PROFESSIONAL INFORMATION FOR CORYX COUGH AND COLD

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL solution contains:	Dextromethorphan hydrobromide	10,0 mg
	Pseudoephedrine hydrochloride	30,00 mg
	Triprolidine hydrochloride	1,25 mg
Contains alcohol:	Alcohol 96 %	0,50 mL
Contains 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 70 %	2,40 g
Contains sweetener:	Saccharine sodium	7,50 mg

For the full list of excipients, see **section 6.1.**

3. PHARMACEUTICAL FORM

Solution.

CORYX COUGH AND COLD is a clear red syrup with a strawberry flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CORYX COUGH AND COLD is indicated for the alleviation of cough.

4.2 Posology and method of administration

Posology

Adults and children over 12 years: 10 mL

Children 6 to 12 years: 5 mL

CORYX COUGH AND COLD should be given three times daily.

The dosage must not be exceeded.

Paediatric population

CORYX COUGH AND COLD is contraindicated in children under the age of 6 years (see **section 4.3**).

4.3 Contraindications

CORYX COUGH AND COLD is contraindicated in:

- patients with known hypersensitivity to dextromethorphan hydrobromide, pseudoephedrine hydrochloride, triprolidine hydrochloride or to any of the excipients in CORYX COUGH AND COLD (see **section 6.1**).
- patients younger than 6 years of age.
- patients with cardiovascular disease (especially coronary insufficiency).
- patients with hypertension.
- patients with prostatism.
- patients with thyrotoxicosis.
- patients with bladder dysfunction.
- patients with narrow angle glaucoma.

- patients with phaeochromocytoma.
- patients being treated with monoamine oxidase inhibitors and within two weeks of stopping such treatment (see **section 4.5**).
- patients being treated with ephedrine and other sympathomimetic agents, as a hypertensive response may result (see **section 4.5**).
- patients who are pregnant or breast feeding as the safety has not been established (see **section 4.6**).
- patients with asthma during an asthma attack.
- patients at risk of developing respiratory failure.
- patients with severe hypertension or uncontrolled hypertension (not being treated or resistant to treatment).
- patients with severe acute or chronic kidney disease/renal failure.

4.4 Special warnings and precautions for use

CORYX COUGH AND COLD may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents (see **section 4.7**).

It is possible that some sedating antihistamines, such as triprolidine, and therefore CORYX COUGH AND COLD, could mask the warning signs of ototoxic damage caused by medicines, such as aminoglycoside antibiotics.

CORYX COUGH AND COLD contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take CORYX COUGH AND COLD.

CORYX COUGH AND COLD contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine.

CORYX COUGH AND COLD contains glucose and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

CORYX COUGH AND COLD contains sorbitol and may cause gastrointestinal discomfort and a mild laxative effect. Patients with the rare hereditary condition of sorbitol/maltitol/lactitol intolerance should not take CORYX COUGH AND COLD.

CORYX COUGH AND COLD contains methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

Pseudoephedrine, and therefore CORYX COUGH AND COLD, should be given with caution to patients with organic heart disease, cardiac decompensation or angina of effort and in patients receiving digoxin.

CORYX COUGH AND COLD should be used with caution in patients with diabetes mellitus, and with occlusive vascular disorders (arteriosclerosis).

Use carefully in elderly and debilitated patients. Elderly patients are more susceptible to the central nervous system depressant and hypnotic effects.

CORYX COUGH AND COLD should be used with caution in patients with cardiovascular disease, glaucoma, liver impairment, prostatic hypertrophy, pyloroduodenal obstruction and urinary retention.

CORYX COUGH AND COLD should be used with caution in patients with epilepsy.

CORYX COUGH AND COLD should be used with care in patients with renal and hepatic impairment.

Antitussive medicines should not be administered to patients with productive coughs. Dextromethorphan, and therefore CORYX COUGH AND COLD, should not be given to patients in, or at risk of, developing respiratory failure (see **section 4.3**).

