ITTENSY® *BLAST CENTRE* MENTHOL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
S0

ITTENSY® *BLAST CENTRE* MENTHOL
L-menthol 20,0 mg
Contains sweeteners (1,65 mg sucralose per lozenge and 3574,120 mg isomalt per lozenge)
Contains sugar alcohol (327,315 mg maltitol 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.
ITTENSY® *BLAST CENTRE* MENTHOL is available without a doctor's prescription, for you or your child to maintain your health. Nevertheless, you still need to take ITTENSY® *BLAST CENTRE* MENTHOL carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share ITTENSY® *BLAST CENTRE* MENTHOL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- Consult your healthcare provider if your or your child's sore throat worsens or persists for more than 2 days.

What is in this leaflet
1. What ITTENSY® *BLAST CENTRE* MENTHOL is and what it is used for.
2. What you need to know before you take ITTENSY® *BLAST CENTRE* MENTHOL.
3. How to take ITTENSY® *BLAST CENTRE* MENTHOL.
4. Possible side effects.
5. How to store ITTENSY® *BLAST CENTRE* MENTHOL.
6. Contents of the pack and other information.

1. What ITTENSY® *BLAST CENTRE* MENTHOL is and what it is used for
ITTENSY® *BLAST CENTRE* MENTHOL provides a cooling sensation and/or soothing action for the throat, for the temporary relief of pain of a (minor) sore throat.
It helps to ease/relieve nasal congestion and makes nasal passages feel clearer.

2. What you need to know before you take ITTENSY® *BLAST CENTRE* MENTHOL
Do not take ITTENSY® *BLAST CENTRE* MENTHOL
- If you or your child are hypersensitive (allergic) to l-menthol or to any of the other ingredients of ITTENSY® *BLAST CENTRE* MENTHOL (listed in section 6).
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- If you or your child have epilepsy (seizure disorder), a persistent or chronic cough or other lung conditions.

Warnings and precautions
Take special care with ITTENSY® *BLAST CENTRE* MENTHOL
- If your or your child's symptoms persist or worsen, reoccur, or are accompanied by a fever, rash or persistent headache, stop use and contact your healthcare provider.
- If you experience pain, swelling or blistering, stop use and get medical help right away.

Children
Not suitable for children under the age of 6 years.

Other medicines and ITTENSY® *BLAST CENTRE* MENTHOL
Always tell your healthcare provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)
Do not take with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

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 ITTENSY® *BLAST CENTRE* MENTHOL.
ITTENSY® *BLAST CENTRE* MENTHOL should not be taken during pregnancy or
breastfeeding (see **Do not take ITTENSY® *BLAST CENTRE* MENTHOL**).

Driving and using machines
ITTENSY® *BLAST CENTRE* MENTHOL may cause side effects like dizziness which may affect your ability to drive and use machines. Do not drive a vehicle or operate machinery until you know how ITTENSY® *BLAST CENTRE* MENTHOL affects you.

ITTENSY® *BLAST CENTRE* MENTHOL contains sucralose, isomalt and maltitol
Each lozenge contains 1,65 mg sucralose, 3,6 g isomalt and 327,3 mg maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ITTENSY® *BLAST CENTRE* MENTHOL. May have a mild laxative effect.

3. How to take ITTENSY® *BLAST CENTRE* MENTHOL
Always take ITTENSY® *BLAST CENTRE* MENTHOL exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.
Adults
Dissolve 1 lozenge slowly in the mouth every 2 hours as needed.
Maximum Daily Dose: 8 lozenges
Children 6 - 12 years: Do not exceed a maximum of 4 lozenges per day.
Not to be used in children under 6 years of age without medical advice.

If you take more ITTENSY® *BLAST CENTRE* MENTHOL 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 rest of the ITTENSY® *BLAST CENTRE* MENTHOL with you so the doctor will know what you have taken.

If you forget to take ITTENSY® *BLAST CENTRE* MENTHOL
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
ITTENSY® *BLAST CENTRE* MENTHOL can have side effects.
Not all side effects reported for ITTENSY® *BLAST CENTRE* MENTHOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ITTENSY® *BLAST CENTRE* MENTHOL, please consult your healthcare provider for advice.

If any of the following happens, stop using ITTENSY® *BLAST CENTRE* MENTHOL 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 or your child have them, you may have had a serious allergic reaction to ITTENSY® *BLAST CENTRE* MENTHOL. 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:
- Nausea (feeling sick).
- Headache, dizziness.
- Burning discomfort.

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 ITTENSY® *BLAST CENTRE* MENTHOL.

