

PROFESSIONAL INFORMATION FOR HOT TODDY™ ADULT SACHETS

SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM:

HOT TODDY™ ADULT SACHETS powder

COMPOSITION:

Active Ingredients:

Each sachet contains:

<i>Siphonochilus aethiopicus</i> B.L. Burt (African Ginger)	300 mg
<i>Hedera helix</i> L. (Ivy extract)	150 mg
Vitamin C	100 mg
<i>Citrus limon</i> (Lemon extract equivalent to)	50 mg
Honey Powder	25 mg
<i>Zingiber Officinale</i> Rosc. (Ginger root extract equivalent to)	10 mg
<i>Cinnamomum cassia</i> Presl. (Cinnamon bark extract equivalent to)	10 mg
Contains sugar (sucrose)	3927 mg
Contains artificial sweetener (acesulfame K, sodium cyclamate).....	43 mg

Inactive Ingredients:

Citric acid, colourants, flavourants, menthol, silicon dioxide anhydrous, 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 as *Siphonochilus* sesquiterpenoid or *siphonochilone*.

Hedera helix L. – extract (Ivy) is well known to assist in treating respiratory infections and 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.

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.

Citrus limon (Lemon) is well known to assist in relieving symptoms related to colds and flu. This is believed to be due to bioflavonoids contained in lemon that has an antioxidant effect.

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

Zingiber Officinale Rosc. root (Ginger) is traditionally used in herbal medicine as an expectorant and antitussive to relieve coughs and colds. Active constituents of ginger include gingerol, gingerdione, shogaol and sesquiterpene and monoterpene volatile oils.

Cinnamomum cassia Presl. (Cinnamon) 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™ ADULT SACHETS are indicated to assist in soothing the symptoms of colds and flu including cough and congestion.

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™ ADULT SACHETS** if you are allergic or sensitive to any of the ingredients (see “**COMPOSITION**” and “**CONTRAINDICATIONS**”).

Do not use **HOT TODDY™ ADULT SACHETS** if you are pregnant or breastfeeding your baby (see “**HUMAN REPRODUCTION**”).

Consult a doctor or other healthcare professional if symptoms persist or worsen.

Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Effects on ability to drive and use machines:

Due to the nature of the product, **HOT TODDY™ ADULT SACHETS** might affect your ability to drive or use machines.

Do not drive or use machines until you know how **HOT TODDY™ ADULT SACHETS** might affect you.

INTERACTIONS:

None known.

HUMAN REPRODUCTION:**Pregnancy:**

HOT TODDY™ ADULT SACHETS are not intended for use during pregnancy.

Lactation:

HOT TODDY™ ADULT SACHETS are not intended for use during lactation.

DOSAGE AND DIRECTIONS FOR USE:

Dosage: Adults: 1 sachet 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: 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.

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 and 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:

Beige powder with dark speckles and a characteristic lemon and menthol taste. Once mixed with water, it becomes a yellow solution with a lemon and menthol odour. The contents of the sachet may not dissolve completely due to the nature of the natural ingredients.

PRESENTATION:

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

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

1 Van Tonder Street

Sunderland Ridge

Centurion

0157

info@brunel.co.za

www.brunel.co.za

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

To be allocated upon registration.

DATE OF REGISTRATION:

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.