SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

COLCAPS® CHILDREN'S SYRUP

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

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your / your child's symptoms worsen or do not improve after 10 days.

WHAT COLCAPS CHILDREN'S SYRUP CONTAINS

The active substances are (per 5 ml):

Codeine phosphate	5 mg
Promethazine HCl	6,5 mg
Pseudoephedrine HCl	25 mg
Paracetamol	120 mg

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

WHAT COLCAPS CHILDREN'S SYRUP IS USED FOR

COLCAPS CHILDREN'S SYRUP provides symptomatic relief of colds and flu associated with cough in children 2 years and older.

Paracetamol is used to relieve pain and reduce fever associated with colds and flu. Pseudoephedrine

hydrochloride works by narrowing the blood vessels, leading to clearing of nasal congestion. Promethazine is an antihistamine, which works by preventing the effects of a substance produced by the body called histamine.

BEFORE USING COLCAPS CHILDREN'S SYRUP

Do not use COLCAPS CHILDREN'S SYRUP:

- If your child has a hypersensitivity to any of the stated ingredients (See WHAT COLCAPS CHILDREN'S SYRUP CONTAINS).
- If your child has a severe liver disease.
- If your child is taking monoamine oxidase inhibitor treatment (certain medicines used for depression), or within 14 days of termination of such treatment.
- If your child is under 2 years of age.

Take special care with COLCAPS CHILDREN'S SYRUP:

- **COLCAPS CHILDREN'S SYRUP** contains paracetamol, do not give your child more than there recommended dosage, this may cause severe damage to the liver.
- Do not use continuously for more than 10 days without consulting your doctor.
- If your child suffers from liver or kidney disease, do not give paracetamol-containing preparations without consulting a doctor.
- **COLCAPS CHILDREN'S SYRUP** may cause some people to become drowsy, dizzy or less alert than they are normally.
- Make sure you know how your child reacts to this medicine before he/she does anything that could be dangerous if he/she is drowsy or not alert.
- **Do not use COLCAPS CHILDREN'S SYRUP** without consulting a doctor or pharmacist if your child is taking monoamine oxidase inhibitors or other medicines for depression, psychiatric or emotional conditions or hypertension.
- **COLCAPS CHILDREN'S SYRUP** should be used with caution in children with overactive thyroid gland, heart disease such as irregular or rapid heartbeat, progressive narrowing and blocking of the arteries, including hardening of the arteries, high blood pressure or bulging of the arteries, diabetes mellitus, high pressure in the eye and enlargement of the gland surrounding the neck of the male tube through which urine passes.

Taking COLCAPS CHILDREN'S SYRUP with food and drink:

Alcohol and other central nervous system depressants should be consumed during treatment with COLCAPS CHILDREN'S SYRUP

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while taking / having this medicine, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

- COLCAPS CHILDREN'S SYRUP may make you feel drowsy/sleepy
- Do not drive because COLCAPS CHILDREN'S SYRUP could interfere with your ability to drive safely
- Do not operate any tools or machines or performing potentially dangerous tasks where loss of concentration may lead to accidents.

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

COLCAPS CHILDREN'S SYRUP: 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.

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.

Taking other medicines with COLCAPS CHILDREN'S SYRUP:

Always tell your healthcare professional if you are taking other medicine.

(This include complementary or traditional medicines.)

Tell your doctor if you are taking any medication for depression, antibiotics or any other medication that makes you sleepy or drowsy including alcohol and some of the antihypertensive medicines.

HOW TO TAKE COLCAPS CHILDREN'S SYRUP

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

DO NOT GIVE MORE OF COLCAPS CHILDREN'S SYRUP THAN YOU SHOULD.

Always give **COLCAPS CHILDREN'S SYRUP** exactly according to instructions. You should check with a doctor or pharmacist if you are unsure.

The usual dose is:

Children 2 to 5 years of age: One medicine measure (5,0 ml) three times a day.

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

Not for use in children under 2 years of age.

Do not use **COLCAPS CHILDREN'S SYRUP** for longer than 10 days without consulting a doctor.

If you forget to give COLCAPS CHILDREN'S SYRUP:

Do not give a double dose to make up for forgotten individual doses.

If you use more COLCAPS CHILDREN'S SYRUP than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center **immediately.**

Should your child or somebody else have taken an overdose of **COLCAPS CHILDREN'S SYRUP**, the following symptoms may be experienced (due to paracetamol overdose): loss of appetite, nausea,vomiting, pale skin and stomach pain. These symptoms may be mild and do not reflect the potential seriousness of the overdosage which can result in **liver damage or death.** Treatment must be started within 24 hours in order to prevent this.

POSSIBLE SIDE EFFECTS

COLCAPS CHILDREN'S SYRUP can have side-effects. If any of the following happens, stop giving COLCAPS CHILDREN'S SYRUP to your child and tell your doctor immediately or go to the casualty department at your nearest hospital:

- He/she have an allergic reaction. The signs may include: shortness of breath, wheezing, difficulty breathing, rash, itching, hives on the skin, swelling of your lips, face or throat.
- He/she get a headache, feel confused or have a seizure.
- He/she has an excessive fluid accumulation in the lungs.
- If their blood vessels narrows resulting in high blood pressure.

- He/she has bleeding in the brain tissue
- He/she has low blood pressure with dizziness and flushing
- He/she has excessive salivation

These are all very serious side effects. If your child has any of them, he/she may have had a serious allergic reaction to **COLCAPS CHILDREN'S SYRUP**. Your child may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if any of the following side effects get serious or lasts longer than a few days in your child:

- Nausea (feeling sick)
- Abdominal cramps or stomach pain
- Diarrhoea
- Vomiting
- Loss of appetite,
- Difficult or painful urination
- Ringing in the ears
- Dizziness
- Light-headedness
- Fainting
- Unusual bleeding or bruising
- Disorders of the blood
- Abnormally low body temperature
- Irritability
- Inability to concentrate
- Depression
- Nightmares
- Fast or irregular heartbeat
- Abnormal slow pulse rate
- Feeling of heaviness in the chest
- Shaking
- Sweating

- Unusual tiredness or weakness
- Dryness of mouth
- Incoordination
- Muscle weakness
- Muscle twitching
- Heaviness and weakness of hands
- Calming effect
- Ringing in the ear
- Tingling in infants and children
- Constipation
- Contraction of the pupil of the eye.
- Sedation varying from slight drowsiness to deep sleep, paradoxical central nervous stimulation (especially in children) may occur, this usually presents as tremor, anxiety, euphoric mood, hallucinations, restlessness and inability to sleep.

Not all side effects reported for this medicine are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF COLCAPS CHILDREN'S SYRUP

Keep all medicines out of the reach and sight of children.

Store in a safe place at or below 25 °C.

Protect from light.

Store in the original container in a cool place. Keep the container tightly closed and do not store the product in bathrooms in order to protect from moisture.

Do not use after the expiry date on the label.

Do not dispose of unused medicines in drains or sewerage systems.

PRESENTATION OF COLCAPS CHILDREN'S SYRUP

Bottles of 100 ml.

IDENTIFICATION OF COLCAPS CHILDREN'S SYRUP

Clear orange syrup, orange flavour.

REGISTRATION NUMBER

D/5.8/0054

NAME AND ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

DATE OF PUBLICATION

02 March 2012

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.