Proposed patient information leaflet for EXPECTALIN WITH CODEINE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

EXPECTALIN WITH CODEINE liquid

Diphenhydramine hydrochloride / codeine phosphate / ammonium chloride

Contains sugar alcohol: Each 5 mL contains 2,5 g sorbitol.

Contains sweetener: Each 5 mL contains 1,5 mg saccharin sodium and 20 mg sodium cyclamate.

Sugar free.

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

EXPECTALIN WITH CODEINE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use EXPECTALIN WITH CODEINE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share EXPECTALIN WITH CODEINE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What EXPECTALIN WITH CODEINE is and what it is used for.
2. What you need to know before you use EXPECTALIN WITH CODEINE.
3. How to use EXPECTALIN WITH CODEINE.

4. Possible side effects.
5. How to store EXPECTALIN WITH CODEINE.
6. Contents of the pack and other information.

1. What EXPECTALIN WITH CODEINE is and what it is used for

EXPECTALIN WITH CODEINE is a medicine which is used to help relieve coughing and related congestion symptoms in adults. The liquid contains diphenhydramine (an antihistamine) that helps relieve coughing and dry secretions in the nose and levomenthol which helps you breathe more easily by relieving congestion. It also contains ammonium chloride, an expectorant, that helps loosen mucus so you can cough it up and codeine (a cough suppressant).

2. What you need to know before you use EXPECTALIN WITH CODEINE

Do not use EXPECTALIN WITH CODEINE

- If you are hypersensitive (allergic) to diphenhydramine, codeine, ammonium chloride or any of the other ingredients of EXPECTALIN WITH CODEINE (see **What EXPECTALIN WITH CODEINE contains**).
- If you are taking or have taken within the last 14 days, monoamine oxidase inhibitors (MAOIs) for depression (e.g. moclobemide).
- During an acute asthma attack.
- If you suffer from head injuries or increased pressure inside your skull (causing symptoms such as headache, nausea, vomiting, confusion, double vision).
- If you have liver or kidney disease.
- If you are under the age of 18 years.
- If you know that you metabolise codeine very rapidly into morphine.
- If you are pregnant or breastfeeding your baby.
- No more than 4 doses in a day.

Warnings and precautions

Take special care with EXPECTALIN WITH CODEINE

- EXPECTALIN WITH CODEINE may lead to drowsiness and affect your concentration. Do not use it with another medicine which also causes drowsiness.
- If you suffer from fits (seizures).
- If you are elderly.
- If you have a problem of medicine abuse (now or in the past).
- If you have a family history of substance abuse.
- If you suffer from any mental health disorder.
- If you suffer from any respiratory diseases such as emphysema (lungs are enlarged and damaged), persistent inflammation of the bronchi (chronic bronchitis) or acute or persistent bronchial asthma, water on the lungs or blocked airway disease.
- If you have a persistent cough accompanied by excessive, mucus (phlegm) unless you are advised to use EXPECTALIN WITH CODEINE under the supervision of your doctor.
- If you have glaucoma (increased pressure in your eye), difficulty urinating, an enlarged prostate gland.
- If you have a liver disease or diseases of the heart and blood vessels.
- If you suffer from or suddenly develop any sleep-related breathing problems. You should inform your doctor before using EXPECTALIN WITH CODEINE if this applies to you or if this happens while using EXPECTALIN WITH CODEINE.
- If you are severely overweight (obese).
- If you have an underactive thyroid (hypothyroidism).
- If your adrenal glands are not working properly (adrenocortical insufficiency).
- If you are in shock.
- If you suffer from a blocked bowel causing symptoms such as abdominal pain, vomiting (being sick) bloating, passing gas (intestinal obstruction).
- If you suffer from a condition called myasthenia gravis (a muscle disorder causing

weakness).

Avoid alcohol when you take EXPECTALIN WITH CODEINE.

EXPECTALIN WITH CODEINE can affect the outcome of skin tests that are performed.

