

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

### SCHEDULING STATUS:

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### PROPRIETARY NAME AND DOSAGE FORM:

**HOT TODDY™ COLD & FLU SYRUP** syrup

### COMPOSITION:

#### Active Ingredients:

Each 5 ml contains:

<i>Echinacea purpurea</i> (L.) Moench (Echinacea) .....	2,22 mg
[Aerial parts, 45:1 extract providing 100 mg of dried herb equivalent]	
Ascorbic acid (Vitamin C) .....	60 mg
<i>Hedera helix</i> L. (Ivy) .....	10 mg
[Leaf, 5:1 extract providing 50 mg dried herb equivalent]	
Honey .....	50 mg
Alpha-tocopherol (Vitamin E) .....	2 mg
Zinc gluconate .....	2 mg
providing Zinc (elemental) .....	0,25 mg
Pyridoxine (Vitamin B <sub>6</sub> ) .....	1,5 mg
<i>Camellia sinensis</i> (L.) Kuntze (Green tea extract) .....	1 mg
Cyanocobalamin (Vitamin B <sub>12</sub> ) .....	2 µg
Retinol (Vitamin A) .....	375 I.U.
Cholecalciferol (Vitamin D <sub>3</sub> ) .....	165 I.U.
Contains sugar (sorbitol, sucrose, honey) .....	4 030 mg

#### Preservatives:

Methylparaben 0,1 % *m/v*, Propylparaben 0,02 % *m/v*.

#### Inactive Ingredients:

Colourant, flavourant, menthol, preservatives, sugar, water.

### CATEGORY AND CLASS:

D 33.7 Combination product.

### PHARMACOLOGICAL ACTION:

*Echinacea purpurea* L. Moench (Echinacea) has an immunostimulant function. The immunostimulant effect is brought on by three mechanisms: activation of the phagocytosis and stimulation of fibroblasts; increasing respiratory activity; and increased mobility of the leukocytes.

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.

*Hedera helix* L. extract (Ivy) is well known to act as an expectorant. The mechanism of action is not known but it is suggested that Ivy extract acts on the gastric mucosa to cause stimulation of the mucous glands and the bronchi via parasympathetic sensory pathways.

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

Zinc assists to maintain immune function and is a factor in the maintenance of good health.

Vitamin E acts as an antioxidant and as a factor in the maintenance of good health.

Green tea extract is a well-known source of antioxidants as a factor in the maintenance of good health.

Vitamin B<sub>6</sub>, B<sub>12</sub> and D is included as factors in the maintenance of good health.

Vitamin A contributes to the maintenance of immune function.

### INDICATIONS:

**HOT TODDY™ COLD & FLU SYRUP** contains ingredients that has been traditionally used to assist in relieving cough and soothing a sore throat. It might also assist in shortening the duration of upper respiratory tract infections and contains vitamins and minerals as factors in the maintenance of good health.

## **CONTRAINDICATIONS:**

Allergies or sensitivity to any of the ingredients of **HOT TODDY™ COLD & FLU SYRUP** (see “**COMPOSITION**”).  
Do not use if you have any of the following serious conditions: tuberculosis, collagenosis, multiple sclerosis, AIDS, HIV infection or any autoimmune disorder.

Do not use if you are taking immunosuppressants (see “**INTERACTIONS**”).

Do not use during pregnancy and lactation (see “**HUMAN REPRODUCTION**”).

Allergies to any plants in the *Asteraceae* (Daisy) family.

## **WARNINGS AND SPECIAL PRECAUTIONS:**

### **Warnings:**

If symptoms persist or worsen, consult a healthcare provider.

Do not use for longer than 10 days without consulting a healthcare provider.

### **Special precautions:**

Consult a healthcare provider prior to use if you have a liver disorder or develop symptoms of a liver disorder (such as abdominal pain, dark urine or jaundice).

**HOT TODDY™ COLD & FLU SYRUP** contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomaltase insufficiency should not take

**HOT TODDY™ COLD & FLU SYRUP**.

Patients with the rare hereditary condition of sorbitol/maltitol/lactitol intolerance should not take

**HOT TODDY™ COLD & FLU SYRUP**.

**HOT TODDY™ COLD & FLU SYRUP** contains sorbitol which may have a laxative effect.

**HOT TODDY™ COLD & FLU SYRUP** contains sucrose and honey which may have an effect on the glycaemic control of patients with diabetes mellitus.

Consult a healthcare provider prior to use if you have an iron deficiency.

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

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

## **INTERACTIONS:**

### **Immunosuppressants:**

Since **HOT TODDY™ COLD & FLU SYRUP** can have a stimulatory effect on the immune system, it might interfere with and have an effect on the efficacy of the immunosuppressant treatment. Do not use if you are on any immunosuppressant treatment (see “**CONTRAINDICATIONS**”).

## **HUMAN REPRODUCTION:**

Safety during pregnancy and lactation has not been established. Do not use **HOT TODDY™ COLD & FLU SYRUP** if you are pregnant or lactating.

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

- **PREVENTATIVE DOSE:**  
Children 3 - 6 years: 5 ml twice daily.  
Children older than 6 years: 10 ml twice daily.
- **ONSET DOSE:**  
Children 3 - 6 years: 5 ml three times daily.  
Children older than 6 years: 10 ml three times daily.
- Should be taken after food.
- Shake the bottle before use.
- Do not exceed the recommended dosage.
- Consult a doctor if your symptoms worsen or do not improve after 10 days.

## **SIDE EFFECTS:**

### **Side Effect Profile:**

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

*Frequency unknown:* Allergic reactions (rash, swelling of throat or mouth that could lead to difficulty in breathing) is known to occur to some of the ingredients of **HOT TODDY™ COLD & FLU SYRUP** (see “**CONTRAINDICATIONS**”).

**Nervous system disorders:**

*Frequency unknown:* Tiredness.

**Gastrointestinal disorders:**

*Frequency unknown:* Mild and transient gastrointestinal side effects (abdominal cramping, nausea and diarrhoea).

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:****Symptoms of Overdosage:**

Symptoms of an overdose are not known but can include severe nausea, vomiting, diarrhoea and abdominal pain. In the event of an overdose, consult a doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**Treatment of Overdosage:**

Treatment should be symptomatic and supportive.

**IDENTIFICATION:**

Red/orange syrup with a sweet (herbal) strawberry/menthol taste and odour.

**PRESENTATION:**

Red/orange syrup in a brown 200 ml plastic bottle packed inside a carton.

**STORAGE INSTRUCTIONS:**

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

Keep tightly closed.

Keep the bottle in the outer carton.

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

1 Van Tonder Street

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

To be allocated upon registration.

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To be allocated upon registration.

**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.