Caution is needed in patients with a history of asthma, and it should not be given during an acute attack (see **section 4.3**). Care is also advisable in patients with bronchitis, emphysema, or in other conditions where chronic or persistent cough occurs.
Dextromethorphan abuse and dependence may occur, especially following prolonged use of high doses of CORYX COUGH AND COLD.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
Cases of serious conditions affecting the cerebral blood vessels (PRES and RCVS) have been reported with the use of pseudoephedrine-containing products (see **section 4.8**). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see **section 4.3**).

Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

4.5 Interaction with other medicines and other forms of interaction

Triprolidine, and therefore CORYX COUGH AND COLD, may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives, and tranquillisers.

Triprolidine, and therefore CORYX COUGH AND COLD, may have an additive antimuscarinic action when combined with other antimuscarinic medicines, such as atropine and some antidepressants (both tricyclic anti-depressants and monoamine oxidase inhibitors).

It is possible that some sedating antihistamines, such as triprolidine, and therefore CORYX COUGH AND COLD, could mask the warning signs of ototoxic damage caused by medicines, such as aminoglycoside antibiotics.

Since antihistamines may suppress the cutaneous histamine response to allergen extracts, CORYX COUGH AND COLD should be discontinued several days before skin testing.

Triprolidine, and therefore CORYX COUGH AND COLD, may affect the metabolism of certain medicines in the liver.

Pseudoephedrine, and therefore CORYX COUGH AND COLD, may give rise to a hypertensive crisis in patients receiving monoamine oxidase inhibitors (MAOIs) [including reversible inhibitors of monoamine oxidase A (RIMAs)]. In addition, there have been reports of severe and sometimes fatal reactions following the use of dextromethorphan in patients receiving MAOIs (see **section 4.3**).

Due to a possible interaction with pseudoephedrine, caution should be exercised when CORYX COUGH AND COLD is administered to patients undergoing anaesthesia with halothane or other halogenated anaesthetics.

There is an increased risk of dysrhythmias in patients receiving cardiac glycosides (digoxin), quinidine, or tricyclic antidepressants, as well as an increased risk of vasoconstrictor or pressor effects in patients receiving ergot alkaloids or oxytocin.

CORYX COUGH AND COLD should not be co-administered with quinidine or tricyclic antidepressants. Quinidine blocks the metabolism of dextromethorphan, which can increase plasma levels of dextromethorphan, possibly leading to dextromethorphan toxicity if dextromethorphan is co-administered with quinidine.

The absorption rate of pseudoephedrine hydrochloride, as contained in CORYX COUGH AND COLD, was increased by a mixture of the antacid, aluminium hydroxide. The absorption rate was however decreased by kaolin.

The effects of pseudoephedrine are diminished by guanethidine, reserpine and probably methyldopa and may be diminished or enhanced by antidepressants. Pseudoephedrine, and

therefore CORYX COUGH AND COLD, may also diminish the effects of guanethidine and may increase the possibility of dysrhythmias in digitalised patients.

Concomitant use of CORYX COUGH AND COLD with sympathomimetic medicines, such as nasal decongestants, appetite suppressants and amphetamine-like psychostimulants, or with medicines that interfere with the catabolism of sympathomimetic medicines, may cause a rise in blood pressure largely because of interaction with pseudoephedrine (see **section 4.3**).
Because of its pseudoephedrine content, CORYX COUGH AND COLD may partially reverse the hypotensive action of medicines which interfere with sympathetic activity including bretylium, bethanidine, debrisoquine, methyldopa and beta-adrenergic blocking medicines.

Since dextromethorphan is primarily metabolised by the cytochrome P450 isoenzyme CYP2D6, the possibility of interactions with inhibitors of this enzyme, including amiodarone, fluoxetine, haloperidol, paroxetine, propafenone, quinidine, and thioridazine, should be borne in mind when these medicines are co-administered with CORYX COUGH AND COLD.