Stop using EXPECTALIN WITH CODEINE and tell your doctor immediately if you experience any of the following

- If you notice any of the following side effects, you must stop using EXPECTALIN WITH CODEINE and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness.
- If you notice any of the following side effects, you must stop using EXPECTALIN WITH CODEINE and seek immediate medical advice: low libido (sex drive), loss of sexual ability in men, absence of menstruation in women or infertility (signs of androgen deficiency).
- If you notice any of the following side effects, you must stop using EXPECTALIN WITH CODEINE and seek immediate medical advice: agitation, restlessness, confusion, rapid heart rate, high blood pressure, dilated pupils (signs of serotonin syndrome).

Children and adolescents

Do not use EXPECTALIN WITH CODEINE in children and adolescents below 18 years of age (see **Do not use EXPECTALIN WITH CODEINE**).

Other medicines and EXPECTALIN WITH CODEINE

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is especially important to tell your doctor or pharmacist if you are taking any of the following medicines:

- atropine (used to treat some eye conditions and occasionally bowel conditions);

- tricyclic antidepressants (medicines used to treat mood disorders);
- monoamine oxidase inhibitors (MAOIs) inhibitors (used to treat depression);
- antibiotic medicines (used to treat bacterial infections);
- hypnotics, centrally acting muscle relaxants, or other medicines that work on the central nervous system, such as, alcohol, sleeping tablets, painkillers, anti-psychotic medicines;
- opioid analgesics (medicines used to relieve pain);
- tranquillisers or sedatives (medicine used to relax muscles or decrease anxiety);
- anaesthetics (used to produce loss of consciousness before and during an operation);
- phenothiazines (used to treat serious mental and emotional disorders);
- quinidine (used to treat heart rhythm disorders);
- methadone, tramadol (used to treat pain);
- triptans (used to treat migraines);
- antidepressants such as paroxetine, trazodone or mirtazapine (used to treat depression);
- linezolid (an antibiotic used to treat bacterial infections);
- intravenous methylene blue (used to treat a condition called methemoglobinemia – when your blood cannot deliver oxygen where it is needed).

If you are not sure about any of the medicines you are using or taking, show the bottle or pack to your pharmacist or health care provider for advice.

EXPECTALIN WITH CODEINE with food, drink and alcohol

Do not drink any alcohol while you are using EXPECTALIN WITH CODEINE.

Pregnancy, breastfeeding and fertility

Do not use EXPECTALIN WITH CODEINE if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking EXPECTALIN WITH CODEINE.

Driving and using machines

EXPECTALIN WITH CODEINE may cause side effects, such as drowsiness, dizziness, incoordination or blurred vision. Do not drive a vehicle, operate machinery or climb dangerous heights if you are affected by EXPECTALIN WITH CODEINE.

EXPECTALIN WITH CODEINE contains sorbitol

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in EXPECTALIN WITH CODEINE may affect the bioavailability of other medicines for oral use administered concomitantly.

EXPECTALIN WITH CODEINE contains sodium benzoate

EXPECTALIN WITH CODEINE contains sodium benzoate which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

EXPECTALIN WITH CODEINE contains propylene glycol

EXPECTALIN WITH CODEINE contains 100 mg propylene glycol in each 5 mL which is equivalent to 20 mg/mL.

EXPECTALIN WITH CODEINE contains sodium

EXPECTALIN WITH CODEINE contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially 'sodium-free'.

3. How to use EXPECTALIN WITH CODEINE

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

For oral use only.

Shake the bottle before use.

DO NOT USE MORE THAN THE RECOMMENDED DOSE.

Adults 18 years and older: One to two medicine measures medicine measures (5 mL – 10 mL) every 4 hours.

Use the lowest effective dose for the shortest duration.

DO NOT USE FOR LONGER THAN 3 DAYS.

Children and adolescents under 18 years of age:

Do not give EXPECTALIN WITH CODEINE to children younger than 18 years.

EXPECTALIN WITH CODEINE can be taken with or without food.

If you have the impression that the effect of EXPECTALIN WITH CODEINE is too strong or too weak, tell your doctor or pharmacist.

