SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM: HOT TODDY[™] ADULT SACHETS powder

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 treat a mild illness. Nevertheless you still need to use HOT TODDY[™] ADULT SACHETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **HOT TODDY™ ADULT SACHETS** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT HOT TODDY[™] ADULT SACHETS CONTAINS:

	ne active substances are:	
Е	ach 6.3 g sachet of powder contains:	
Α	frican Ginger (<i>Siphonochilus aethiopicus</i> B.L. Burtt)	300 mg
١١	y (Hedera helix L. extract)	150 mg
V	itamin C	100 mg
L	emon (<i>Citrus limon</i> extract equivalent to)	50 mg
Н	loney Powder	25 mg
G	Singer (Zingiber Officinale Rosc. root extract equivalent to)	10 mg
С	innamon (Cinnamomum cassia Presl. bark extract equivalent to)	10 mg
С	Contains sugar (sucrose)	3927 mg
С	Contains artificial sweetener (acesulfame K, sodium cyclamate)	43 mg

The other ingredients are:

Citric acid, colourants, flavourants, menthol, silicon dioxide anhydrous, sugar, sweetener.

2. WHAT HOT TODDY[™] ADULT SACHETS IS USED FOR:

HOT TODDY[™] ADULT SACHETS may assist in soothing the symptoms of colds and flu including cough and congestion.

3. 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").

Take special care with HOT TODDY[™] ADULT SACHETS:

 Do not use HOT TODDY[™] ADULT SACHETS if you are pregnant or breastfeeding your baby (see "PREGNANCY AND BREASTFEEDING").

Taking HOT TODDY[™] ADULT SACHETS with food and drink:

• HOT TODDY[™] ADULT SACHETS can be taken with or without food.

Pregnancy and Breastfeeding:

- Do not take **HOT TODDY[™] ADULT SACHETS** if you are pregnant or breastfeeding your baby.
- If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking this medicine.

Driving and using machinery:

• Due to the nature of the product, **HOT TODDY[™] ADULT SACHETS** might affect your ability to drive or use machinery. Do not drive or use machinery until you know how **HOT TODDY[™] ADULT SACHETS** might affect you.

Important information about some of the ingredients of HOT TODDY[™] ADULT SACHETS:

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take HOT TODDY[™] ADULT SACHETS.
- HOT TODDY[™] ADULT SACHETS contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with HOT TODDY[™] ADULT SACHETS:

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

4. HOW TO TAKE HOT TODDY[™] ADULT SACHETS:

- Do not share medicines prescribed to you with any other person.
- Always take HOT TODDY[™] ADULT SACHETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- Do not exceed the recommended dosage.
- The usual dose is:
- Adults: 1 sachet 3 times a day.
- Empty contents of sachet into a glass and fill half of the glass with very hot water. Stir mixture. If necessary, add cold water but it is advisable to drink as hot as possible without burning your mouth.

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 control centre.
- If you take more **HOT TODDY[™] ADULT SACHETS** than you should, you might feel very nauseous, start to vomit (throw up), get diarrhoea (runny, loose stool) and/or stomach pains.

If you forget to take/missed a dose of HOT TODDY[™] ADULT SACHETS:

- Take the missed dose as soon as you remember.
- Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

HOT TODDY[™] ADULT SACHETS can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, 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 the 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 as soon as possible if you notice any of the following:

- Frequency unknown: Tiredness.
- Frequency unknown: Nausea (feeling nauseous).
- Frequency unknown: Diarrhoea (runny loose stools).
- Frequency unknown: Stomach cramps.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF HOT TODDY[™] ADULT SACHETS:

- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Protect from direct sunlight and moisture.
- Do not store in bathroom.
- Do not use after the expiry date stated on the sachet/carton.
- Use sachet immediately once opened. Do not store an unsealed/opened sachet.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF HOT TODDY[™] ADULT SACHETS:

6.3 g sachets packed inside a carton. Available in pack sizes of 4 and 8 sachets.

8. IDENTIFICATION OF HOT TODDY[™] ADULT SACHETS:

Beige powder with dark speckles and a characteristic lemon and menthol taste. A yellow solution with a lemon and menthol odour when dissolved in water. The contents of the sachet may not dissolve completely due to the nature of the natural ingredients.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

To be allocated upon registration.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Brunel Laboratoria (Pty) Ltd 1 Van Tonder Street Sunderland Ridge Centurion 0157 info@brunel.co.za www.brunel.co.za

11. DATE OF PUBLICATION:

To be allocated upon registration.

12. DATE OF REGISTRATION:

To be allocated upon registration.

13. COMPLEMENTARY MEDICINE:

Complementary Medicine: Combination Product – Western Herbal Medicine. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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

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