Serotonin syndrome-like symptoms have occurred when dextromethorphan, as contained in CORYX COUGH AND COLD, has been taken with linezolid.

4.6 Fertility, pregnancy and lactation

Pregnancy

The use of CORYX COUGH AND COLD is contraindicated during pregnancy and lactation (see **section 4.3**).

Breastfeeding

The use of CORYX COUGH AND COLD is contraindicated during pregnancy and lactation (see **section 4.3**).

4.7 Effects on ability to drive and use machines

CORYX COUGH AND COLD may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant medicines. Patients should not drive, climb dangerous heights or operate machinery as impaired decision-making could lead to accidents.

4.8 Undesirable effects

Sedation or insomnia may occur.

Triprolidine as contained in CORYX COUGH AND COLD:

Blood and lymphatic system disorders:

Less frequent:	Blood dyscrasias, including agranulocytosis, leukopenia, haemolytic anaemia, and thrombocytopenia.

Immune system disorders:

Frequency unknown:	Allergy, anaphylaxis, and hypersensitivity reactions (including bronchospasm and angioedema).

Metabolism and nutrition disorders:

Frequency unknown:	Sweating.

Psychiatric disorders:

Frequent:	Sedation varying from slight drowsiness to deep sleep, and including lassitude, dizziness, and incoordination, although paradoxical stimulation may occasionally occur, especially at high doses and in children or the elderly. Symptoms of cerebral stimulation in adults include insomnia, nervousness, tachycardia, tremors, muscle twitching, and convulsions.
Frequency unknown:	Inability to concentrate, elation or depression, irritability, nightmares, and sleep disturbances.

Nervous system disorders:

Frequent:	Headache, and psychomotor impairment.
Frequency unknown:	Paraesthesia, tremor, muscular weakness, confusion, deepening coma, extrapyramidal effects, as well as tingling, heaviness, and weakness of the hands. Large doses may precipitate fits in epileptics.

Eye disorders:

Frequent:	Blurred vision.

Ear and labyrinth disorders:

Frequency unknown:	Tinnitus.

Cardiac disorders:

Frequency unknown:	Hypotension, palpitations, dysrhythmias, impaired circulation to the extremities.

Respiratory, thoracic and mediastinal disorders:

Frequent:	Thickened respiratory tract secretions.
Frequency unknown:	Tightness of the chest.

Gastrointestinal disorders:

Frequent:	Dryness of the mouth, constipation, and increased gastric reflux.
Frequency unknown:	Nausea, vomiting, diarrhoea, colic, epigastric pain, and anorexia.

Skin and subcutaneous tissue disorders:

Frequency unknown:	Dermatological reactions may occur, including photosensitisation of the skin and lichenoid skin eruption, hair loss, sweating.

Musculoskeletal, connective tissue and bone disorders:

Frequency unknown:	Myalgia.

Renal and urinary disorders:

Frequent:	Urinary difficulty or retention.

Pseudoephedrine as contained in CORYX COUGH AND COLD:

Endocrine disorders:

Frequency unknown:	Disturbances of glucose metabolism.

Metabolism and nutrition disorders:

Less frequent:	Sweating.
Frequency unknown:	Thirst.

Psychiatric disorders:

Frequent:	Anxiety, restlessness, insomnia, and nervousness.
Less frequent:	Hallucinations.
Frequency unknown:	Giddiness, agitation, fear, irritability, and psychotic states. Adverse mental effects (particularly in children) have been associated with combination preparations containing pseudoephedrine.

Nervous system disorders:

Less frequent:	Convulsions, dizziness, headache, weakness and tremors.
Frequency unknown:	Confusion, fainting, and muscular weakness. Posterior reversible encephalopathy syndrome (PRES) (see **section 4.4**). Reversible cerebral vasoconstriction syndrome (RCVS) (see **section 4.4**).

Eye disorders:

Frequency unknown:	Miosis.

Cardiac disorders:

Frequent:	Tachycardia.

