Paracetamol (used to treat pain and fever).
 - Amiodarone (used to treat heart conditions).
 - Carbamazepine (used to treat epilepsy).
 - Isoniazid (used to treat TB).
 - Methotrexate (used to treat inflammation of the joints known as rheumatoid arthritis).
 - Methylodopa (used to treat high blood pressure).

ITTENSYS® GREEN TEA LOZENGES with food and drink

Do not take ITTENSYS® GREEN TEA LOZENGES with other caffeine-containing food and drinks, such as coffee, tea, cola nut, cocoa, guarana and maté.

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® GREEN TEA LOZENGES.

ITTENSYS® GREEN TEA LOZENGES should not be taken during pregnancy or breastfeeding. Total caffeine intake of more than 200,0 mg per day is not recommended during pregnancy and breastfeeding.

Driving and using machines

ITTENSYS® GREEN TEA LOZENGES may cause side effects like muscle tremors (shaking muscles) which may affect your ability to drive and use machines. Do not drive a vehicle or operate machinery until you know how ITTENSYS® GREEN TEA LOZENGES affects you.

ITTENSYS® GREEN TEA LOZENGES contains sucrose and glucose

Each lozenge contains 1591,850 mg sucrose and 857,150 mg liquid glucose syrup. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

3. How to use ITTENSYS® GREEN TEA LOZENGES

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

Adults:

Take 1 lozenge every 2 - 3 hours as needed, maximum 8 lozenges per day. Suck the lozenge (keep in mouth until completely dissolved, do not chew).
Daily dose: 8 lozenges.

If you take more ITTENSYS® GREEN TEA 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® GREEN TEA LOZENGES with you so the doctor will know what you have used.

If you forget to take ITTENSYS® GREEN TEA LOZENGES

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

4. Possible side effects

ITTENSYS® GREEN TEA LOZENGES can have side effects.

Not all side effects reported for ITTENSYS® GREEN TEA LOZENGES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ITTENSYS® GREEN TEA LOZENGES, please consult your healthcare provider for advice.

If any of the following happens, stop using ITTENSYS® GREEN TEA 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® GREEN TEA LOZENGES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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

- Anxiety, restlessness, headache.
- Insomnia (difficulty falling or staying asleep).
- Muscular tremors (shaking muscles).
- Diuresis (frequent and increased urination).
- Diarrhoea (loose, watery stools), stomach irritation, nausea (feeling sick), bloating, heartburn, windiness, constipation (difficulty to pass stools).

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® GREEN TEA LOZENGES.

5. How to store ITTENSYS® GREEN TEA 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® GREEN TEA LOZENGES contains

Each 2,5 g lozenge contains:

Green tea extract (80 %) 40,0 mg (Equivalent to 30,0 mg caffeine)

The other ingredients are caramel dye (E150a), coffee flavour (carriers: E1520, E1518; flavour enhancer E636, methylcyclopentolone, ethylvanillin, ethylcyclopentolone, diacetyl, butyric acid), glucose syrup, sucralose (E955), sucrose and purified water.

What ITTENSYS® GREEN TEA LOZENGES look like and contents of the pack

Brown to opaque brown 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
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400 16th Road, Randjespark, Midrand, 1685
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Tel. no: 011 848 3050

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Registration number

Will be allocated by SAHPRA upon registration.

ITTENSY® GREEN TEA LOZENGES

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

50

ITTENSY® GREEN TEA LOZENGES

Groentee-ekstrak (80 %) 40,0 mg (ekwivalent aan 30,0 mg kaffeien)
Bevat suiker (1591,850 mg sukrose en 857,150 mg vloeibare glukose per suigtablet)

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

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

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

- ITTENSY® GREEN TEA LOZENGES is beskikbaar sonder 'n dokter se voorskrif sodat jy jou gesondheid in stand kan hou. Jy moet ITTENSY® GREEN TEA 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® GREEN TEA LOZENGES met 'n ander persoon deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.
- Moenie vir langer as 12 weke gebruik sonder om jou gesondheidsorgverskaffer te raadpleeg nie.

