

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S0****HOT TODDY™ COLD & FLU RELIEF effervescent tablets**

Siphonochilus aethiopicus (Schweinf.) B.L. Burt (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 overdose, 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:

<i>Siphonochilus aethiopicus</i> (Schweinf) B.L. Burt (African ginger)	400 mg
[rhizome powder]	
Ascorbic acid (Vitamin C)	300 mg
Honey	50 mg
<i>Cinnamomum cassia</i> (L.) J. Presl. (Cinnamon)	2,5 mg
[bark, 4:1 extract providing 10 mg of dried herb equivalent]	

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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