PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
S0

HOT TODDY™ ADULT SACHETS powder for oral solution

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (african ginger), *Hedera helix* L. (ivy extract), ascorbic acid (vitamin C), *Citrus limon* (L.) Osbeck (lemon), honey, *Zingiber officinale* Roscoe (ginger), *Cinnamomum cassia* (L.) J. Presl. (cinnamon).
Contains sugar: Each sachet contains 3 927 mg sucrose.
Contains sweetener: Each sachet contains 43 mg Sweetener A100 (containing acesulfame K and sodium cyclamate).

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.
HOT TODDY™ ADULT SACHETS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take HOT TODDY™ ADULT SACHETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask you pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What HOT TODDY™ ADULT SACHETS is and what it is used for.
2. What you need to know before you take HOT TODDY™ ADULT SACHETS.
3. How to take HOT TODDY™ ADULT SACHETS.
4. Possible side effects.
5. How to store HOT TODDY™ ADULT SACHETS.
6. Contents of the pack and other information.

1. What HOT TODDY™ ADULT SACHETS is and what it is used for

HOT TODDY™ ADULT SACHETS may assist in soothing the symptoms associated with colds and flu, such as cough and congestion.

2. What you need to know before you take HOT TODDY™ ADULT SACHETS

Do not take HOT TODDY™ ADULT SACHETS:

- if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of HOT TODDY™ ADULT SACHETS (see **What HOT TODDY™ ADULT SACHETS contains**).

Warnings and precautions

Take special care with HOT TODDY™ ADULT SACHETS:

- if you have a bleeding disorder;
- if you are having any surgical procedure done. You should stop taking HOT TODDY™ ADULT SACHETS two weeks before an operation;
- if you have inflammation of your stomach or you have a stomach ulcer.

Children and adolescents

Do not give HOT TODDY™ ADULT SACHETS to children under the age of 18 years.
HOT TODDY™ ADULT SACHETS is not indicated for use in children.

Other medicines and HOT TODDY™ ADULT SACHETS

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

HOT TODDY™ ADULT SACHETS with food, drink and alcohol
See section 3 (**How to take HOT TODDY™ ADULT SACHETS**).

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 HOT TODDY™ ADULT SACHETS.
Safety and efficacy of HOT TODDY™ ADULT SACHETS during pregnancy and breastfeeding have not been established. Do not use HOT TODDY™ ADULT SACHETS if you are pregnant or breastfeeding your baby.

Driving and using machines
Safety and efficacy when driving or operating machinery have not been established. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how HOT TODDY™ ADULT SACHETS affects you.

HOT TODDY™ ADULT SACHETS contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking HOT TODDY™ ADULT SACHETS.

HOT TODDY™ ADULT SACHETS contains egg yellow colourant (containing quinoline yellow, salt and sunset yellow)
HOT TODDY™ ADULT SACHETS contains egg yellow colourant which may cause allergic reactions.

3. How to take HOT TODDY™ ADULT SACHETS

Do not share medicines with any other person.
Always take HOT TODDY™ ADULT SACHETS exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is:
Adults: Take 1 sachet three times a day with half a glass of hot water. Stir the mixture. If necessary, add cold water. It is advisable to drink the solution as hot as possible, without burning your mouth.

If you have the impression that the effect of HOT TODDY™ ADULT SACHETS is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.
HOT TODDY™ ADULT SACHETS can be taken with or without food.

If you take more HOT TODDY™ ADULT SACHETS than you should
In the event of 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 remaining HOT TODDY™ ADULT SACHETS with you so the doctor will know what you have taken.

4. Possible side effects

HOT TODDY™ ADULT SACHETS can have side effects.
Not all side effects reported for HOT TODDY™ ADULT SACHETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HOT TODDY™ ADULT SACHETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking HOT TODDY™ ADULT SACHETS 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 HOT TODDY™ ADULT SACHETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Side effects occurring frequently:

- redness of your skin;
- stomach pain or discomfort;
- burping;
- indigestion;
- heartburn
- nausea (feeling sick) or vomiting (being sick);
- diarrhoea (runny, loose stool).

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 "**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 HOT TODDY™ ADULT SACHETS.