Wat is in hierdie inligtingsblad

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

1. Wat is ITTENSY® GREEN TEA LOZENGES en waarvoor word dit gebruik

ITTENSY® GREEN TEA LOZENGES bevat kaffeien wat tydelik kan help om moegheid te verlig, verstandelike aktiwiteit te verhoog en wakkerheid te bevorder.

2. Wat jy moet weet voordat jy ITTENSY® GREEN TEA LOZENGES neem

- Moenie ITTENSY® GREEN TEA LOZENGES neem nie
- Indien jy hipersensitief (allergies) is vir kaffeien, groentee of vir enige van die ander bestanddele van ITTENSY® GREEN TEA LOZENGES (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met ITTENSY® GREEN TEA LOZENGES

- BEVAT KAFFEÏEN. Elke suigtablet bevat 30,0 mg kaffeien. A koppie kitskoffie bevat ongeveer 80,0 mg kaffeien.
- Hou twee weke voor enige chirurgiese prosedure (operasie) op om ITTENSY® GREEN TEA LOZENGES te neem indien jy 'n bloedingsversteuring het.
- As jy hartprobleme of hoë bloeddruk het.
- As jy gloukoom het ('n toestand wat verhoogde druk agter u oog veroorsaak).
- As jy nierprobleme of oorkotiewe blaasindroom het.
- Moenie ITTENSY® GREEN TEA LOZENGES voor slaapyd neem nie, want dit kan slaaptkort tot gevolg hê.
- As jy diabetes mellitus (hoë bloedsuiker) het en jy medisyne gebruik om jou bloedsuikervlakke te beheer.
- As jy lewerprobleme het of as jou simptome ontwikkel soos die verkleuring van die vel of oë (geelsug), maagpyn, donker urine, sweet, naarheid, ongewone moegheid en/of verlies van eetlus. Hou op om ITTENSY® GREEN TEA LOZENGES te gebruik en raadpleeg 'n gesondheidsorgverskaffer onmiddellik.
- As jy 'n ystertekort het (bepaal deur 'n bloedtoets).

Kinders

Nie geskik vir kinders jonger as 6 jaar nie.

Ander medisyne en ITTENSY® GREEN TEA 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:

- Antikoagulant-/antiplaattijemidisyne (word gebruik om jou bloed dun te hou) of kruise-aanvullings met bloedverdunnende effekte.
- Efedrien en ander stimulant, soos bitterlemoen-ekstrak, synefrien, oktopamien en efedra.
- Ander kaffeien-bevattende produkte.
- Monoamienoksidasie inhibeërs (MAOIs) (gebruik om depressie te behandel).
- Litium (gebruik om jou gemoed te stabiliseer).
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel) of kruise-aanvullings met bloedsuikerverlagende effekte.
- Diuretiese medisyne/watertablette (gebruik om swelling te behandel).
- Hepatotoksiese medisyne (medisyne wat jou lewer kan beskadig) soos:
 - Parasetamol (word gebruik om pyn en koors te behandel).
 - Amiodaroon (word gebruik om hartkwalte te behandel).
 - Karbamasepin (word gebruik om epilepsie te behandel).
 - Isoniasied (word gebruik om TB te behandel).
 - Metotreksaat (word gebruik om inflammasie van die gewrigte, bekend as rumatoïede artritis, te behandel).
 - Metildopa (word gebruik om hoë bloeddruk te behandel).

ITTENSY® GREEN TEA LOZENGES met voedsel en drank

Moenie ITTENSY® GREEN TEA LOZENGES saam met ander kaffeien-bevattende voedsel en drank, soos koffie, tee, kola-neut, kakao, guarana en maté neem nie.

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® GREEN TEA LOZENGES neem. Moenie ITTENSY® GREEN TEA LOZENGES neem indien jy swanger is of borsvoed nie. Totale daaglikse kaffeien-inname van meer as 200,0 mg is nie aanbeveel tydens swangerskap en borsvoeding nie.