5. How to store ITTENSY® *BLAST CENTRE* MENTHOL
- Store in a cool, dry place, at or below 25 °C.
- Store all medicines out of reach of children.
- Do not take 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 ITTENSY® *BLAST CENTRE* MENTHOL contains
Each lozenge contains:
L-menthol 20,0 mg

The other ingredients in the lozenge are Fir balsam Canadian, d-camphor, isomalt, sucralose, pine needle oil, strong capsicum tincture and eucalyptol.
The other ingredients in the centre filled part are lecithin, glycerine, maltitol syrup, sucralose, carrageenan, pectin, strong capsicum tincture and eucalyptol.

What ITTENSY® *BLAST CENTRE* MENTHOL looks like and contents of the pack
An oval shaped, white to yellowish white opaque coloured centre filled lozenge.
Plain ALU/PVC/PE/PVDC 2 of blister strips packed in a cardboard box carton containing 8 lozenges.
LAMI plain PET/MET CPP pillow pouch containing 16 lozenges.
PU plain PET/ALU/PE twist wrap pouch containing 16 lozenges.
Not all pack sizes may be marketed.

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Registration number
To allocated by SAHPRA upon registration.

ITTENSY® *BLAST CENTRE* MENTHOL

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

S0

ITTENSY® *BLAST CENTRE* MENTHOL
L-mentol 20,0 mg
Bevat versoeters (1,65 mg sukralose per suigtablet en 3574,120 mg isomalt per suigtablet)
Bevat suikeralkohol (327,315 mg maltitol per suigtablet)

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

Lees hierdie hele inligtingspamflet aandagtig deur want dit bevat inligting wat belangrik is vir jou.
ITTENSY® *BLAST CENTRE* MENTHOL is beskikbaar sonder 'n dokter se voorskrif sodat jy jou of jou kind se gesondheid in stand kan hou. Jy moet ITTENSY® *BLAST CENTRE* MENTHOL nietemin steeds versigtig gebruik om die beste resultate te verkry.
- Hou hierdie inligtingspamflet. Dit mag nodig wees dat jy dit weer lees.
- Moenie ITTENSY® *BLAST CENTRE* MENTHOL met 'n ander persoon deel nie.
- Vra gerus jou gesondheidsorgverskaffer indien jy verdere inligting of advies nodig het.
- Raadpleeg jou gesondheidsorgverskaffer indien jou of jou kind se keelseer vererger of vir langer as 2 dae aanhou.

Wat is in hierdie inligtingspamflet
1. Wat is ITTENSY® *BLAST CENTRE* MENTHOL en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy ITTENSY® *BLAST CENTRE* MENTHOL neem.
3. Hoe om ITTENSY® *BLAST CENTRE* MENTHOL te neem.
4. Moontlike newe-effekte.
5. Hoe om ITTENSY® *BLAST CENTRE* MENTHOL te bewaar.
6. Inhoud van die pak en ander inligting.

1. Wat is ITTENSY® *BLAST CENTRE* MENTHOL en waarvoor word dit gebruik
ITTENSY® *BLAST CENTRE* MENTHOL bied 'n verkoelende sensasie en/of strelende werking vir die keel vir die tydelike pynverligting van 'n (geringe) seer keel.
Dit help om nasale kongestie te verlig en die neus oper te laat voel.

2. Wat jy moet weet voordat jy ITTENSY® *BLAST CENTRE* MENTHOL neem
Moenie ITTENSY® *BLAST CENTRE* MENTHOL neem nie
- Indien jy of jou kind hipersensitief (allergies) is vir l-mentol of vir enige van die ander bestanddele van ITTENSY® *BLAST CENTRE* MENTHOL (gelys by afdeling 6).
- Indien jy swanger is of borsvoed (sien **Swangerskap, borsvoeding en vrugbaarheid**).
- Indien jy of jou kind epilepsie (aanvalle), asma, 'n aanhoudende of chroniese hoes of ander longkondisies het.

Waarskuwings en voorsorgmaatreëls
Wees versigtig met ITTENSY® *BLAST CENTRE* MENTHOL
- Indien jou of jou kind se simptome voortduur of vererger, terugkeer, of gepaard gaan met 'n koors, uitslag of aanhoudende hoofpyn, staak gebruik en kontak jou gesondheidsorgverskaffer.
- Staak gebruik en kry dadelik mediese hulp indien jy pyn, swelling of blasies ontwikkel.

Kinders
Nie geskik vir kinders jonger as 6 jaar nie.

