APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM

BENCOUGH (SOLUTION)

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

BENCOUGH is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **BENCOUGH** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **BENCOUGH** with any 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 7 days

WHAT BENCOUGH CONTAINS

The active substances per 5 ml are:

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

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

Contains sugar.

WHAT BENCOUGH IS USED FOR

BENCOUGH is used to help relieve coughing.

BEFORE YOU TAKE BENCOUGH

Do not take BENCOUGH:

If you are hypersensitive (allergic) to diphenhydramine hydrochloride, sodium citrate, ammonium chloride or any of the other ingredients of **BENCOUGH.**

Some of the symptoms of an allergic reaction may include:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath
- skin rash

- If you are pregnant or breastfeeding. (see "**Pregnancy and breastfeeding"**)
- During an asthma attack
- In the presence of impaired renal function (decrease in kidney function)
- In the presence of impaired hepatic function (decrease in liver function)

Take special care with BENCOUGH:

BENCOUGH should be used cautiously in patients with:

- heart failure,

- high blood pressure
- decrease in kidney function,
- swelling of hands and feet due to retained fluid (peripheral oedema)
- excessive fluid accumulation in the lungs (Pulmonary oedema) and
- in serious metabolic abnormalities during pregnancy associated with increased blood pressure (pregnancy toxaemia).

Extreme caution should be exercised by patients taking BENCOUGH in conjunction with nervous system depressants as their effects may be enhanced by diphenhydramine (see "**Taking other medicines with BENCOUGH"**).

Taking BENCOUGH with food and drink:

BENCOUGH should not be consumed with alcohol. Drowsiness and impaired concentration may be aggravated by the simultaneous intake of alcohol.

Pregnancy and Breastfeeding:

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BENCOUGH** (see "**Do not take BENCOUGH**")

Driving and using machinery:

BENCOUGH may make you feel drowsy or sleepy and may lead to impaired concentration. It is unsafe to drive a vehicle or be in charge of

machinery while using **BENCOUGH,** as impaired decision making could lead to accidents.

Taking other medicines with BENCOUGH:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- 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.

Extreme caution should be exercised by patients taking BENCOUGH in conjunction with nervous system depressants (see "**Take special care with BENCOUGH")** 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)
- anticholinergic agents (a substance to stop the release of certain nerve impulses involving acetylcholine) and
- tricyclic antidepressants

HOW TO TAKE BENCOUGH

Do not share medicines prescribed for you with any other person.

Always take **BENCOUGH** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dosage of **BENCOUGH** is:

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.

If you take more BENCOUGH than you should:

If you take more **BENCOUGH** than you should and you start to experience accumulation of fluid, restlessness, weakness, thirst, reduced secretion of saliva and tears, swollen tongue, flushing of the skin, fever, dizziness, headache, reduced urine production, low blood pressure, increased rate in heartbeat, illusions and hallucinations, abnormally rapid and deep breathing and loss of effective ability to breathe, stomach upset, drowsiness, excitement, muscle tremor, fits, dilated pupils, dry mouth, loss of muscle co-ordination, drowsiness, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BENCOUGH:

Take the missed dose as soon as you remember it. However, if it is almost time for you next regular dose, do not take your missed dose. If you miss two or more doses, consult your doctor or pharmacist

Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

BENCOUGH can have side effects

If any of the following happens, stop taking BENCOUGH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Allergic reactions, including skin rashes
- Fits or numbness

These are all serious side effects. If you have them you may have had a serious allergic reaction to BENCOUGH. You may need urgent medical attention or hospitalisation.

The most common side effect caused by the diphenhydramine component of **BENCOUGH** is:

- sedation (sedative effect) which includes drowsiness, inability to concentrate, lassitude (lack of energy/fatigue), dizziness, hypotension (low blood pressure), muscular weakness and incoordination.

Other side effects include:

- gastro-intestinal (stomach and intestines) disturbances,
- headaches,
- blurred vision,
- tinnitus (ringing in the ears),
- high spirit 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 occur with large doses of the ammonium chloride component of **BENCOUGH** is:

- 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).

Not all side-effects reported for BENCOUGH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BENCOUGH, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF BENCOUGH

Store all medicine out of reach of children.

Store at or below 25 °C. Protect from light.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF BENCOUGH

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

IDENTIFICATION OF BENCOUGH

A brown syrupy liquid.

REGISTRATION NUMBER

Y/10.1/261

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

DEZZO TRADING 392 (PTY) LTD.

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