Bestuur en die gebruik van masjiene

ITTENSY® GREEN TEA LOZENGES kan nuwe-effekte soos spiertremore (spiere wat bewe) 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® GREEN TEA LOZENGES jou beïnvloed nie.

ITTENSY® GREEN TEA LOZENGES bevat sukrose en glukose

Elke suigtablet bevat 1591,850 mg sukrose en 857,150 mg vloeibare glukose. Dit moet in gedagte gehou word by pasiënte met diabetes mellitus. Kan skadelik wees vir tande.

3. Hoe om ITTENSY® GREEN TEA LOZENGES te neem

Neem ITTENSY® GREEN TEA 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:

Neem 1 suigtablet 2 - 3 elke ure soos benodig, maksimum van 8 suigtablette per dag. Suig die suigtablet (hou in die mond totdat dit heeltemal opgelos is, moenie kou nie).
Daaglikse dosis: 8 suigtablette.

Indien jy meer ITTENSY® GREEN TEA 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® GREEN TEA LOZENGES saam sodat die dokter kan sien wat jy gebruik het.

Indien jy vergeet om ITTENSY® GREEN TEA LOZENGES te neem

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

4. Moontlike nuwe-effekte

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

Indien enige van die volgende gebeur, hou op om ITTENSY® GREEN TEA LOZENGES te neem en vertel 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 gejuke.
- Floute.

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

Vertel jou dokter of gaan na die ongevalle-afdeling in u naaste hospitaal as u een van die volgende opmerk:

- Nuwe-effekte wat met onbekende frekwensie voorkom:*
- Vergelying van die vel en oë, donker urine, en moegheid wat simptome van lewerprobleme kan wees.

Hierdie is almal ernstige nuwe-effekte. Jy benodig moontlik dringende mediese hulp.

Vertel jou dokter indien jy enige van die volgende opmerk:

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

- Angstigheid, rusteloosheid, hoofpyn.
 - Slapeloosheid (sukkel om aan die slaap te raak of te bly).
 - Spiertremore (spiere wat bewe).
 - Diuresis (gereelde en verhoogde urinering).
 - Diarree (los, waterige stoelgange), maagiritasie, naarheid, opgeblasenheid, sootbrand, windgerigtheid, hardlywigheid.
- 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 **vorm om ongunstige geneesmiddelleaksies te rapporteer**, wat aanlyn 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® GREEN TEA LOZENGES te verskaf.

5. Hoe om ITTENSY® GREEN TEA 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® GREEN TEA LOZENGES bevat

Elke 2,5 g suigtablet bevat:
Groentee-ekstrak (80 %) 40,0 mg (ekwivalent aan 30,0 mg kaffeien)

Die ander bestanddele is karamelkleursel (E150a), koffiegeursel (draers: E1520, E1518; geurversterker E636, metielsiklopentanolon, etielvanillien, etielsiklopentanolon, diasetiel, bottersuur), glukosestroop, sukralose (E955), sukrose en gesuiwerde water.

Hoe ITTENSY® GREEN TEA LOZENGES lyk en inhoud van die verpakking

Bruin tot ondeursigtige bruin gekleurde, sirkelvormige suigtablette met 'n plat oppervlak en growwe kante, met lugborrels hier en daar vasgevang. 12 suigtablette word in 'n stulpstrook verpak. 2 stulpstroke word in 'n kartonhouer verpak.
Verpakkingsgrootte: 24 suigtablette.

Houer van die registrasiesertifikaat

Biotech Laboratories (Edms.) Bpk.
Grondvloer, Blok K WES, Central Park
400 16^{de} Weg, Randjespark, Midrand, 1685
Suid-Afrika
Tel. 011 848 3050

Hierdie inligtingsblad is hersien in

September 2022.

Registrasienommer

Sal met registrasie deur SAHPRA aangedui word.