PATIENT INFORMATION LEAFLET FOR

CORYX COUGH AND COLD

SCHEDULING STATUS: S2

CORYX COUGH AND COLD (10 mg/30 mg/1,25 mg per 5 mL solution)

Dextromethorphan hydrobromide 10,00 mg; Pseudoephedrine hydrochloride 30,00 mg; Triprolidine hydrochloride 1,25 mg

Contains alcohol: Alcohol 96 % 0,50 mL per 5 mL solution.

Contains sugar: Liquid glucose 1,50 g per 5 mL solution.

Sucrose 1,00 g per 5 mL solution.

Sorbitol 70% 2,40 g per 5 mL solution.

Contains sweetener: Saccharine sodium 7,50 mg per 5 mL solution.

Contains preservatives: Propyl hydroxybenzoate 0,02 % *m/v*

Methyl hydroxybenzoate 0,12 % *m/v*

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

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 have 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 removal of phlegm from the airways.

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**).
- if you have heart disease or any disease of your blood vessels, especially those blood vessels supplying the heart with blood.
- if you have high blood pressure (hypertension) or you have high blood pressure that is severe or uncontrolled (you are not being treated for it or the treatment is not working).
- if you have been diagnosed with an enlarged prostate gland.
- if you have been diagnosed with an overactive thyroid gland.
- if you have bladder dysfunction.
- if you have been diagnosed with narrow angle glaucoma (a condition characterised by raised pressure inside the eye that may lead to blindness).

- if you have been diagnosed with a tumour (abnormal growth) of your adrenal gland known as a phaeochromocytoma.
- if you 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**).
- if you are taking ephedrine or other medicines known as sympathomimetic agents (which 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.
- if you are pregnant or breast feeding your baby (see **Pregnancy, breastfeeding and fertility**).
- if you have asthma and are suffering from an asthma attack.
- if you have been diagnosed with severe lung disease compromising your lung function.
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

CORYX COUGH AND COLD should not be given to children younger than 6 years of age.

Warnings and precautions

Take special care with CORYX COUGH AND COLD:

- 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.

- if you suffer from diabetes or conditions that can cause your blood vessels to become blocked (such as arteriosclerosis, which is the stiffening and hardening of blood vessels).
- if you are elderly or weak, you are more likely to become very sleepy and to have slowed reflexes when you take CORYX COUGH AND COLD.
- if you have heart or blood vessel disease, glaucoma (a condition characterised by raised pressure inside the eye that may lead to blindness), impaired functioning of the liver, enlargement of your prostate gland, pyloroduodenal obstruction (a condition where the stomach is unable to empty food into the intestines properly due to a blockage) or are unable to fully empty your bladder when you pee, 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 (mucus), you should not take CORYX COUGH AND COLD.
- if you have impaired functioning of the lungs or are likely to develop impaired lung function, you should not take CORYX COUGH AND COLD.
- if you have a history of asthma.
- if you are having an acute asthma attack, do not take CORYX COUGH AND COLD.
- if you suffer from bronchitis (a condition where the airways become swollen and produce thick mucus), emphysema (a condition in which the air sacs of the lungs are damaged causing breathlessness) or any other conditions where a chronic or persistent cough occurs.
- 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 suffer from epilepsy (a condition of the brain that causes one to lose consciousness).
- if you have impaired functioning of the kidneys.
- if you are taking antibiotic medication known as aminoglycosides. Taking CORYX COUGH AND COLD can mask the early signs and symptoms of hearing loss (known as ototoxic damage) caused by aminoglycosides.

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.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine, as contained in CORYX COUGH AND COLD. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using CORYX COUGH AND COLD immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see **section 4 "Possible side effects"** for symptoms).

Children

Do not give CORYX COUGH AND COLD to children under the age of 6 years.

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), hypnotics (sleeping

tablets), narcotic analgesics (pain killers), sedatives (calming agents) and tranquillisers (relaxing and/or calming agents).

- Atropine (used to relieve spasms from the gut or bladder, reduce secretions from various organs or to assist with heart function). Triprolidine, as contained in CORYX COUGH AND COLD, can have an additive impact on the effects caused by atropine such as drying of the mouth or reduced heart rate.
- Tricyclic antidepressants (used for the treatment of depression). Triprolidine, as contained in CORYX COUGH AND COLD, can have an additive impact on the effects caused by tricyclic antidepressants such as sleepiness and slowed down reflexes.
- Any medicines that have the potential to cause hearing loss, such as aminoglycoside antibiotics.
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (used for the treatment of depression). Dextromethorphan, as contained in CORYX COUGH AND COLD, can cause severe and sometimes life-threatening reactions in patients who are taking MAOIs. Pseudoephedrine, as contained in CORYX COUGH AND COLD, can cause severely increased blood pressure levels in patients taking MAOIs.
- Cardiac glycosides (such as digoxin used for the treatment of heart failure or abnormal heart rhythm), quinidine (used for abnormal heart rhythms), ergot alkaloids (used for migraine), and oxytocin (used to stimulate contraction of the womb). Taking CORYX COUGH AND COLD can increase the risk of abnormal heart rhythms in patients taking cardiac glycosides, quinidine or tricyclic antidepressants. Taking CORYX COUGH AND COLD can increase the risk of increased blood pressure levels in patients taking ergot alkaloids or oxytocin. Taking dextromethorphan, as contained in CORYX COUGH AND COLD, with quinidine, can lead to higher than normal levels of dextromethorphan in the blood, possibly causing dextromethorphan toxicity.

