HOT TODDY™

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
S0

HOT TODDY™ COLD & FLU RELIEF effervescent tablets
Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (african ginger), ascorbic acid (vitamin C), honey, *Cinnamomum cassia* (L.) J. Presl. (cinnamon).
Preservative: Sodium benzoate 0,94 % *m/m*.
Contains sugar: Each effervescent tablet contains 50 mg honey.
Contains sweetener: Each effervescent tablet contains 1 100 mg sorbitol, 100 mg Sweetener A100 (containing acesulfame K and sodium cyclamate) and 1,7 mg sodium saccharin.

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™ COLD & FLU RELIEF is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use HOT TODDY™ COLD & FLU RELIEF carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or 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™ COLD & FLU RELIEF is and what it is used for.
2. What you need to know before you take HOT TODDY™ COLD & FLU RELIEF.
3. How to take HOT TODDY™ COLD & FLU RELIEF.
4. Possible side effects.
5. How to store HOT TODDY™ COLD & FLU RELIEF.
6. Contents of the pack and other information.

1. What HOT TODDY™ COLD & FLU RELIEF is and what it is used for

HOT TODDY™ COLD & FLU RELIEF is a soothing drink that may assist in relieving the symptoms related to cold and flu.

2. What you need to know before you take HOT TODDY™ COLD & FLU RELIEF

Do not take HOT TODDY™ COLD & FLU RELIEF:

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

Warnings and precautions
Take special care with HOT TODDY™ COLD & FLU RELIEF:

- if you have a bleeding disorder;
- if you are having any surgical procedure done. You should stop taking HOT TODDY™ COLD & FLU RELIEF two weeks before an operation;
- if you are diabetic and you are taking medicines to control your blood sugar levels.

Other medicines and HOT TODDY™ COLD & FLU RELIEF
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 using:

- anticoagulant medicines (used to prevent your blood from clotting) or herbal supplements with blood thinning effects;
- antidiabetic medicine (used to treat high blood sugar).

HOT TODDY™ COLD & FLU RELIEF with food, drink and alcohol
See section 3 (**How to take HOT TODDY™ COLD & FLU RELIEF**).

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™ COLD & FLU RELIEF.
Safety and efficacy of HOT TODDY™ COLD & FLU RELIEF during pregnancy and breastfeeding have not been established. Do not use HOT TODDY™ COLD & FLU RELIEF if you are pregnant or breastfeeding your baby (see **HOT TODDY™ COLD & FLU RELIEF contains preservatives**).

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™ COLD & FLU RELIEF affects you.

HOT TODDY™ COLD & FLU RELIEF contains sorbitol
HOT TODDY™ COLD & FLU RELIEF contains 1 100 mg sorbitol in each effervescent tablet.
Sorbitol is a source of fructose. If your doctor has told you that you 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 take HOT TODDY™ COLD & FLU RELIEF.

HOT TODDY™ COLD & FLU RELIEF contains preservatives
HOT TODDY™ COLD & FLU RELIEF contains 47 mg sodium benzoate in each effervescent tablet, which is equivalent to 0,94 % *m/m*.
Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old) (see **Pregnancy, breastfeeding and fertility**).

3. How to take HOT TODDY™ COLD & FLU RELIEF

Do not share your medicines with any other person.
Always take HOT TODDY™ COLD & FLU RELIEF 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: 1 effervescent tablet taken three times per day, dissolved in a glass (250 ml) of hot or cold water.

If you have the impression that the effect of HOT TODDY™ COLD & FLU RELIEF is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.
HOT TODDY™ COLD & FLU RELIEF can be taken with or without food.

If you take more HOT TODDY™ COLD & FLU RELIEF 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 remaining HOT TODDY™ COLD & FLU RELIEF with you so the doctor will know what you have taken.

4. Possible side effects

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

If any of the following happens, stop taking HOT TODDY™ COLD & FLU RELIEF 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™ COLD & FLU RELIEF. You may need urgent medical attention or hospitalisation.