5. How to store HOT TODDY™ ADULT SACHETS

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the sachet / carton.
- Use sachet immediately once opened. Do not store an unsealed / opened sachet.
- Store in the original packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HOT TODDY™ ADULT SACHETS contains
Each sachet contains:
The active substances are:

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (African ginger) [rhizome powder]	300 mg
Hedera helix L. (Ivy extract) [leaf, 5:1 extract providing 150 mg of dried herb equivalent]	30 mg
Ascorbic acid (Vitamin C)	100 mg
Citrus limon (L.) Osbeck (Lemon) [fruit, 10:1 extract providing 50 mg of dried herb equivalent]	5 mg
Honey	25 mg
Zingiber officinale Roscoe (Ginger) [root, 4:1 extract providing 10 mg of dried herb equivalent]	2,5 mg
Cinnamomum cassia (L.) J. Presl. (Cinnamon) [bark, 4:1 extract providing 10 mg of dried herb equivalent]	2,5 mg

The other ingredients are citric acid anhydrous (E330), egg yellow colourant (containing quinoline yellow (E104), salt and sunset yellow (E110)), ginger flavour, lemon flavour, maltodextrin (E1400), menthol flavour, silicon dioxide anhydrous (E331), sucrose and Sweetener A100 (containing acesulfame K and sodium cyclamate (E952)).

What HOT TODDY™ ADULT SACHETS looks like and contents of the pack
Beige powder with dark speckles and characteristic lemon and menthol taste.
After dilution: Yellow solution with a lemon and menthol odour.
HOT TODDY™ ADULT SACHETS are packed in 6,4 g printed foil sachets, packed in an outer carton.
Pack size(s): 4 or 8 sachets.

Holder of certificate of registration

Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
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info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

The Professional Information for HOT TODDY™ ADULT SACHETS is available on http://www.brunel.co.za/hot-toddy-2/ or can be requested from the contact details above.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS
S0

HOT TODDY™ ADULT SACHETS poeier vir orale oplossing

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (wildegemmer), *Hedera helix* L. (klimop-ekstrak), askorbiensuur (vitamien C), *Citrus limon* (L.) Osbeck (suurlemoen), heuning, *Zingiber officinale* Roscoe (gemmer), *Cinnamomum cassia* (L.) J. Presl. (kaneel).
Bevat suiker: Elke sakkie bevat 3 927 mg sukrose.
Bevat versoeter: Elke sakkie bevat 43 mg Sweetener A100 (bevattende asesulfaam K en natriumsiklamaat).

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

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.
HOT TODDY™ ADULT SACHETS is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy HOT TODDY™ ADULT SACHETS versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.
- Jy moet 'n dokter sien indien jou simptome vererger of nie verbeter na 10 dae nie.

Wat is in hierdie inligtingsblad

1. Wat HOT TODDY™ ADULT SACHETS is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy HOT TODDY™ ADULT SACHETS neem.
3. Hoe om HOT TODDY™ ADULT SACHETS te neem.
4. Moontlike newe-effekte.
5. Hoe om HOT TODDY™ ADULT SACHETS te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat HOT TODDY™ ADULT SACHETS is, en waarvoor dit gebruik word

HOT TODDY™ ADULT SACHETS mag help met die verligting van verkoue- en griep-geassosieerde simptome, soos hoes en kongestie.

2. Wat jy moet weet voordat jy HOT TODDY™ ADULT SACHETS neem

Moet nie HOT TODDY ADULT SACHETS neem:

- indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van HOT TODDY™ ADULT SACHETS nie (sien **Wat HOT TODDY™ ADULT SACHETS bevat**).

Waarskuwings en voorsorgmaatreëls
Wees versigtig met HOT TODDY™ ADULT SACHETS:

- indien jy 'n bloedingsteuring het;
- indien jy enige chirurgiese prosedure moet ondergaan – jy moet twee weke voor 'n operasie ophou om HOT TODDY™ ADULT SACHETS te gebruik;
- indien jy inflammasie in jou maag of 'n maagseer het.

Kinders en adolessente
Moet nie HOT TODDY™ ADULT SACHETS vir kinders jonger as 18 jaar gee nie. HOT TODDY™ ADULT SACHETS is nie aangedui vir gebruik in kinders nie.

Ander medisyne en HOT TODDY™ ADULT SACHETS
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

HOT TODDY™ ADULT SACHETS met eet-, drinkgoed en alkohol
Sien afdeling 3 (**Hoe om HOT TODDY™ ADULT SACHETS te neem**).

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy die medisyne neem.
Dit is nie vasgestel of HOT TODDY™ ADULT SACHETS veilig en doeltreffend is om tydens swangerskap en borsvoeding te gebruik nie. Moet nie HOT TODDY™ ADULT SACHETS gebruik indien jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene
Dit is nie vasgestel of HOT TODDY™ ADULT SACHETS veilig en doeltreffend is tydens bestuur en die gebruik van masjiene nie. Moet nie ’n voertuig bestuur, masjinerie hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe HOT TODDY™ ADULT SACHETS jou affekteer nie.

