

**APPLICANT:** ADCOCK INGRAM LIMITED

**Date:**

**PROPRIETARY NAME:** COLCAPS ® CHILDREN'S SYRUP

14 June 2022

**DOSAGE FORM AND STRENGTH:** Each 5 ml contains: Codeine phosphate 5 mg; Promethazine hydrochloride 6,5 mg; Pseudoephedrine hydrochloride 25 mg; Paracetamol 120 mg

## **CLEAN APPROVED PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS:**

**S2**

### **COLCAPS ® CHILDREN'S SYRUP**

Codeine phosphate 5 mg; Promethazine hydrochloride 6,5 mg; Pseudoephedrine hydrochloride 25 mg and Paracetamol 120 mg

Contains preservatives: Methyl hydroxybenzoate 0,06 % m/v and Propyl hydroxybenzoate 0,03 % m/v

Contains Alcohol 10,0 % v/v

Contains Antioxidants: Ascorbic acid 100 mg and Citric acid 1,1 mg.

Contains sugar: Sucrose 2,0 g; Liquid Glucose 2,2 g

Contains sweeteners: Sodium Cyclamate 15,4 mg and saccharin sodium 4,4 mg.

### **Read all of this leaflet carefully before you start taking COLCAPS CHILDREN'S**

#### **SYRUP:**

COLCAPS CHILDREN'S SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use COLCAPS CHILDREN'S SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share COLCAPS CHILDREN'S SYRUP 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 improve after 10 days.

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

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### **CLEAN APPROVED PATIENT INFORMATION LEAFLET**

1. What COLCAPS ® CHILDREN'S SYRUP is and what it is used for
2. What you need to know before you take COLCAPS ® CHILDREN'S SYRUP
3. How to take COLCAPS ® CHILDREN'S SYRUP
4. Possible side effects
5. How to store COLCAPS ® CHILDREN'S SYRUP
6. Contents of the pack and other information

#### **1. WHAT COLCAPS CHILDREN'S SYRUP IS AND WHAT IT IS USED FOR:**

Preparation for common cold

The symptomatic relief of colds and flu associated with cough in children 2 years and older.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COLCAPS CHILDREN'S SYRUP:**

##### **Do not take/give COLCAPS CHILDREN'S SYRUP:**

- If your child is hypersensitive (allergic) to codeine phosphate, promethazine, pseudoephedrine, paracetamol or any of the other ingredients of COLCAPS CHILDREN'S SYRUP.
- If your child has problems with their liver or kidneys.
- If your child is taking medicine for depression, hyperactivity or personality disorders or is going to be taking such medicines within the next 14 days.
- If you are a breastfeeding mother
- If your child is taking medicines which quickly convert codeine to its active form. This may lead to more codeine available and symptoms such as being very sleepy, confused or shallow breathing. This is serious and can cause death.

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- If your child suffers from a breathing disorder of slow and poor breathing and suffer from a lung disease that block airflow and make it difficult to breathe (obstructive airway disease) especially when their skin turns blue and there is lots of sputum. This breathing disorder can happen after surgery on the organs and ducts that make and store bile.
- If your child is at risk of having a condition in which the muscles that contracting which help move food through their intestines are temporarily paralyzed.
- If your child has uncontrollable muscle contraction disorders, head injuries and conditions which increase pressure between the brain and the skull.
- If your child has had alcohol poisoning
- If your child has a long-term lung disease or in heart disease.
- If your child is under 2 years of age as it can cause the unexpected death of infants.

#### **Take special care with COLCAPS CHILDREN'S SYRUP:**

- Do not use continuously for more than ten days without consulting your doctor.
- If your child has liver and kidney disease, medicines containing paracetamol should be supervised by your doctor. Taking more than they should may cause severe liver damage.

COLCAPS CHILDREN'S SYRUP contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison control centre must be contacted immediately.

- If your child has inflammation of the liver or had alcohol poisoning or recovering from any form of liver disease should not take excessive quantities of COLCAPS CHILDREN'S SYRUP.