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

- difficulty falling and staying asleep (insomnia);
- headaches;
- redness of your skin;
- stomach pain or discomfort; burping; indigestion; 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 "**6.04 Adverse Drug Reaction Reporting Form**", found online **under SAHPRA's publications**: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of HOT TODDY™ COLD & FLU RELIEF.

5. How to store HOT TODDY™ COLD & FLU RELIEF

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the carton or container.
- 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™ COLD & FLU RELIEF contains
Each effervescent tablet contains:
The active substances are:

Siphonochilus aethiopicus (Schweinf) B.L. Burtt (African ginger) .... [rhizome powder]	400 mg
Ascorbic acid (Vitamin C)	300 mg
Honey …………………………………………………….................................	50 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), magnesium stearate (E572), menthol flavour, orange flavour, polyethylene glycol (E1521), sodium saccharin (E954), sodium benzoate (E211), sodium bicarbonate (E500), sorbitol (E420), sunset orange (colourant) and Sweetener A100 (containing acesulfame K and sodium cyclamate (E952)).

What HOT TODDY™ COLD & FLU RELIEF looks like and contents of the pack
Orange coloured, speckled, flat, round effervescent tablet.
Due to the natural ingredients, the colour of some ingredients may vary from batch to batch.
HOT TODDY™ COLD & FLU RELIEF effervescent tablets are wrapped in a silver foil and packed in a tubular container, placed in an outer carton.
Pack size: 10 effervescent tablets.

Holder of Certificate of Registration
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This leaflet was last revised in
Will be allocated by SAHPRA upon registration.

Registration number
Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information
The Professional Information for HOT TODDY™ COLD & FLU RELIEF is available on https://www.brunel.co.za/hot-toddy-2/ or can be requested from the contact details above.

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HOT TODDY™

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS
S0

HOT TODDY™ COLD & FLU RELIEF bruistablette
Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (wildegemmer),
askorbiensuur (vitamien C), heuning, *Cinnamomum cassia* (L.) J. Presl. (kaneel).
Preserveermiddel: Natriumbensoaat 0,94 % *m/m*.
Bevat suiker: Elke bruistablet bevat 50 mg heuning.
Bevat versoeter: Elke bruistablet bevat 1 100 mg sorbitol, 100 mg Sweetener A100 (bevattende asesulfaam K en natriumsiklamaat) en 1,7 mg natriumsakkarien.

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™ COLD & FLU RELIEF is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy HOT TODDY™ COLD & FLU RELIEF 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 as jou simptome vererger of nie verbeter na 10 dae nie.

Wat is in hierdie inligtingsblad

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

1. Wat HOT TODDY™ COLD & FLU RELIEF is, en waarvoor dit gebruik word

HOT TODDY™ COLD & FLU RELIEF is 'n strelende drankie wat kan help om simptome wat verband hou met verkoue en griep, te verlig.

2. Wat jy moet weet voordat jy HOT TODDY™ COLD & FLU RELIEF neem

Moet nie HOT TODDY™ COLD & FLU RELIEF neem:

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

Waarskuwings en voorsorgmaatreëls
Wees versigtig met HOT TODDY™ COLD & FLU RELIEF:

- indien jy 'n bloedingsteuring het;
- indien jy enige chirurgiese prosedure moet ondergaan – jy moet twee weke voor 'n operasie ophou om HOT TODDY™ COLD & FLU RELIEF te gebruik;
- indien jy 'n diabeet is en medisyne neem om jou bloedsuikervlakke te beheer.

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

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- teenstolmiddels (gebruik om te keer dat jou bloed klonte vorm) of kruieaanvullings met bloedverdunnende

effekte;

- antidiabetiese medisyne (gebruik om hoë bloedsuiker te behandel).

HOT TODDY™ COLD & FLU RELIEF met eet-, drinkgoed en alkohol
Sien afdeling 3 (**Hoe om HOT TODDY™ COLD & FLU RELIEF 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 HOT TODDY™ COLD & FLU RELIEF neem.
Dit is nie vasgestel of HOT TODDY™ COLD & FLU RELIEF veilig en doeltreffend is om tydens swangerskap en borsvoeding te gebruik nie. Moet nie HOT TODDY™ COLD & FLU RELIEF gebruik indien jy swanger is of jou baba borsvoed nie (sien **HOT TODDY™ COLD & FLU RELIEF bevat preserveermiddels**).

