PROFESSIONAL INFORMATION FOR

CORYX PAEDIATRIC

SCHEDULING STATUS S2

1. NAME OF THE MEDICINE

CORYX PAEDIATRIC (syrup)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains:

Triprolidine hydrochloride	1,25 mg
Pseudoephedrine hydrochloride	25,00 mg
Vitamin C	75,00 mg

Preservatives:	Sodium benzoate	0,2 % *m/v*
	Potassium sorbate	0,2 % *m/v*

Contains sugar:

Sorbitol 70%	3150, 00 mg/ 5 mL

Contains sweetener:

Sodium saccharin	1,00 mg/5 mL
Sodium cyclamate	10,00 mg/5 mL

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

3. PHARMACEUTICAL FORM

Syrup.

A clear blue to blue-green coloured syrup with a blackcurrant smell and taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CORYX PAEDIATRIC syrup is indicated for the relief of symptoms associated with colds and influenza such as nasal congestion.

4.2 Posology and method of administration

Adults and children over 12 years

2 medicine measures (10,0 mL) three times a day

Children 6 to 12 years

1 medicine measure (5,0 mL) three times a day

Children 2 to 5 years

½ medicine measure (2,5 mL) three times a day

Children 6 months to 2 years

Not recommended.

- A doctor's advice should be obtained before administering Coryx Paediatric syrup to children aged less than 2 years. Do not exceed the stated dose and if symptoms persist consult a doctor.

4.3 Contraindications

CORYX PAEDIATRIC syrup is contraindicated in:

- Hypersensitivity to any of the ingredients in CORYX PAEDIATRIC syrup**.**
- Who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks.
- Diabetes Mellitus
- Phaeochromocytoma
- Cardiovascular disease including hypertension
- Hyperthyroidism
- Closed angle glaucoma
- Severe renal impairment
- Hyperexcitability
- With or at risk of developing, respiratory failure (e.g. those with chronic obstructive airways disease or pneumonia) or those with bronchiolitis or bronchiectasis due to sputum retention.
- Who are receiving other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).
- Severe hypertension or uncontrolled hypertension
- Severe acute or chronic kidney disease/renal failure

The safety of CORYX PAEDIATRIC syrup during pregnancy and lactation has not been established.

CORYX PAEDIATRIC syrup should not be administered to infants under the age of 2 years.

4.4 Special warnings and precautions for use

The use of CORYX PAEDIATRIC syrup may lead to drowsiness which is aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned not to drive or operate dangerous machinery.

CORYX PAEDIATRIC is contraindicated in patients with cardiovascular disease such as ischaemic heart disease, dysrhythmia or tachycardia, occlusive vascular disorders, including arteriosclerosis, hypertension or aneurysms (see **section 4.3**).

Patients with difficulty in urination and/enlargements of the prostate or patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine as contained in CORYX PAEDIATRIC.

Pseudoephedrine Hydrochloride

An increased risk of dysrhythmias may occur when given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

CORYX PAEDIATRIC is contraindicated in patients with hyperthyroidism, diabetes mellitus, closed-angle glaucoma or prostatic enlargement (see **section 4.3**)

Pseudoephedrine should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation (see **section 4.5**).

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS):

Cases of 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.

Severe skin reactions:

Severe skin reactions such as acute generalised exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema or many small pustules are observed, administration of CORYX PAEDIATRIC should be discontinued and appropriate measures taken if needed.

Ischaemic colitis:

Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Ischaemic optic neuropathy:

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Triprolidine hydrochloride

Triprolidine should not be used in conditions such as angle-closure glaucoma, urinary retentions, prostatic hyperplasia, pyloroduodenal obstruction or epilepsy.

Care should be observed when tricyclic antidepressants, guanethidine, reserpine, methyldopa or atropine are taken concomitantly, as the anti-muscarinic effect may be enhanced (see **section 4.5**).

Kidney or liver impairment

Patients suffering from kidney or liver disease should take CORYX PAEDIATRIC under medical supervision. CORYX PAEDIATRIC is contraindicated in severe renal impairment.

Sugar (Sorbitol)

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

CORYX PAEDIATRIC may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opiod analgesics, anxiolytic sedatives and antipsychotics. Sedative interactions apply to a lesser extent with the non-sedating antihistamines, they do not appear to potentiate the effects of alcohol, but it should be avoided in excess.

CORYX PAEDIATRIC has an additive antimuscarinic action with other antimuscarinic medicines, such as atropine and some antidepressants (both tricyclics and MAOIs). Care should therefore be observed when tricyclic antidepressants, reserpine, methyldopa or atropine are taken concomitantly.

CORYX PAEDIATRIC may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

CORYX PAEDIATRIC may cause a hypertensive crisis in patients receiving a MAOI [including a reversible monoamine oxidase inhibitor (RIMA)] (see **section 4.3**).

CORYX PAEDIATRIC should be avoided or used with care in patients undergoing anaesthesia with volatile or halogenated anaesthetics as they may induce ventricular fibrillation (see **section 4.4**). An increased risk of dysrhythmias may occur if given to patients receiving digoxin, quinidine or tricyclic antidepressants and there is an increased risk of vasoconstrictor or pressor effects in patients receiving ergot alkaloids or oxytocin.