HOT TODDY™ ADULT SACHETS bevat sukrose
Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sekere suikers is, raadpleeg jou dokter voordat jy HOT TODDY™ ADULT SACHETS neem.

HOT TODDY™ ADULT SACHETS bevat egg yellow kleurstof (bevattende quinoline yellow, sout en sunset yellow)
HOT TODDY™ ADULT SACHETS bevat egg yellow kleurstof, wat allergiese reaksies mag veroorsaak.

3. Hoe om HOT TODDY™ ADULT SACHETS te neem
Moet nie jou medisyne met enige ander persoon deel nie.
Neem HOT TODDY™ ADULT SACHETS altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is,
Die gewone dosis is:
Volwassenes: Neem 1 sakkie drie keer per dag met ’n halwe glas warm water. Roer die mengsel. Indien nodig, voeg koue water by. Dit is raadsaam om die oplossing so warm as moontlik te drink, sonder om jou mond te brand.

Indien jy die indruk kry dat die uitwerking van HOT TODDY™ ADULT SACHETS te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.
HOT TODDY™ ADULT SACHETS kan met of sonder kos geneem word.

As jy meer HOT TODDY™ ADULT SACHETS neem as wat jy moet
In die geval van oordosering, 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 HOT TODDY™ ADULT SACHETS saam met jou sodat die dokter kan sien wat jy geneem het.

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

Indien enige van die volgende gebeur, hou op om HOT TODDY™ ADULT SACHETS 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 HOT TODDY™ ADULT SACHETS gehad het. Dringende mediese bystand of hospitalisasie mag nodig wees.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat gereeld voorkom:

- rooiheid van die vel;
- maagpyn of -ongemak;
- bring winde op;
- slegte spysvertering;
- sooibrand;
- naarheid of braking;
- diarree (loperige, los stoelgang).

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding 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 “**6.04 Adverse Drug Reactions Reporting Form**”, 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 HOT TODDY™ ADULT SACHETS te verskaf.

5. Hoe om HOT TODDY™ ADULT SACHETS te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C in ‘n koel, droë plek, en beskerm teen lig.
- Moet nie in die badkamer bêre nie.
- Moet nie gebruik word na die vervaldatum soos aangedui op die sakkie / karton nie.
- Gebruik die sakkie onmiddelik na hy oopgemaak is. Moet nie ‘n ongeseëlde / oopgemaakte sakkie bêre nie.
- Bêre in die oorspronklike verpakking.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat HOT TODDY™ ADULT SACHETS bevat
Elke sakkie bevat:
Die aktiewe bestanddele is:

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (Wildegemmer) .... [risoom poeier]	300 mg
Hedera helix L. (Klimop-ekstrak) .... [blaar, 5:1 ekstrak lewer 150 mg gedroogde kruie ekwivalent]	30 mg
Askorbiensuur (Vitamien C)	100 mg
Citrus limon (L.) Osbeck (Suurlemoen) .... [vrug, 10:1 ekstrak lewer 50 mg gedroogde kruie ekwivalent]	5 mg
Heuning	25 mg
Zingiber officinale Roscoe (Gemmer) .... [wortel, 4:1 ekstrak lewer 10 mg gedroogde kruie ekwivalent]	2,5 mg
Cinnamomum cassia (L.) J. Presl. (Kaneel) .... [bas, 4:1 ekstrak lewer 10 mg gedroogde kruie ekwivalent]	2,5 mg

Die ander bestanddele is anhidriese sitroensuur (E330), egg yellow kleurstof (bevattende quinoline yellow (E104), sout, sunset yellow (E110)), gemmergeursel, maltodekstrien (E1400), mentolgeursel, silikondioksied (E331), suurlemoengeursel, sukrose en Sweetener A100 (bevattende asesulfaam K en natriumsiklamaat (E952)).

Hoe HOT TODDY™ ADULT SACHETS lyk en inhoud van die verpakking
Beige poeier met donker spikkels en kenmerkende suurlemoen-en-mentolsmaak.
Na verdunning: Geel oplossing met 'n suurlemoen-en-mentolgeur.
HOT TODDY™ ADULT SACHETS is beskikbaar in 6,4 g gedrukte foelie sakkies, verpak in 'n buitenste karton.
Verpakkingsgrootte: 4 of 8 sakkies.

Houer van die registrasiesertifikaat
Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za

Hierdie inligtingsblad is laas hersien in
Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer
Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad
Die Professionele Inligtingsblad vir HOT TODDY™ ADULT SACHETS is beskikbaar by http://www.brunel.co.za/hot-toddy-2/ of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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