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

HOT TODDY™ COLD & FLU RELIEF bevat sorbitol
Elke HOT TODDY™ COLD & FLU RELIEF bruistablet bevat 1 100 mg sorbitol.
Sorbitol is 'n bron van fruktose. Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sommige suikers is, of indien jy met oorerflike fruktose-intoleransie, 'n seldsame genetiese versteuring wat veroorsaak dat 'n persoon nie fruktose kan afbreek nie, gediagnoseer is, praat eers met jou dokter voordat jy HOT TODDY™ COLD & FLU RELIEF neem.

HOT TODDY™ COLD & FLU RELIEF bevat preserveermiddels
HOT TODDY™ COLD & FLU RELIEF bevat 47 mg natriumbensoaat per bruistablet, wat gelykstaande is aan 0,94 % *m/m*.
Natriumbensoaat kan geelsug (vergeling van die vel en oë) by pasgebore babas (tot 4 weke oud) vererger (sien **Swangerskap, borsvoeding en vrugbaarheid**).

3. Hoe om HOT TODDY™ COLD & FLU RELIEF te neem

Moet nie jou medisyne met enige ander persoon deel nie.
Neem HOT TODDY™ COLD & FLU RELIEF altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus vir jou dokter of apteker indien jy onseker is.
Die gewone dosis is:
Volwassenes: 1 bruistablet drie keer per dag geneem, opgelos in 'n glas (250 ml) warm of koue water.

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

Moet nie die aanbevole dosis oorskry nie.
HOT TODDY™ COLD & FLU RELIEF kan met of sonder kos geneem word.

As jy meer HOT TODDY™ COLD & FLU RELIEF 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™ COLD & FLU RELIEF saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike newe-effekte

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

Indien enige van die volgende gebeur, hou op om HOT TODDY™ COLD & FLU RELIEF 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™ COLD & FLU RELIEF gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

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

- sukkel om aan die slaap te raak en om aan die slaap te bly (slapeloosheid);
- hoofpyn;
- rooiheid van die vel;
- maagpyn of -ongemak; bring winde op; slegte spysvertering; naarheid; braking; diarree.

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 Reaction 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™ COLD & FLU RELIEF te verskaf.

5. Hoe om HOT TODDY™ COLD & FLU RELIEF te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C, in ’n koel, droë plek, beskerm teen lig.
- Hou die buisie dig toe.
- Moet nie gebruik na die vervaldatum soos aangedui op die buisie of die boksie nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat HOT TODDY™ COLD & FLU RELIEF bevat
Elke bruistablet bevat:
Die aktiewe bestanddele is:

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (Wildegemmer) .... [risoom poeier]	400 mg
Askorbiensuur (Vitamien C)	300 mg
Heuning	50 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), magnesiumstearaat (E572), mentolgeursel, lemoengeursel, poliëtileenglikol (E1521), natriumsakkarien (E954), natriumbensoaat (E211), natriumbikarbonaat (E500), sorbitol (E420), sunset orange (kleurstof) en Sweetener A100 (bevattende asesulfaam K en natriumsiklamaat (E952)).

Hoe HOT TODDY™ COLD & FLU RELIEF lyk en inhoud van die verpakking
Oranjekleurige, gespikkelde, plat, ronde bruistablet.
Die kleur van sommige bestanddele kan wissel tussen lotte, omdat dit van natuurlike oorsprong is.
HOT TODDY™ COLD & FLU RELIEF word in silwer foelie omhul en in ’n buisvormige houer verpak, in ’n buitenste karton.
Verpakkingsgrootte: 10 bruistablette.

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

Hierdie inligtingsblad is 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™ COLD & FLU RELIEF is beskikbaar by https://www.brunel.co.za/hot-toddy-2/ of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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