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- If your child suffers from an overactive thyroid gland (hyperthyroidism).
- If your child has heart problems such as an irregular heartbeat or a fast heartbeat.
- If your child has a condition in which narrowed blood vessels reduce blood flow to the limbs, including build-up of fats, cholesterol and other substances in and on the blood vessel walls, high blood pressure (hypertension) or suffer from a ballooning and weakened area in an artery (aneurysms).
- If your child has diabetes mellitus.
- If your child has high pressure in the eye.
- If your child is taking medicine for anxiety, depression, hyperactivity or personality disorders, or is going to be taking such medicines within the next 14 days.
- If your child has an underactive thyroid, a condition where their glands don't produce enough hormones, impaired liver function, or is in shock.
- If your child has a condition in which digested material is prevented from passing normally through the bowel and can cause inflammation
- If your child has a condition that causes weakness and rapid fatigue of any of the muscles under your voluntary control.
- If your child has been taking COLCAPS CHILDREN'S SYRUP for a long period, at a higher than recommended dose with continuous use.
- If your child has a breathing disorder characterized by slow and ineffective breathing,
- COLCAPS CHILDREN SYRUP can be fatal in children under 2 years of age.
- If your child has asthma, inflammation of the lungs or a condition in which the lungs' airways become damaged, making it hard to clear mucus.
- If your child has seizures
- If your child has a condition where you have an obstruction in your stomach or bladder.
- If your child has Reye's Syndrome which is a rare but serious condition that causes confusion, swelling in the brain and liver damage.

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- If your child is taking medicines e.g. salicylates that causes damage to your inner ear and hearing.
- Stop using COLCAPS CHILDREN'S SYRUP, if your child suffers from hallucinations or restlessness

### **Other medicines and COLCAPS CHILDREN'S SYRUP:**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

### **Tell your doctor if your child is taking any of the following medicines:**

- *anaesthetics* for pain, *hypnotics* for sleep or *sedatives* for calming, *antipsychotics* for serious emotional and mental problems as it may increase their effects.
- *Codeine* may delay the effects of *mexiletine*, *cisapride*, *metoclopramide* or *domperidone*.
- *Promethazine* may increase the effects of *atropine* and *tricyclic antidepressants*
- Warning symptoms of damage caused by medicines harmful to the ears such as *aminoglycoside antibiotics* may be masked.
- Taking COLCAPS CHILDREN'S syrup with *alcohol*, *barbiturates*, *hypnotics*, *opioid analgesics*, *anxiolytic sedatives* and *antipsychotics* may increase the calming effect.
- Do not use *pseudoephedrine hydrochloride* in patients undergoing *anaesthesia* as it may cause an abnormal heart rhythm.
- There will be an increased risk of abnormal heart rhythms if given with *cardiac glycosides* or *tricyclic antidepressants*.
- When given with *antihypertensive medicines*, the blood pressure may be lowered even more.
- Using with *amphetamine-like psychostimulants* may increase the risk of hypertension
- May increase the effect of *anticholinergic medicines*.
- When given with *liver toxic medicines*, it may increase the toxicity further

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- May increase the absorption of *metoclopramide*.
- May decrease the effect of COLCAPS CHILDREN'S SYRUP if given within an hour of using *cholestyramine*
- The effect of *probenecid* may be changed when taken together

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

The safety of COLCAPS CHILDREN'S SYRUP during pregnancy and whilst breastfeeding has not been established. COLCAPS CHILDREN'S SYRUP is contraindicated in breastfeeding mothers. No fertility data available.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking COLCAPS CHILDREN'S SYRUP.

### **Driving and using machines**

COLCAPS CHILDREN'S SYRUP may lead to drowsiness and lack of concentration, which may be made worse by taking it with alcohol or other medicines which act on the central nervous system. Patients should be warned against activities requiring mental alertness, judgment and/or sound coordination and vision.

It is not always possible to predict to what extent COLCAPS CHILDREN'S SYRUP 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 COLCAPS CHILDREN'S SYRUP affects them.

### **Important information about some of the ingredients in COLCAPS CHILDREN'S SYRUP:**

COLCAPS CHILDREN'S SYRUP contains liquid glucose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking COLCAPS CHILDREN'S SYRUP.

### **3. HOW TO TAKE COLCAPS CHILDREN'S SYRUP:**

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

Always take COLCAPS CHILDREN'S SYRUP exactly as described in this leaflet or as your doctor, or pharmacist have told you. Check with your doctor or pharmacist, if you are not sure.

The usual dose is:

**DO NOT EXCEED THE RECOMMENDED DOSE.**

2 years - 5 years: One medicine measureful (5,0 ml) three times a day.

5 years - 12 years: One to two medicine measurefuls (5,0 ml - 10,0 ml) three times a day.

Not for use in children under 2 years of age (see **Do not take COLCAPS CHILDREN'S SYRUP**).

If you have the impression that the effect of COLCAPS CHILDREN'S SYRUP is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more COLCAPS CHILDREN'S SYRUP than you should:**

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 COLCAPS CHILDREN'S SYRUP:**

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Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

#### **4. POSSIBLE SIDE EFFECTS:**

COLCAPS CHILDREN'S SYRUP can have side effects.

Not all side effects reported for COLCAPS CHILDREN'S SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLCAPS CHILDREN'S SYRUP, please consult your healthcare provider for advice.