Less frequent:	Reflex bradycardia, palpitations.
Frequency unknown:	Precordial pain, hypertension resulting in intracranial haemorrhage, anginal pain, especially in patients suffering from angina pectoris, cardiac dysrhythmias, cardiac arrest, flushing, vasoconstriction which may result in hypertension, and cerebral haemorrhage, impaired circulation to the extremities.

Respiratory, thoracic and mediastinal disorders:

Less frequent:	Dyspnoea (shortness of breath) or troubled breathing.
Frequency unknown:	Pulmonary oedema.

Gastrointestinal disorders:

Less frequent:	Nausea or vomiting.
Frequency unknown:	Loss of appetite, dry mouth, anorexia. Ischaemic colitis has been reported after acute or chronic use of pseudoephedrine in combination cold and allergy preparations.

Skin and subcutaneous tissue disorders:

Less frequent:	Skin rashes.
Frequency unknown:	Fixed drug eruption due to pseudoephedrine, taking the form of erythematous nummular patches, have been reported.

Renal and urinary disorders:

Less frequent: Urinary retention, difficulty with micturition, especially in patients with prostatic enlargement, or painful urination.

General disorders:

Less frequent: Pallor.

Dextromethorphan as contained in CORYX COUGH AND COLD:

Psychiatric disorders:

Less frequent: Drowsiness.

Frequency unknown: Excitation, toxic psychosis (hyperactivity, visual and auditory hallucinations) may occur.

Nervous system disorders:

Less frequent: Mental confusion, headache, and dizziness.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: Respiratory depression may occur with very high doses.

Gastrointestinal disorders:

Less frequent: Constipation, nausea, vomiting, stomach pain, and gastrointestinal disturbance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP

(Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

4.9 Overdose

The symptoms may include drowsiness, weakness, incoordination, difficulty with micturition, respiratory depression, irritability, convulsions, hypertension, palpitations and gastrointestinal disturbance.

Paranoid psychoses, delusions and hallucinations may follow an overdose with pseudoephedrine.

Triprolidine intoxication may lead to ataxia, death from respiratory failure, and respiratory collapse. Overdosage may be fatal, especially in infants and children in whom main symptoms are central nervous system stimulation and antimuscarinic effects including ataxia, excitement, hallucinations, psychoses, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia.

Respiratory depression can be treated with naloxone.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 10.1 Antitussives and expectorants

Pharmacotherapeutic group: Cough Suppressant, Opium alkaloids and derivatives

ATC code: R05DA09

Triprolidine hydrochloride is a sedating antihistamine with antimuscarinic and mild sedative effects.

Pseudoephedrine is a direct- and indirect-acting sympathomimetic with pressor activity and stimulant effects.

Dextromethorphan hydrobromide is a cough suppressant with a central action on the cough centre in the medulla.

5.2 Pharmacokinetic properties

Triprolidine hydrochloride

After absorption from the gastrointestinal tract, triprolidine is metabolised; a carboxylated derivative accounts for about half the dose excreted in the urine. Reported half-lives vary from 3 to 5 hours or more. Triprolidine is distributed into breast milk.

Pseudoephedrine hydrochloride

Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is excreted largely unchanged in the urine with small amounts of its hepatic metabolite. It has a half-life of about 5 to 8 hours; elimination is enhanced and half-life accordingly shorter in acid urine. Small amounts are distributed into breast milk.

Dextromethorphan hydrobromide

Dextromethorphan is rapidly absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextromethorphan, which has some cough suppressant activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Store well closed.

Protect from light.

6.5 Nature and contents of the container

CORYX COUGH AN COLD is packed in 100 mL amber glass bottle with a 28 mm white polypropylene cap with expanded polyethylene (EPE) liners.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662.

8. REGISTRATION NUMBER(S)

27/10.1/0490

Namibia: NS2 04/10.1/1183

Botswana: S3 BOT0801313

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 19 July 1993

Latest renewal: Not applicable.

10. DATE OF REVISION OF THE TEXT

22 May 2026