CORYX PAEDIATRIC syrup should be used with caution with the concurrent use of desferrioxamine, hormonal contraceptives, hormone replacement therapy, fluphenazine and warfarin.

4.6 Fertility, pregnancy and lactation

The safety of CORYX PAEDIATRIC syrup during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

CORYX may cause drowsiness or sleepiness which may interfere with the patient's ability to drive or operate machines.

Because CORYX may produce sedation, patients should not operate machinery, drive cars, climb dangerous heights or perform potentially dangerous tasks where impaired decision making could

lead to accidents (see **section 4.4**).

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories, frequent, less frequent and frequency unknown.

MedDRA system organ Class	Frequency	Side effects
Blood and lymphatic system disorders	*Frequency unknown*	Cerebral haemorrhage, pulmonary oedema, agranulocytosis, leucopoenia, thrombocytopenia, haemolytic anaemia
Cardiac disorders	*Frequency unknown*	Angina pain, tachycardia, cardiac arrythmias, palpitations, cardiac arrest, hypotension, hypertension
Neurological disorders	*Frequent*	Headache
	Frequency unknown	Sedation, insomnia, lassitude, dizziness, incoordination, euphoria, confusion
Ear and labyrinth disorders	*Frequency unknown*	Tinnitus
Eye disorders	*Frequency unknown*	Blurred vision

Gastrointestinal disorders	*Frequent*	Nausea, vomiting, diarrhoea or constipation, epigastric pain, gastric reflux, appetite increase
Metabolism and nutritional disorders	*Frequency unknown*	Disturbances of glucose metabolism
Musculoskeletal and connective tissue disorders	*Frequency unknown*	Muscular weakness, tremors, convulsions, myalgia
Nervous system disorders	*Frequency unknown*	Sweating, hyper-salivation, dryness of the mouth, including sleep disturbances and hallucinations.
Psychiatric disorders	*Frequency unknown*	Anorexia
Renal and urinary disorders	*Frequency unknown*	Urinary retention, micturition
Respiratory, thoracic and mediastinal disorders	*Frequency unknown*	Dyspnoea, bronchospasm
Skin and subcutaneous tissue Disorders	*Less frequent*	Rash, angioedema, hair loss

Other adverse reactions reported for pseudoephedrine-containing products during the post-marketing period are listed hereunder.

System Organ Class	Frequency	Adverse reactions
Nervous system disorders	*Not known*	Posterior reversible encephalopathy syndrome (PRES) (see **section 4.4**) Reversible cerebral vasoconstriction syndrome (RCVS) (see **section 4.4**)

Cases of severe skin reactions such as acute generalised exanthematous pustulosis (AGEP) have been reported with pseudoephedrine-containing products.

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 drug 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

Overdosage may be fatal, especially in children in whom the main symptoms are central nervous system stimulation and anti-muscarinic effects: ataxia, excitement; hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia.

Deepening coma, cardiorespiratory collapse and death may occur within 18 hours. In adults, the usual symptoms of overdosage are drowsiness, coma and convulsions.

Weakness, dizziness, incoordination, difficulty with micturition, respiratory depression,

hypotension, agitation, irritability, hypertension, palpitations, restlessness and tachycardia, may occur.

Treatment is symptomatic and supportive. The patient must be taken to a doctor or hospital immediately as specialised treatment may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 5.8. Preparations for the common cold including nasal decongestants and antihistaminics.

CORYX PAEDIATRIC syrup has antihistaminic and decongestant properties.

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.

Ascorbic acid

Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the

body tissues. Plasma concentrations of ascorbic acid rise as the dose ingested is increased until a plateau is reached with doses of about 90 to 150 mg daily. Body stores of ascorbic acid in health are about 1,5 g although more may be stored at intakes above 200 mg daily. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. In deficiency states the concentration in leucocytes declines later and at a slower rate and has been considered to be a better criterion for the evaluation of deficiency than the concentration in plasma.

Ascorbic acid is reversibly oxidised to dehydroascorbic acid; some is metabolised to ascorbate-2-sulfate, which is inactive, and oxalic acid which are excreted in the urine.
Ascorbic acid in excess of the body's needs is also rapidly eliminated unchanged in the urine; this generally occurs with intakes exceeding 100 mg daily. Ascorbic acid crosses the placenta and is distributed into breast milk. It is removed by haemodialysis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Glycerol
- Citric acid anhydrous
- Sorbitol solution 70 %
- Sodium benzoate
- Potassium sorbate
- Sodium citrate
- Carmelose sodium
- Black Current flavour 75171-33
- Sodium cyclamate

- Saccharin sodium
- Brilliant blue FCF (CI 420490)
- Propylene glycol
- Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store at or below 25 °C in a well closed container.
- Protect from light.

6.5 Nature and contents of container

CORYX PAEDIATRIC syrup is packed in amber glass bottles of 70 mL, 100 mL or 140 mL with a white plastic screw-on cap. The bottles are packed into an outer carton.

Not all pack sizes may be marketed.

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)

31/5.8/0056

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 April 1997

10. DATE OF REVISION OF THE TEXT

31 March 2026

Namibia: NS1
04/5.6/1652

Botswana: NS3 BOT0801263 100 mL

Botswana: NS3BOT0801263A 140 mL