

## PROFESSIONAL INFORMATION FOR HOT TODDY™ COLD & FLU RELIEF

### SCHEDULING STATUS:

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### PROPRIETARY NAME AND DOSAGE FORM:

**HOT TODDY™ COLD & FLU RELIEF** effervescent tablet

### COMPOSITION:

#### *Active Ingredients:*

Each effervescent tablet contains:

<i>Siphonochilus aethiopicus</i> B.L. Burt (African Ginger) .....	400 mg
Vitamin C .....	300 mg
Honey powder .....	50 mg
<i>Cinnamomum cassia</i> Presl. (Cinnamon bark extract equivalent to) .....	10 mg
Contains sugar (sorbitol) .....	1100 mg
Contains artificial sweeteners (sodium saccharin, sodium cyclamate, acesulfame K) ....	102 mg

#### *Inactive Ingredients:*

Citric acid, colourants, flavourants, magnesium stearate, menthol, polyethylene glycol, sodium benzoate, sodium bicarbonate, sugar, sweetener.

### CATEGORY AND CLASS:

D 33.7 Combination Product.

### PHARMACOLOGICAL ACTION:

*Siphonochilus aethiopicus* B.L. Burt (African Ginger) has been traditionally used to assist in the treatment of colds and flu and symptoms related to colds and flu. The exact mechanism of action is not known but is believed to be due to a single compound referred to *Siphonochilus* sesquiterpenoid or *siphonochilone*.

Vitamin C contributes to the normal function of the immune system and acts as an antioxidant for the maintenance of good health. Vitamin C is well absorbed, metabolised and excreted in urine.

Honey is well known to assist in relieving cough, the mechanism of action is not clear.

*Cinnamomum cassia* Presl. (Cinnamon bark) is well known to assist in the treatment of symptoms related to colds and flu, the mechanism of action is not clear.

### INDICATIONS:

**HOT TODDY™ COLD & FLU RELIEF** is a soothing drink to assist in shortening the duration of colds and flu and to assist in relieving symptoms related to colds and flu.

### CONTRAINDICATIONS:

Allergies or sensitivity to any of the ingredients (see “**COMPOSITIONS**” and “**WARNINGS AND SPECIAL PRECAUTIONS**”).  
Pregnancy or lactation (see “**HUMAN REPRODUCTION**”).

## **WARNINGS AND SPECIAL PRECAUTIONS:**

### **Warnings:**

Do not use **HOT TODDY™ COLD & FLU RELIEF** if you are allergic or sensitive to any of the ingredients (see “**COMPOSITION**” and “**CONTRAINDICATIONS**”).

Do not use **HOT TODDY™ COLD & FLU RELIEF** if you are pregnant or lactating (see “**HUMAN REPRODUCTION**”).

Patients with the rare hereditary condition of sorbitol/maltitol/lactitol intolerance should not take **HOT TODDY™ COLD & FLU RELIEF**.

Consult a doctor or other healthcare professional if symptoms persist or do not improve within 10 days.

### **Effects on ability to drive and use machines:**

Due to the nature of the product, **HOT TODDY™ COLD & FLU RELIEF** might affect your ability to drive or use machines. Do not drive or use machines until you know how **HOT TODDY™ COLD & FLU RELIEF** might affect you.

## **INTERACTIONS:**

None known.

## **HUMAN REPRODUCTION:**

### **Pregnancy:**

**HOT TODDY™ COLD & FLU RELIEF** is not intended for use during pregnancy.

### **Lactation:**

**HOT TODDY™ COLD & FLU RELIEF** is not intended for use during lactation.

## **DOSAGE AND DIRECTIONS FOR USE:**

### **Dosage:**

Adults: 1 effervescent tablet 3 times a day. Consult a doctor or other healthcare professional if symptoms worsen or do not improve within 10 days.

### **Directions for use:**

Adults: Dissolve 1 effervescent tablet in a glass (250 ml) of hot or cold water. The ingredients of the effervescent tablet may not dissolve completely due to the nature of the natural ingredients.

## **SIDE EFFECTS:**

### **Side Effect Profile:**

#### **Immune system disorders:**

*Frequency unknown:* Allergic reactions (see “**CONTRAINDICATIONS**” and “**WARNINGS AND SPECIAL PRECAUTIONS**”).

#### **Nervous system disorders:**

*Frequency unknown:* Fatigue.

#### **Gastrointestinal disorders:**

*Frequency unknown:* Mild and transient gastrointestinal disorders including nausea, diarrhoea, abdominal pain.

## **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

### **Symptoms of Overdosage:**

Symptoms of an overdosage are not known but can include severe nausea, vomiting, diarrhoea and abdominal pain.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison control centre.

### **Treatment of Overdosage:**

Treatment should be symptomatic and supportive.

**IDENTIFICATION:**

Orange coloured, speckled, flat, round effervescent tablet. Once dissolved, the mixture becomes orange coloured with a characteristic orange and menthol odour.

Due to the natural ingredients, the colour of some ingredients may vary from batch to batch. The ingredients of the effervescent tablet may not dissolve completely due to the nature of the natural ingredients.

**PRESENTATION:**

10 effervescent tablets wrapped in silver foil and packed inside a white tubular container.

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C in a cool, dry place, protected from light.

Keep tightly closed.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER/REFERENCE NUMBER:**

To be allocated upon registration.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Brunel Laboratoria (Pty) Ltd

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**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:**

To be allocated upon registration.

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**COMPLEMENTARY MEDICINE:**

This is a Complementary Medicine: Combination Product – Western Herbal Medicine.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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