If you use more EXPECTALIN WITH CODEINE than you should

Signs of too much EXPECTALIN WITH CODEINE can include nausea (feeling sick), vomiting (being sick), thirst, headache, fits or tremors, hallucinations, coma, low blood pressure, abnormal heart rate or difficulty in breathing.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of EXPECTALIN WITH CODEINE

You should only give this medicine as required and by following the dosage instructions above carefully. If you forget to take a dose, take the next dose when needed provided that the last dose

was at least 4 hours ago. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

EXPECTALIN WITH CODEINE can have side effects.

Not all side effects reported for EXPECTALIN WITH CODEINE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking EXPECTALIN WITH CODEINE, please consult your health care provider for advice.

If any of the following happens, stop using EXPECTALIN WITH CODEINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EXPECTALIN WITH CODEINE. 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:

- bleeding or bruising more easily than normal;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- fits (seizures);
- changes in the way your heart beats (beating faster, slower or irregular);
- difficulty breathing, shallow breathing (respiratory depression);
- difficulty urinating, pain when urinating, inability to empty your bladder completely;

- hypothermia (a medical emergency that occurs when your body loses heat faster than it can produce heat, causing a dangerously low body temperature);
- increased pressure within your skull (a life-threatening condition that can cause symptoms such as headache, nausea, vomiting, confusion, double vision);
- stomach pain including inflammation of your pancreas known as pancreatitis (pain of the stomach area that radiates to your back, tenderness when touching your abdomen, fever, rapid pulse, nausea, vomiting).

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

Tell your doctor if you notice any of the following:

Side effect occurring frequently:

- sedation (depressed consciousness);
- drowsiness;
- nausea (feeling sick), vomiting (being sick), constipation.

Side effects occurring less frequently:

- pain in the upper, middle region of your stomach;
- lack/loss of appetite (anorexia), increased appetite;
- unrealistic feeling of well-being;
- changes in your mood, being confused or agitated;
- seeing or hearing things that do not exist;
- difficulty falling or staying asleep (insomnia);
- feeling irritated or nervous;
- headache or dizziness;
- feeling restless;
- abnormal coordination;
- tingling or numbness of your hands and feet (pins and needles);

- tremors (involuntary trembling or shaking of your hands and feet);
- blurred vision, constriction of your pupils;
- ringing in your ears;
- vertigo (sensation of spinning or swaying);
- low blood pressure, dizziness or light-headedness when getting up from a lying or sitting position;
- redness of your skin;
- tightness of your chest, dry throat, nasal dryness;
- dry mouth, diarrhoea, indigestion;
- sweating;
- muscle weakness;
- abnormal physical weakness or lack of energy.

Side effects occurring with unknown frequency:

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of EXPECTALIN WITH CODEINE.

For further information, please contact the Consumer Care Contact Centre: www.kenvuecontact.eu.

5. How to store EXPECTALIN WITH CODEINE

- Store at or below 25 ˚C.
- Store in a cool place.
- Keep the bottle in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EXPECTALIN WITH CODEINE contains

Each 5 mL contains:

Diphenhydramine hydrochloride	12,5 mg
Codeine phosphate	10,0 mg
Ammonium chloride	125,0 mg

The other ingredients are citric acid (E330), D & C Yellow No 10 (colourant) (E104), F D & C Blue No 1 (colourant) (E133), F D & C Red No 40 (colourant) (E129), glycerine (E422), L-menthol (flavourant), propylene glycol (E1520), purified water, raspberry flavour (flavourant), saccharin sodium (E954), sodium benzoate (E211), sodium carboxymethylcellulose (E466), sodium citrate (E331), sodium cyclamate (E952(iv)) and sorbitol (E420).

Preservative: sodium benzoate 0,5 % *m/v*

EXPECTALIN WITH CODEINE is alcohol free.

What EXPECTALIN WITH CODEINE looks like and contents of the pack

A clear, light brown liquid with a raspberry odour and taste.

Amber glass bottle containing 100 mL, with a plastic measuring cup.

Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

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7945

South Africa

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