- Guanethidine, reserpine and methyldopa (used for the treatment of high blood pressure). The effectiveness of Pseudoephedrine, as contained in CORYX COUGH AND COLD, is decreased by guanethidine, reserpine and methyldopa. Pseudoephedrine, as contained in CORYX COUGH AND COLD, can also decrease the effectiveness of guanethidine.
- Decongestants (used to open a blocked nose), appetite suppressants (used to decrease appetite), drugs of abuse and medicines that interfere with the breakdown of medication with a stimulant effect. These medicines can cause an increase in blood pressure levels because they interact with pseudoephedrine, as contained in CORYX COUGH AND COLD.
- Medicines for treating high blood pressure, such as bretylium, bethanidine, debrisoquine, methyldopa, and beta-blockers. Pseudoephedrine, as contained in CORYX COUGH AND COLD, can reverse the blood pressure lowering effects of this medication. Please speak to your doctor or pharmacist if you are unsure.
- Amiodarone (used for irregular heartbeat), fluoxetine (an antidepressant), haloperidol (used for certain psychiatric disorders), paroxetine (an antidepressant), propafenone (used for abnormal heart rhythm), and thioridazine (used for the treatment of certain psychiatric disorders). These medicines interfere with the breakdown of dextromethorphan, as contained in CORYX COUGH AND COLD.
- Linezolid. Serotonin syndrome-like symptoms have occurred when dextromethorphan, as contained in CORYX COUGH AND COLD, was taken with linezolid (used for treatment of bacterial infections). Serotonin syndrome is a life-threatening condition where there is unusually high levels of the hormone called serotonin in the blood. It causes symptoms such as increased blood pressure, fever, sweating, diarrhoea, changes in mental state.

- Triprolidine, as contained in CORYX COUGH AND COLD, can interfere with the breakdown of certain medicines in the liver.
- Aluminium hydroxide (used for heartburn and indigestion) and kaolin (used for management of diarrhoea). The absorption rate of pseudoephedrine, as contained in CORYX COUGH AND COLD, can be increased by aluminium hydroxide and decreased by kaolin.

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 (such as halothane).

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.

CORYX COUGH AND COLD with food, drink and alcohol

Avoid alcohol when you are taking CORYX COUGH AND COLD as this can increase the effects caused by alcohol such as drowsiness, slow functioning of the brain and slowed reflexes.

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 CORYX COUGH AND COLD.

Do not use CORYX COUGH AND COLD if you are pregnant or breastfeeding your baby.

Driving and using machines

CORYX COUGH AND COLD may lead to drowsiness and impaired concentration that may be made worse by the simultaneous intake of alcohol or other medicines which suppress brain function. 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.

CORYX COUGH AND COLD contains liquid glucose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

CORYX COUGH AND COLD can affect the blood sugar level of diabetic patients.

CORYX COUGH AND COLD contains sorbitol

CORYX COUGH AND COLD may cause an upset tummy and may have a mild laxative effect.

CORYX COUGH AND COLD contains methyl hydroxybenzoate and propyl hydroxybenzoate

CORYX COUGH AND COLD may cause allergic reactions.

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.

The usual dose is:
Adults and children over 12 years old: 10 mL (2 medicine measures) three times a day.
Children 6 to 12 years old: 5 mL (1 medicine measure) three times a day.

These dosages should not be exceeded.
CORYX COUGH AND COLD should not be given to children younger than 6 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, difficulty with coordination, difficulty with passing urine, irritability, high blood pressure, noticeable pounding of the heart, upset stomach, breathing difficulties or convulsions (epileptic fits).
Paranoid psychoses (a condition where there is a collection of symptoms which can lead one to have anxious thoughts and feelings of perceived threats), delusions (having beliefs that are based on a wrong perception of reality) and hallucinations (seeing things that are not present) may also occur following an overdose with pseudoephedrine, as contained in CORYX COUGH AND COLD.
Overdosage with triprolidine, as contained in CORYX COUGH AND COLD, may lead to ataxia (a condition where there is a lack of coordination of muscle movements) or death from inability to properly breathe on your own. Overdosage may result in death, especially in children and infants. Following overdosage, children usually become stimulated or excited and may experience a lack of coordination of muscle movements, see or hear things that are not real,

involuntary shaking of the muscles, convulsions (epileptic fits), psychoses (a condition where one is out of touch with reality) or develop dilated pupils, dry mouth, flushed face and fever. Difficulty in breathing caused by slowing down of the activities of the airways can be treated using Naloxone.

