APPROVED PROPOSED PACKAGE INSERT:

SCHEDULING STATUS

S2

PROPRIETARY NAME (AND DOSAGE FORM):

BENCOUGH (SOLUTION)

COMPOSITION:

Each 5 ml contains:

Diphenhydramine hydrochloride	14 mg
Sodium citrate	56 mg
Ammonium chloride	136 mg
Preservative: Nipastat	0,02 % *m/v*

Other ingredients: levomenthol, propylene glycol, invert syrup, caramel 4800, essence of raspberry no.1, potable water.

Contains sugar.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and Expectorants.

(Prevents/reduces coughing and medicines that promote coughing and expulsion of mucous).

INDICATIONS:

The alleviation of cough.

CONTRAINDICATIONS:

Hypersensitivity (allergy) to any of the ingredients. BENCOUGH is contra-indicated in the presence of impaired hepatic function (decrease in liver function) or impaired renal function (decrease in kidney function). During an attack of asthma. Safety in pregnancy and lactation has not been established (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:

The use of BENCOUGH leads to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol and it is unsafe to drive a vehicle or be in charge of machinery while using the medicine, as impaired decision making could lead to accidents.

Special precautions:

Extreme caution should be exercised by patients taking BENCOUGH in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics (causes sleep), narcotic analgesic (dependence producing substances used for the relief of pain), sedatives (for calming) and tranquillisers (agent used for calming nerves) and anticholinergic agents (a substance to stop the release of certain nerve impulses involving acetylcholine) and tricyclic antidepressants as their effects may be enhanced by diphenhydramine. BENCOUGH should be used cautiously in patients with cardiac (heart) failure, hypertension (high blood pressure) impaired renal function (decrease in kidney function), peripheral oedema (swelling of hands and feet due to retained fluid) and pulmonary oedema (excessive fluid accumulation in the lungs) and in

toxaemia of pregnancy (serious metabolic abnormalities during pregnancy associated with increased blood pressure).

Monoamine oxidase inhibitors may enhance the anticholinergic effects of diphenhydramine hydrochloride. The warning signs of damage caused by ototoxic medicines may be masked by diphenhydramine hydrochloride.

INTERACTIONS:

Interactions with BENCOUGH have not been established.

PREGNANCY AND LACTATION:

The safety and efficacy of BENCOUGH in pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE:

Should not be given to children under 6 years.

Children: 6 to 12 years: A half to one medicine measure (2,5 ml – 5 ml) every four hours.

Adults: One to two medicine measures (5 ml – 10 ml) every four hours.

SIDE EFFECTS:

The most common side effect caused by diphenhydramine is sedation (sedative effect) which includes drowsiness, inability to concentrate, lassitude (lack of energy/fatigue), dizziness, hypotension (low blood pressure), muscular weakness and inco-ordination. Other side effects include gastro-intestinal (affecting the stomach and intestines) disturbances, headaches, blurred vision,

tinnitus (ringing in the ears), elation (high spirits) or depression, irritability, nightmares, anorexia (lack of appetite), difficulty in micturition (passing urine), dryness of the mouth and tightness of the chest, tingling, heaviness and weakness of the hands. Constipation (infrequent bowel movement), diarrhoea (frequent or loose watery stools), epigastric pain (pain in upper, middle region of stomach), nausea (feeling that one is about to be sick), allergic (hypersensitivity) reactions, epileptiform seizures (resembling certain types of fits), euphoria (unrealistic feeling of well-being), extrapyramidal effects (effects on the brain), haemolytic anaemia (lack of red blood cells due to destruction of circulating cells), leucopenia (too few white blood cells) and photosensitisation (sensitisation of the skin to sunlight). Symptoms of stimulation such as insomnia (inability to sleep), nervousness, muscle twitching and convulsions (fits) may also occur.

Side effects that may arise from large doses of ammonium chloride are nausea (feeling that one is about to vomit), vomiting (to be sick), thirst, headache, hyperventilation (abnormally deep and rapid breathing), progressive drowsiness, mental confusion, hyperchloraemic acidosis (abnormally high levels of chloride in the blood causing the blood to be acidic) and hypokalaemia (low blood levels of potassium).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Retention of sodium leads to the accumulation of fluid, with cerebral oedema (accumulation of the fluid on the brain), peripheral oedema (swelling of the hands and feet due to retained fluid) and pulmonary oedema (excessive

accumulation of fluid in the lungs). Symptoms of hypernatraemia (too much sodium in the blood) may include restlessness, weakness, thirst, reduced salivation (secretion of saliva) and lachrymation (secretion of tears), swollen tongue, flushing of the skin, pyrexia (fever), dizziness, headache, oliguria (reduced urine production), hypotension (low blood pressure), tachycardia (increased rate in heart beat), delirium (rapid succession of confused and unconnected ideas often associated with illusions and hallucinations) hyperpnoea (abnormally rapid and deep breathing) and respiratory arrest (loss of effective ability to breathe). Other symptoms of overdosage are gastro-intestinal (affecting the stomach and intestines) upset, drowsiness, hypochloraemic acidosis (abnormally high levels of chloride in the blood causing the blood to be acidic), and hypokalaemia (low blood levels of potassium).

Diphenhydramine hydrochloride overdose may be fatal especially in children whose main symptoms are central nervous system (brain) stimulation and antimuscarinic (the opposite effect of acetyl- choline) effects including ataxia (loss of muscle co-ordination), excitement, hallucinations (false perceptions), muscle tremor, convulsions (fits), dilated pupils, dry mouth, flushed face and hyperpyrexia (abnormally high blood temperature), respiratory collapse (failure of the breathing process), death may occur from respiratory failure (inability to breathe). Ataxia (loss of muscle co-ordination), drowsiness, hyperpyrexia (abnormally high body temperature), hypotension (low blood pressure) may occur.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A brown syrupy liquid.

PRESENTATION:

100 ml, 2,5 litre and 25 litre containers.

STORAGE INSTRUCTIONS:

Store in a cool place at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Y/10.1/261

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

DEZZO TRADING 392 (PTY) LTD.

Loch House Unit 003,

3A Eton Road

Parktown

Johannesburg

South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:

To be allocated.