ITTENSY IVY SYRUP

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

ITTENSY IVY SYRUP
Hedera helix L. (ivy) (Leaf) (4-8:1 Extract) .... 7,0 mg
Contains sugar alcohol (500,0 mg sorbitol per 1 ml)
Contains sweetener (150,0 mg isomalt per 1 ml)

COMPLEMENTARY MEDICINE: WESTERN HERBAL MEDICINE
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 IVY SYRUP is available without a doctor's prescription, for you or your child to maintain your health. Nevertheless, you still need to use ITTENSY IVY SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ITTENSY IVY SYRUP with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- Contact your healthcare provider if symptoms do not improve within 7 days.

What is in this leaflet

1. What ITTENSY IVY SYRUP is and what it is used for.
2. What you need to know before you or your child takes ITTENSY IVY SYRUP.
3. How to take ITTENSY IVY SYRUP.
4. Possible side effects.
5. How to store ITTENSY IVY SYRUP.
6. Contents of the pack and other information.

1. What ITTENSY IVY SYRUP is and what it is used for
ITTENSY IVY SYRUP is a complementary medicine which may assist with loosening phlegm in the case of a productive (wet) cough. ITTENZY IVY SYRUP has anti-inflammatory properties and may assist with opening airways.

2. What you need to know before you take ITTENSY IVY SYRUP
Do not take ITTENSY IVY SYRUP

- If you or your child are hypersensitive (allergic) to *Hedera helix* L. (ivy), other plants of the Araliaceae family or to any of the other ingredients of ITTENSY IVY SYRUP (listed in section 6).
- Do not give ITTENSY IVY SYRUP to children under the age of 2 years.

Warnings and precautions
Take special care with ITTENSY IVY SYRUP

- If you or your child have gastritis (inflammation of the stomach) or a stomach ulcer.
- Consult a healthcare provider if you or your child experience shortness of breath, fever, or sputum with a yellow or green tinge.

Children

- Do not give ITTENSY IVY SYRUP to children younger than 2 years (see **Do not take ITTENSY IVY SYRUP**).
- Do not give ITTENSY IVY SYRUP to children between 2 and 4 years old with a persistent or recurrent cough.

Other medicines and ITTENSY IVY SYRUP
Always tell your healthcare provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)
Tell your doctor or pharmacist if you or your child are taking any other medicine or are suffering from a medical condition.

Pregnancy, breastfeeding and fertility
Safety in pregnancy and lactation has not been established. 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 IVY SYRUP.

Driving and using machines
ITTENSY IVY SYRUP is unlikely to affect your ability to drive and use machines. Do not drive a vehicle or operate machinery until you know how ITTENSY IVY SYRUP affects you.

ITTENSY IVY SYRUP contains sorbitol and isomalt
Each 1 ml of ITTENSY IVY SYRUP contains 500,0 mg sorbitol and 150,0 mg isomalt. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take ITTENSY IVY SYRUP.
Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.

3. How to take ITTENSY IVY SYRUP
Always take ITTENSY IVY SYRUP exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.
SHAKE BOTTLE WELL BEFORE USE.

Adults and children older than 12 years
5 mL to 7,5 ml three times daily.

Children 6 to 12 years
5 ml three times daily.

Children 2 to 5 years
2,5 ml three times daily.

Consult a healthcare provider if symptoms do not improve within 7 days.

If you take more ITTENSY IVY SYRUP 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 IVY SYRUP with you so the doctor will know what you have taken.

If you forget to take ITTENSY IVY SYRUP
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
ITTENSY IVY SYRUP can have side effects.
Not all side effects reported for ITTENSY IVY SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ITTENSY IVY SYRUP, please consult your healthcare provider for advice.

If any of the following happens, stop taking ITTENSY IVY SYRUP 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 ITTENSY IVY SYRUP. 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), vomiting (being sick), diarrhoea.

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 IVY SYRUP.