Ander medisyne en ITTENSY® *BLAST CENTRE* MENTHOL
Vertel altyd vir jou gesondheidsorgverskaffer indien jy of jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Moenie saam met produkte wat kamfer, mentol, bloekom en/of bloekom essensiële olies bevat, neem nie.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of jou baba borsvoed, vermoed dat jou swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy ITTENSY® *BLAST CENTRE* MENTHOL neem.
ITTENSY® *BLAST CENTRE* MENTHOL moenie geneem word tydens swangerskap of borsvoeding nie (sien **Moenie ITTENSY® *BLAST CENTRE* MENTHOL neem nie**).

Bestuur en die gebruik van masjiene
ITTENSY® *BLAST CENTRE* MENTHOL kan newe-effekte soos duiseligheid 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® *BLAST CENTRE* MENTHOL jou beïnvloed nie.

ITTENSY® *BLAST CENTRE* MENTHOL bevat sukralose, isomalt en maltitol
Elke suigtablet bevat 1,65 mg sukralose, 3,6 g isomalt en 327,3 mg maltitol. Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sekere suikers is, bespreek dit met jou dokter voordat jy ITTENSY® *BLAST CENTRE* MENTHOL neem. Mag 'n geringe lakserende uitwerking hê.

3. Hoe om ITTENSY® *BLAST CENTRE* MENTHOL te neem
Neem ITTENSY® *BLAST CENTRE* MENTHOL altyd presies soos wat in hierdie inligtingspamflet aangedui word, of soos wat jou apteker vir jou aangewys het. Vra gerus jou apteker indien jy onseker is.
Volwassenes
Los 1 suigtablet stadig elke 2 uur in die mond op of soos nodig.
Maksimum daalikse dosis: 8 suigtablette
Kinders 6 - 12 jaar: Moenie 'n maksimum van 4 suigtablette per dag oorskry nie. Moet nie by kinders jonger as 6 jaar gebruik word sonder mediese advies nie.

Indien jy meer ITTENSY® *BLAST CENTRE* MENTHOL 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 inligtingspamflet en die oorblywende ITTENSY® *BLAST CENTRE* MENTHOL saam sodat die dokter kan sien wat jy geneem het.

Indien jy vergeet om ITTENSY® *BLAST CENTRE* MENTHOL te neem
Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat oorgeslaan is nie.

4. Moontlike newe-effekte
ITTENSY® *BLAST CENTRE* MENTHOL kan newe-effekte hê.
Nie alle newe-effekte wat vir ITTENSY® *BLAST CENTRE* MENTHOL gerapporteer is, word in hierdie inligtingspamflet ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy ITTENSY® *BLAST CENTRE* MENTHOL neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om ITTENSY® *BLAST CENTRE* MENTHOL 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 gejeuk.
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy of jou kind enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op ITTENSY® *BLAST CENTRE* MENTHOL gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Die volgende newe-effekte mag voorkom, maar die frekwensie daarvan is onbekend:
- Naarheid (siek gevoel).
- Hoofpyn, duiseligheid.
- Brandende ongemak.

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

Rapportering van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **vorm om ongunstige geneesmiddelreaksies** te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: http://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van ITTENSY® *BLAST CENTRE* MENTHOL te verskaf.

5. Hoe om ITTENSY® *BLAST CENTRE* MENTHOL te bewaar
- Bewaar in 'n koel, droë plek, teen of benede 25 °C.
- Bewaar alle medisyne buite bereik van kinders.
- Moenie neem 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® BLAST CENTRE MENTHOL bevat
Elke suigtablet bevat:
L-mentol 20,0 mg

Die ander bestanddele in die suigtablet is Kanadese Fir balsem, d-kamfer, isomalt, sukralose, dennenaaldolie, sterk kapsikumtinktuur en bloekom.
Die ander bestanddele in die suigtablet se vulsel is lesitien, gliserien, maltitolstroop, sukralose, karrageen, pektien, sterk kapsikumtinktuur en bloekom.

Hoe ITTENSY® *BLAST CENTRE* MENTHOL lyk en inhoud van die verpakking
'n Ovaalvormige, wit tot geel-wit ondeursigtige gevulde suigtablet.
Gewone ALU/PVC/PE/PVDC 2 stulpstroke verpak in 'n karton wat 8 suigtablette bevat.
LAMI gewone PET/MET CPP pofsakkie wat 16 suigtablette bevat.
PU gewone PET/ALU/PE toedraaisakkie wat 16 suigtablette bevat.
Nie alle verpakkingsgrootes word bemark nie.

Houer van die registrasiesertifikaat
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Hierdie inligtingsblad is hersien in
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Registrasienommer
Sal met registrasie deur SAHPRA aangedui word.