Treatment of overdosage is supportive and based on symptoms.

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.

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.

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

- fever, coughing, sneezing, sore throat, skin ulcers and other signs of infection, 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 serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- sedation varying from slight drowsiness to deep sleep, and including lassitude (lack of energy), dizziness, and lack of coordination. In children and the elderly, stimulation can occur, causing symptoms such as inability to fall asleep, nervousness, uncontrolled shaking and twitching of the muscles, a fast-beating heart and loss of consciousness (epileptic fits).
- headache, slowing down and reduction of mental and physical activities.
- blurred vision.
- thickened airway secretions.
- dryness of the mouth, constipation and increased heartburn.
- difficulty with passing urine or inability to fully empty the bladder.
- persistent worry and fear (anxiety), restlessness, inability to fall asleep and nervousness.
- increased heart rate.

Less frequent side effects:

- reduced levels of white blood cells (the blood cells responsible for fighting infections), reduced levels of red blood cells (the blood cells responsible for transporting oxygen around the body), reduced levels of blood platelets (the blood cells responsible for the clotting of blood during bleeding).
- sweating.
- seeing or hearing things which are not real.
- loss of consciousness (epileptic fits), dizziness, headache, weakness and uncontrolled shaking and twitching of the muscles.

- decreased heart rate and noticeable pounding of the heart.
- shortness of breath.
- nausea or vomiting.
- skin rashes.
- difficulty passing urine, pain on urination or inability to fully empty the bladder, especially in patients with an enlarged prostate gland.
- paleness of the skin.
- drowsiness.
- mental confusion, headache and dizziness.
- constipation, nausea, vomiting, stomach pain and an upset or cramping stomach.

Side effects with unknown frequency:

- allergic reactions, hypersensitivity reactions and anaphylaxis (an allergic reaction characterised by swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing). This also includes swelling and tightening of the airways (bronchospasm) and the swelling of the tissues under the skin (angioedema).
- sweating.
- inability to concentrate, happiness or depression, irritability, nightmares and sleep disturbances.
- tingling or prickling sensation in the hands or feet, heaviness or weakness of the hands, uncontrolled shaking and twitching of the muscles, weakness of the muscles, prolonged unconsciousness, extrapyramidal effects (uncontrolled muscle contractions, restlessness, involuntary facial movements, slowed and irregular movements). Large doses can cause loss of consciousness (epileptic fits).

- ringing sound in the ears.
- decreased blood pressure, noticeable pounding of the heart, irregular heartbeat, lack of blood supply to the hands and feet.
- tightness of the chest.
- nausea, vomiting, diarrhoea, pain from the stomach, intestines or urinary area, pain from the upper abdomen and anorexia (an eating disorder characterised by a very low body weight and a fear of gaining weight).
- skin reactions including sensitivity of the skin to light, the appearance of small, red or purple bumps on the skin (lichenoid skin eruption), hair loss, sweating.
- muscle pain.
- disturbances in the breakdown and use of the sugar glucose in the body.
- thirst.
- feeling lightheaded and off-balance, agitation, fear, irritability, mental state characterised by a disconnection from reality. Unfavourable mental effects (particularly in children) have been associated with combination preparations containing pseudoephedrine.
- confusion, fainting and muscle weakness.
- posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. The symptoms include severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures (epileptic fits) or changes in vision. Stop using CORYX COUGH AND COLD immediately and seek urgent medical attention if you develop these symptoms.
- shrinking of the pupil (the part of the eye that lets in light).

- chest pain, increased blood pressure causing bleeding in the brain, abnormal heart rhythm, sudden loss of heart function, redness of the skin, shrinking of blood vessels causing decreased blood supply to the hands and feet.
- fluid build-up in the lungs.
- loss of appetite and dry mouth.
- swelling of the large intestine (ischaemic colitis) has been reported after acute or chronic use of pseudoephedrine in combination cold and allergy preparations.
- fixed drug eruption (a distinctive skin reaction that occurs at a particular part of the body each time the medicine which causes the reaction is administered).
- excitation, toxic psychosis (a mental state characterised by a disconnection from reality which is caused by toxicity with a medicine, resulting in hyperactivity and seeing and hearing things that are not real) can occur.
- slowing down of breathing can occur at very high doses.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). 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 at or below 25 ºC.

Store all medicines out of reach of children.

Protect from light.

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

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 CORYX COUGH AND COLD contains

- The active substances are dextromethorphan hydrobromide 10,00 mg, pseudoephedrine hydrochloride 30,00 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. CORYX COUGH AND COLD is packed in a 100 mL amber glass bottle with a 28 mm white polypropylene cap with expanded polyethylene (EPE) liners.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer care: 080 222 6662.

This leaflet was last revised in

First authorisation: 19 July 1993

Latest renewal: Not applicable

Revision: 22 May 2026

Registration number(s)

27/10.1/0490

Namibia: NS2 04/10.1/1183

Botswana: S3 BOT0801313

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR code below.

PLACE HOLDER: The QR Code to be generated and included after approval.