

**PROPOSED CLEAN PATIENT INFORMATION LEAFLET****CORYX COUGH AND COLD (SOLUTION)****SCHEDULING STATUS:** S2**CORYX COUGH AND COLD**, 5 mL/ 10mg/ 30 mg/ 1,25 mg solution**Active substances:**

Each 5 mL contains:	Triprolidine hydrochloride	1,25 mg
	Pseudoephedrine hydrochloride	30,00 mg
	Dextromethorphan hydrobromide	10,00 mg
	Alcohol 96 %	0,5 mL
Preservatives:	Propyl hydroxybenzoate	0,02 % m/v
	Methyl hydroxybenzoate	0,12 % m/v
Contains sugar:	Liquid glucose	1,50 g
	Sucrose	1,00 g
	Sorbitol	2,40 g
Contains sweetener:	Saccharine sodium	7,50 mg

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

*Zaahid Osman*

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

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

### **What is in this leaflet**

1. What CORYX COUGH AND COLD is and what it is used for
2. What you need to know before you take CORYX COUGH AND COLD
3. How to take CORYX COUGH AND COLD
4. Possible side effects
5. How to store CORYX COUGH AND COLD
6. Contents of the pack and other information.

#### **1. What CORYX COUGH AND COLD is and what it is used for**

CORYX COUGH AND COLD belongs to a group of medicines called antitussives and expectorants which relieve coughing and assist in the secretion of phlegm from the airways.

CORYX COUGH AND COLD is used to relieve coughing.

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## 2. What you need to know before you take CORYX COUGH AND COLD

### Do NOT take CORYX COUGH AND COLD if you:

- Are hypersensitive (allergic) to dextromethorphan hydrobromide, pseudoephedrine hydrochloride, triprolidine hydrochloride or any of the other ingredients of CORYX COUGH AND COLD (listed in section 6).
- Have heart disease or any disease of your blood vessels, especially those blood vessels supplying the heart with blood.
- Have high blood pressure (hypertension).
- Have been diagnosed with an enlarged prostate gland.
- Have been diagnosed with an overactive thyroid gland.
- Have bladder dysfunction.
- Have been diagnosed with narrow angle glaucoma (a condition characterised by raised pressure inside the eye that may lead to blindness).
- Have been diagnosed with a tumour (abnormal growth) of your adrenal gland known as a pheochromocytoma.
- Are taking medicines known as monoamine oxidase inhibitors (for depression) or have stopped such treatment within the last 2 weeks (see **other medicines and CORYX COUGH AND COLD**).
- Are taking ephedrine or other medicines known as sympathomimetic agents (increase blood pressure or heart rate) (see **other medicines and CORYX COUGH AND COLD**). Please discuss this with your treating doctor or pharmacist if you are unsure.

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- Are pregnant or breast feeding your baby (see **Pregnancy, breastfeeding and fertility**).
- Have asthma and are suffering from an asthma attack.
- Have been diagnosed with severe lung disease compromising your lung function.

CORYX COUGH AND COLD should not be given to children younger than 2 years of age.

### **Warnings and precautions**

Take special care with CORYX COUGH AND COLD.

CORYX COUGH AND COLD may lead to drowsiness and impaired concentration, which may become worse if you combine it with alcohol or other medicines or substances that suppress the function of the brain. You should not drive, climb dangerous heights or operate machinery as impaired decision-making may lead to accidents.

If you suffer from heart disease, heart failure (or are at risk of developing heart failure), chest pain when you are active (angina) or are taking digoxin (for heart failure or abnormal heart rhythms), you should not take CORYX COUGH AND COLD without discussing it with your treating doctor.

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You should also discuss the use of CORYX COUGH AND COLD with your doctor if you have diabetes or calcification of your arteries (atherosclerosis).

If you are elderly or debilitated, you are more likely to become very sleepy when you take CORYX COUGH AND COLD or develop adverse events involving suppression of brain function.

If you have heart or blood vessel disease, glaucoma, impaired liver function, enlargement of your prostate gland or are unable to pass urine, you should not take CORYX COUGH AND COLD without discussing it with your doctor (see **Do not take CORYX COUGH AND COLD if you**).