If any of the following happens, stop taking COLCAPS CHILDREN'S SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to COLCAPS CHILDREN'S SYRUP. 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:

<b>System Organ Class</b>	<b>Frequency</b>	<b>Undesirable effect</b>
<b>Blood and lymphatic system disorders</b>	Less frequent	Low platelet counts, low white blood cell count, an abnormal condition or disease of the blood,

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		a disorder in which red blood cells are destroyed faster than they can be made
	Unknown	Low circulation of white blood cells in the body, too few blood cells, low white blood cell count, low red blood cells and haemoglobin.
<b>Immune system disorders</b>	Less frequent	Allergic reactions (some serious), Hives
<b>Metabolism and nutrition disorders</b>	Less frequent	An eating disorder characterized by markedly reduced appetite or total dislike to food.
	Unknown	Reduced appetite, altered metabolism and disturbances of glucose metabolism.
<b>Psychiatric disorders</b>	Frequent	Restlessness and sleeplessness.
	Less frequent	Confusion.
	Unknown	Changes of mood, hallucinations, depression, elation, irritability, nightmares and nervousness, fear, anxiety, and psychotic state.
<b>Nervous system disorders</b>	Frequent	Drowsiness
	Less frequent	Tremor
	Unknown	Headache, dizziness, incoordination, tremors, muscular weakness, sedation, ringing in the ears, convulsions, tingling and brain stimulation (in infants and children).
<b>Eye disorders</b>	Less frequent	excessive constriction of the pupil of the eye
	Unknown	Increased pressure between the brain and spinal chord
<b>Ear and labyrinth disorders</b>	Less frequent	Dizziness
	Unknown	a sensation of feeling off balance

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<b>Cardiac disorders</b>	Less frequent	slow or irregular heart rhythm; rapid pulse; rapid beating of the heart; irregular heartbeat; abrupt loss of heart function, breathing and consciousness or sudden and severe shortness of breath, or difficulty in breathing
	Unknown	chest pain caused by reduced blood flow to the heart, Swelling of the heart due to excess fluid in the tissues
<b>Vascular disorders</b>	Less frequent	A drop in blood pressure that occurs when moving from a laying down position to a standing position, hypotension, dizziness
	Unknown	a medical emergency that occurs when your body loses heat faster than it can produce heat, high blood pressure, loss of blood from damaged blood vessels in the brain, low blood pressure with dizziness and flushing
<b>Respiratory, thoracic &amp; mediastinal disorders</b>	Frequent	Tightness of chest.
	Unknown	abnormal buildup of fluid in the lungs.
<b>Gastrointestinal disorders</b>	Frequent	Constipation.
	Less frequent	Nausea, vomiting and dry mouth.
	Unknown	Inflammation of the pancreas, diarrhoea, epigastric pain and gastrointestinal disturbances, producing lots of saliva
<b>Hepato-biliary disorders</b>	Less frequent	Inflammation of the liver, Gall bladder spasm.
<b>Skin and subcutaneous tissue disorders</b>	Less frequent	Skin rash (usually abnormal redness and inflamed or like

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		hives), sweating, facial flushing and itchy skin.
<b>Musculoskeletal and connective tissue disorders</b>	Unknown	Muscle twitching, heaviness and weakness of hands.
<b>Renal and urinary disorders</b>	Less frequent	Acute and severe loin pain, kidney failure, finding of white blood cells in the urine in the absence of bacteria, urinating may be difficult, spasm in the tube that carries urine from the kidney to the bladder, inability to voluntarily pass an adequate amount of urine
<b>General disorders and administration site conditions</b>	Unknown	Inability to concentrate, weakness, fainting, fatigue.

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 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 COLCAPS CHILDREN'S SYRUP.

**5. HOW TO STORE COLCAPS CHILDREN'S SYRUP**

Store at or below 25 °C.

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Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What COLCAPS CHILDREN'S SYRUP contains**

The active ingredients are:

<b>Each 5 ml contains:</b>	
Codeine phosphate	5 mg
Promethazine hydrochloride	6,5 mg
Pseudoephedrine hydrochloride	25 mg
Paracetamol	120 mg

The other ingredients are alcohol, ascorbic acid, blackcurrant flavour, citric acid, liquid glucose, methyl hydroxybenzoate, orange colour, orange sweet flavour, propylene glycol, propyl hydroxybenzoate, purified water, saccharin sodium, sodium cyclamate, sodium hydroxide pellets and sucrose.

### **What COLCAPS CHILDREN'S SYRUP looks like and contents of the pack**

Clear orange syrup, orange flavour.

100 ml amber glass bottle with a white screw-on closure and an EXPE liner.

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**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

**This leaflet was last revised in**

10 June 2022.

**REGISTRATION NUMBER**

D/5.8/0054