5. How to store ITTENSY IVY SYRUP

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Keep the container tightly closed.
- 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 ITTENSY IVY SYRUP contains
Each 1 ml contains:
Hedera helix L. (ivy) (Leaf) (4-8:1 Extract) .... 7,0 mg
The other ingredients are cherry flavour SD10950 (consisting of propylene glycol, nature identical flavouring substances, natural flavouring substances and Class I preservative (260)), citric acid monohydrate, isomalt, potassium sorbate 0,13 % m/v (preservative), Povidone/Plasdone K-29/32, purified water and sorbitol EP (non-crystallising).

What ITTENSY IVY SYRUP looks like and contents of the pack
Brown coloured syrupy liquid with a pleasant flavour of cherry.
ITTENSY IVY SYRUP is packed in a 100 ml PET amber bottle with a 25 mm milky white plastic cap.

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

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Registration number
Will be allocated by SAHPRA upon registration.

ITTENSY IVY SYRUP

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S0

ITTENSY IVY SYRUP
Hedera helix L. (klimopplant) (Blaar) (4-8:1 Ektrak) .... 7,0 mg
Bevat suikeralkohol (500,0 mg sorbitol per 1 ml)
Bevat versoeter (150,0 mg isomalt per 1 ml)

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

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.
ITTENSY IVY SYRUP is beskikbaar sonder 'n dokter se voorskrif sodat jy jou of jou kind se gesondheid in stand kan hou. Jy moet ITTENSY IVY SYRUP nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie ITTENSY IVY SYRUP met 'n ander persoon deel nie.
- Vra gerus jou gesondheidsorgverskaffer indien jy verdere inligting of advies nodig het.
- Kontak jou gesondheidsorgverskaffer indien simptome nie binne 7 dae verbeter nie.

Wat is in hierdie inligtingsblad

1. Wat is ITTENSY IVY SYRUP en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy of jou kind ITTENSY IVY SYRUP neem.
3. Hoe om ITTENSY IVY SYRUP te neem.
4. Moontlike newe-effekte.
5. Hoe om ITTENSY IVY SYRUP te bewaar.
6. Inhoud van die pak en ander inligting.

1. Wat is ITTENSY IVY SYRUP en waarvoor word dit gebruik
ITTENSY IVY SYRUP is 'n komplementêre medisyne wat mag help om slym los te maak indien jy 'n produktiewe (nat) hoes het.
ITTENZY IVY STROOP het anti-inflammatoriese eienskappe en kan help met die opening van lugweë.

2. Wat jy moet weet voordat jy ITTENSY IVY SYRUP neem
Moenie ITTENSY IVY SYRUP neem nie

- Indien jy of jou kind hipersensitief (allergies) is vir *Hedera helix* L. (klimopplant), ander plante van die Araliaceae familie of vir enige van die ander bestanddele van ITTENSY IVY SYRUP (gelys by afdeling 6).
- Moenie ITTENSY IVY SYRUP aan kinders jonger as 2 jaar gee nie.

Waarskuwings en voorsorgmaatreëls
Wees versigtig met ITTENSY IVY SYRUP

- Indien jy of jou kind gastritis (inflammasie van die maag) of 'n maagseer het.
- Raadpleeg 'n gesondheidsorgverskaffer indien jy of jou kind kortasem of koorsig raak, of indien jou of jou kind se slym 'n geel of groen skynsel kry.

Kinders

- Moenie ITTENSY IVY SYRUP aan kinders jonger as 2 jaar gee nie (sien **Moenie ITTENSY IVY SYRUP neem nie**).
- Moenie ITTENSY IVY SYRUP aan kinders tussen 2 en 4 jaar oud wat aanhoudend en herhaaldelike hoes, gee nie.

Ander medisyne en ITTENSY IVY SYRUP
Vertel altyd vir jou gesondheidsorgverskaffer indien jy of jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)
Vertel vir jou dokter of apteker indien jy of jou kind enige ander medisyne neem of ly aan 'n mediese toestand.