If you are coughing up phlegm (sputum), you should not take CORYX COUGH AND COLD. You should also not take CORYX COUGH AND COLD if you have impaired lung function.

If you have a history of asthma, you should use CORYX COUGH AND COLD with caution and inform your doctor or pharmacist. Caution is also advised if you have bronchitis, emphysema (a condition in which the air sacs of the lungs are damaged causing breathlessness) or any other conditions where a chronic persistent cough occurs.

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If you take high doses of CORYX COUGH AND COLD over a long period of time, you may become dependent on (addicted to) it.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CORYX COUGH AND COLD.

CORYX COUGH AND COLD contains glucose and sucrose which may have an effect of the control of your blood sugar if you have diabetes mellitus.

CORYX COUGH AND COLD contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take CORYX COUGH AND COLD.

### **Other medicines and CORYX COUGH AND COLD**

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

- Any medicines or substances that suppress the function of the brain, including alcohol, barbiturates (used prior or during anaesthesia or for epilepsy), sleeping tablets, pain killers, calming agents and tranquillisers.
- Atropine to relieve spasms from the gut or bladder, reduce secretions from various organs or to assist with heart function.
- Tricyclic antidepressants for the treatment of depression.

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- Any medicines that have the potential to cause hearing loss, such as aminoglycoside antibiotics.
- Monoamine oxidase inhibitors for depression (see **Do not take CORYX COUGH AND COLD if you**), since combination with CORYX COUGH AND COLD may cause severe and life-threatening adverse reactions, such as severe increases in blood pressure.
- Cardiac glycosides (such as digoxin for the treatment of heart failure or abnormal heart rhythm), quinidine (for abnormal heart rhythms), ergot alkaloids (for migraine), and oxytocin (to stimulate contraction of the womb).
- Guanethidine, reserpine and methyldopa for the treatment of high blood pressure.
- Decongestants (to open a blocked nose), appetite suppressants, and drugs of abuse.
- Medicines for treating high blood pressure, such as bretylium, bethanidine, debrisoquine, methyldopa, and beta-blockers. Please speak to your doctor or pharmacist if you are unsure.
- Amiodarone (for irregular heart beat), fluoxetine (an antidepressant), haloperidol (for certain psychiatric disorders), paroxetine (an antidepressant), propafenone (for abnormal heart rhythm), and thioridazine (for the treatment of certain psychiatric disorders).
- Linezolid or other anti-bacterials, as it may cause serotonin like syndrome (These include conditions such as shivering, diarrhoea, fever, seizures etc.).

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If you are scheduled to undergo surgery, please inform your doctor or anaesthetist that you are taking CORYX COUGH AND COLD, as it may interact with some of the medicines administered during general anaesthesia.

If you are scheduled to undergo allergic skin tests, you have to stop taking CORYX COUGH AND COLD several days before the tests, since it may interfere with the results of these tests. Please discuss with your doctor if you are unsure.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, 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 this medicine.

### **Driving and using machines**

CORYX COUGH AND COLD may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other medicines. You should take care while operating vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

It is not always possible to predict to what extent CORYX COUGH AND COLD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CORYX COUGH AND COLD affects them.

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**CORYX COUGH AND COLD contains**

- Alcohol 96 %
- Citric acid
- Colourant – Raspberry red (Colour index number 14720)
- Liquid glucose
- Menthol
- Methyl hydroxybenzoate
- Propyl hydroxybenzoate
- Purified water
- Saccharine sodium
- Sodium citrate
- Sorbitol 70 %
- Sucrose
- Strawberry flavour D421.

**3. How to take CORYX COUGH AND COLD**

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

Always take CORYX COUGH AND COLD exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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- The dosage in adults and children over 12 years is 10 mL (2 teaspoons) three times a day.
- For children aged between 6 and 12 years the dosage is 5 mL (1 teaspoon) three times a day.
- In children 2 to 5 years the dosage is 2,5 mL (half a teaspoon) three times a day.

These dosages should not be exceeded.

CORYX COUGH AND COLD should not be given to children younger than 2 years of age.

