

PATIENT INFORMATION LEAFLET FOR HOT TODDY™ COLD & FLU SYRUP

SCHEDULING STATUS:

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PROPRIETARY NAME AND DOSAGE FORM:

HOT TODDY™ COLD & FLU SYRUP syrup

Read all of this leaflet carefully because it contains important information for you.

HOT TODDY™ COLD & FLU SYRUP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use HOT TODDY™ COLD & FLU SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share HOT TODDY™ COLD & FLU SYRUP 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™ COLD & FLU SYRUP CONTAINS:

The active substances are:

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 ₆)	1,5 mg
<i>Camellia sinensis</i> (L.) Kuntze (Green tea extract)	1 mg
Cyanocobalamin (Vitamin B ₁₂)	2 µg
Retinol (Vitamin A)	375 I.U.
Cholecalciferol (Vitamin D ₃)	165 I.U.
Contains sugar (sorbitol, sucrose, honey)	4 030 mg

The other ingredients are:

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

Preservatives:

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

2. WHAT HOT TODDY™ COLD & FLU SYRUP IS USED FOR:

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 infections in the upper airways and contains vitamins and minerals as factors in the maintenance of good health.

3. BEFORE YOU TAKE HOT TODDY™ COLD & FLU SYRUP:

Do not take HOT TODDY™ COLD & FLU SYRUP:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of HOT TODDY™ COLD & FLU SYRUP (see "WHAT HOT TODDY™ COLD & FLU SYRUP CONTAINS").
- If you have any of the following serious conditions:
 - tuberculosis (TB),
 - collagenosis (rare skin disorder),
 - multiple sclerosis (MS),
 - AIDS,
 - HIV infection,
 - or any autoimmune disorders (disease where your immune system attacks your body).
- If you are taking immunosuppressants (medicines that suppress your immune system). (See "TAKING OTHER MEDICINES WITH HOT TODDY™ COLD & FLU SYRUP").
- If you are pregnant or breastfeeding your baby (see "PREGNANCY AND BREASTFEEDING").
- If you have any allergies to any plants in the Daisy family.

Take special care with HOT TODDY™ COLD & FLU SYRUP:

- Consult a healthcare provider before you use **HOT TODDY™ COLD & FLU SYRUP** if you have a liver disorder, or develop symptoms of liver trouble (such as abdominal pain, dark urine or jaundice).
- If you suffer from a rare hereditary condition such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency (see “**IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF HOT TODDY™ COLD & FLU SYRUP**”).
- If you suffer from a rare hereditary condition of sorbitol/maltitol/lactitol intolerance (see “**IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF HOT TODDY™ COLD & FLU SYRUP**”).
- Consult a healthcare provider before you use **HOT TODDY™ COLD & FLU SYRUP** if you have an iron deficiency.
- Do not take **HOT TODDY™ COLD & FLU SYRUP** for longer than 10 days without consulting your healthcare provider.

Taking HOT TODDY™ COLD & FLU SYRUP with food and drink:

- **HOT TODDY™ COLD & FLU SYRUP** should be taken after food.

Pregnancy and Breastfeeding:

- Do not take **HOT TODDY™ COLD & FLU SYRUP** 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™ COLD & FLU SYRUP** might affect your ability to drive or use machinery. Do not drive or use machinery until you know how **HOT TODDY™ COLD & FLU SYRUP** might affect you.

Important information about some of the ingredients of HOT TODDY™ COLD & FLU SYRUP:

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take **HOT TODDY™ COLD & FLU SYRUP**.
- **HOT TODDY™ COLD & FLU SYRUP** contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take **HOT TODDY™ COLD & FLU SYRUP**.
- **HOT TODDY™ COLD & FLU SYRUP** contains sorbitol which may increase bowel movements and loosen stools.
- **HOT TODDY™ COLD & FLU SYRUP** contains sucrose and honey which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with HOT TODDY™ COLD & FLU SYRUP:

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).
- 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 immunosuppressant treatment. Do not use **HOT TODDY™ COLD & FLU SYRUP** if you are on any immunosuppressant treatment (see “**DO NOT TAKE HOT TODDY™ COLD & FLU SYRUP**”).

4. HOW TO TAKE HOT TODDY™ COLD & FLU SYRUP:

- Do not share medicines prescribed to you with any other person.
- Always take **HOT TODDY™ COLD & FLU SYRUP** 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.
- Shake the bottle before use.
- **HOT TODDY™ COLD & FLU SYRUP** should be taken after food.

The usual dose is:

- **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.
- Consult your doctor if your symptoms worsen or do not improve after 10 days.

If you take more HOT TODDY™ COLD & FLU SYRUP 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.

- The symptoms of overdosage are not known but if you take more **HOT TODDY™ COLD & FLU SYRUP** 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 or missed a dose of HOT TODDY™ COLD & FLU SYRUP:

- 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™ COLD & FLU SYRUP** 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™ COLD & FLU SYRUP 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™ COLD & FLU SYRUP**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Abdominal pain, dark urine or yellowing of the skin and eyes, also called jaundice (see “**TAKE SPECIAL CARE WITH HOT TODDY™ COLD & FLU SYRUP**”).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor 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™ COLD & FLU SYRUP:

- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Store in the original bottle.
- Keep the bottle in the outer carton.
- Protect from light and moisture.
- Do not store in the bathroom.
- Keep tightly closed.
- Do not use after the expiry date stated on the label or carton.
- 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™ COLD & FLU SYRUP:

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

8. IDENTIFICATION OF HOT TODDY™ COLD & FLU SYRUP:

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

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

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™ COLD & FLU SYRUP** is available on <http://www.brunel.co.za/hot-toddy-2/> or can be requested from the contact details above.