Swangerskap, borsvoeding en vrugbaarheid
Dit is nie bepaal of ITTENSY IVY SYRUP veilig is om tydens swangerskap en borsvoeding te gebruik nie. 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 IVY SYRUP neem.

Bestuur en die gebruik van masjiene
Dit is onwaarskynlik dat ITTENSY IVY SYRUP jou vermoë om 'n voertuig te bestuur en masjiene te gebruik sal affekteer. Moenie 'n voertuig bestuur of masjinerie hanteer, totdat jy weet hoe ITTENSY IVY SYRUP jou beïnvloed nie.

ITTENSY IVY SYRUP bevat sorbitol en isomalt
Elke 1 ml ITTENSY IVY SYRUP bevat 500,0 mg sorbitol en 150,0 mg isomalt. Sorbitol is 'n bron van fruktose. Indien jou dokter jou ingelig het dat jy (of jou kind) onverdraagsaam vir sekere suikers is of indien jy met oorerflike fruktose-intoleransie gediagnoseer is, 'n seldsame genetiese afwyking waar 'n persoon se liggaam nie fruktose kan afbreek nie, bespreek dit met jou dokter voordat jy (of jou kind) ITTENSY IVY SYRUP neem.
Sorbitol mag 'n gevoel van ongemak in die spysverteringskanaal veroorsaak en 'n geringe lakserende uitwerking hê.

3. Hoe om ITTENSY IVY SYRUP te neem
Neem ITTENSY IVY SYRUP 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.
SKUD DIE BOTTEL GOED VOOR GEBRUIK.

Volwassenes en kinders ouer as 12 jaar
5 ml tot 7,5 ml drie keer daagliks.

Kinders 6 tot 12 jaar
5 ml drie keer daagliks.

Kinders 2 tot 5 jaar
2,5 ml drie keer daagliks.

Raadpleeg 'n gesondheidsorgverskaffer indien die simptome nie binne 7 dae verbeter nie.

Indien jy meer ITTENSY IVY SYRUP 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 IVY SYRUP saam sodat die dokter kan sien wat jy geneem het.

Indien jy vergeet om ITTENSY IVY SYRUP te neem
Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat oorgeslaan is nie.

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

Indien enige van die volgende gebeur, hou op om ITTENSY IVY SYRUP 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 enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op ITTENSY IVY SYRUP gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Die volgende newe-effekte mag voorkom, maar die frekwensie daarvan is onbekend:

- Naarheid, braking, diarree.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad 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 IVY SYRUP te verskaf.

5. Hoe om ITTENSY IVY SYRUP te bewaar

- Bewaar teen of benede 25 °C.
- Bewaar alle medisyne buite bereik van kinders.
- Hou die bottel styf toe.
- 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 IVY SYRUP bevat
Elke 1 ml bevat:
Hedera helix L. (klimopplant) (Blaar) (4-8:1 Ektrak) .... 7,0 mg
Die ander bestanddele is kersiegeursel SD10950 (wat bestaan uit propileenglikol, natuur-identiese geurstowwe, natuurlike geurstowwe en klas I preserveermiddel (260)), sitroensuurmono-hidraat, isomalt, kaliumsorbaat 0,13 % m/v (preserveermiddel), Povidoon/Plasdone K-29/32, gesuiwerde water en sorbitol (nie kristalliserend).

Hoe ITTENSY IVY SYRUP lyk en inhoud van die verpakking
Bruin gekleurde stroopagtige vloeistof met 'n aangename kersiegeur.
ITTENSY IVY SYRUP is gevul in 'n 100 ml PET amber bottel met 'n 25 mm melkwit platiese prop.

Houer van die registrasiesertifikaat
Biotech Laboratories (Edms.) Bpk.
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400 16de Weg, Randjespark, Midrand, 1685
Suid Afrika
Tel. 011 848 3050

Hierdie inligtingsblad is hersien in
Augustus 2022.

Registrasienommer
Sal met registrasie deur SAHPRA aangedui word.