**If you take more CORYX COUGH AND COLD than you should**

If you take more CORYX COUGH AND COLD than you should, you may experience drowsiness, weakness, incoordination, difficulty with passing urine, irritability, high blood pressure, palpitations, stomach upset or struggle to breathe or develop convulsions (epileptic fits). Overdosage may result in death, especially in children and infants. Following overdosage children usually become stimulated or excited and may experience lack of coordination of muscle movements, see or hear things that are not real, experience muscle tremor, convulsions, or develop dilated pupils, dry mouth, flushed face and fever. Paranoid psychoses, delusions and hallucinations (seeing things that are not present) may also occur following an overdose of Pseudoephedrine which is contained in CORYX COUGH AND COLD.

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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 CORYX COUGH AND COLD**

If you miss a dose, take it as soon as you remember, and then continue as before. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosing schedule.

Do not take a double dose to make up for the missed dose.

### **4. Possible side effects**

CORYX COUGH AND COLD can have side effects.

Not all side effects reported for CORYX COUGH AND COLD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CORYX COUGH AND COLD, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Fever, coughing, sneezing, sore throat, skin ulcers and other signs of infection,

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as this may be due to low white cell counts.

- Pallor (paleness) accompanied by tiredness, shortness of breath, and chest pain, as this may indicate low red blood cell counts.
- Pinpoint red spots on the skin, easy bruising or bleeding from the gums, as this may be due to low platelet counts.
- Convulsions or epileptic fits.
- Confusion or any alteration in mental status.
- Loss of consciousness or loss of function of one side of the face or body or inability to move an arm or a leg.
- Chest pain.
- Extreme restlessness, involuntary movements and/or uncontrollable speech.
- Tightness of the chest or shortness of breath.
- Inability to pass urine.
- Hearing or seeing things which are not real.

These are all very serious side effects. If you have them, you may have had a serious reaction to CORYX COUGH AND COLD. You may need urgent medical attention or hospitalisation.

- Reduction of physical movements.
- Muscle weakness.
- Pins and needles as this may indicate nerve damage.
- Blurred vision.

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- Ringing in the ears.
- Thickened airway secretions.
- Any skin rash, including a rash that is worse on areas exposed to the sun.
- Difficulty to pass urine or pain with urination.
- Excessive thirst, excessive hunger and frequent urination, as this may indicate high blood glucose (sugar) levels.
- Impaired blood flow to the extremities (Hands and feet).

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

- Sweating.
- Sedation varying from slight drowsiness to deep sleep and including lassitude (lack of energy or listlessness), dizziness or incoordination.
- Sleeplessness, nervousness, rapid heart rate, tremors, or muscle twitching.
- Inability to concentrate, elation or depression, irritability, nightmares or other sleep disturbances, anxiety, restlessness, giddiness, or fear.
- Adverse mental effects (Especially in children).
- Headache.
- Tingling, heaviness and weakness of the hands.
- Palpitations.
- Dryness of the mouth, constipation, or heartburn.
- Nausea, vomiting, runny stomach, stomach cramps, stomach pain or loss of appetite.

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- Hair loss.
- Muscle pain.
- Thirst.
- Flushing or pallor.
- Low blood pressure.
- Abnormal heart rhythms as well as slow or rapid heart rates.
- Constriction of the pupil.
- Ischaemic colitis (Inflammation of the large intestine).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CORYX COUGH AND COLD.

### **5. How to store CORYX COUGH AND COLD**

Store all medicines out of reach of children.

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

Do not use after the expiry date stated on the packaging material.

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Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

## **6. Contents of the pack and other information**

### **What CORYX COUGH AND COLD contains**

- The active substances are: Dextromethorphan hydrobromide 10 mg, pseudoephedrine hydrochloride 30 mg and triprolidine hydrochloride 1,25 mg.
- The other ingredients are: Alcohol 96 %, citric acid, colourant (raspberry red – colour index number 14720), liquid glucose, menthol, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water, saccharine sodium, sodium citrate, sorbitol 70 %, sucrose and strawberry flavour D421.

### **What CORYX COUGH AND COLD looks like and contents of the pack**

Clear red syrup with strawberry flavour packed in amber glass bottles containing 100 mL.

### **Holder of Certificate of Registration**

CIPLA MEDPRO (PTY) LTD.

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