PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ADCO-DIATUSSIN SYRUP

Each 10 mL contains:

Theophylline 56,31 mg

Diphenhydramine hydrochloride 28,15 mg

Sodium citrate 113,83 mg

Menthol 2,28 mg

Ammonium chloride 273,86 mg

Contains preservatives

Methyl hydroxybenzoate 0,10 % m/v

Propyl hydroxybenzoate 0,02 % m/v

Contains sugar: Sucrose 5,78 g

Contains alcohol: 0,001 mL (0,01 % v/v)

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

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

- Keep this leaflet. You may need to read it again
- Do not share ADCO-DIATUSSIN SYRUP with any other person.

- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What ADCO-DIATUSSIN SYRUP is and what it is used for

2. What you need to know before you take ADCO-DIATUSSIN SYRUP

3. How to take ADCO-DIATUSSIN SYRUP

4. Possible side effects

5. How to store ADCO-DIATUSSIN SYRUP

6. Contents of the pack and other information

1. What ADCO-DIATUSSIN SYRUP is and what it is used for

ADCO-DIATUSSIN SYRUP is an antitussive (helps stop or reduce coughing) and an expectorant (helps loosen mucus in the lungs).

ADCO-DIATUSSIN SYRUP is used to assist in reducing or treating coughing.

2. What you need to know before you take ADCO-DIATUSSIN SYRUP

Do not take ADCO-DIATUSSIN SYRUP

- If you are hypersensitive (allergic) to theophylline, diphenhydramine hydrochloride, sodium citrate, menthol, ammonium chloride, or any of the other ingredients of ADCO-DIATUSSIN SYRUP (listed in section 6).
- if you have liver or kidney problems
- if you are experiencing an asthma attack.
- if you suffer from a stomach ulcer, gout, or extremely low blood pressure.
- if you are pregnant or breastfeeding
- if you have conditions such as imbalanced blood pH, low calcium levels, or low stomach acid.
- if you have a history of seizures or epilepsy.
- if you have a rare condition that affects your blood cells called porphyria.

- ADCO-DIATUSSIN SYRUP should not be given to children younger than 6 years old.
- if you are taking monoamine oxidase inhibitors (MAOIs) for depression or other conditions.
- if you have recently had a heart attack.
- if you have a heart condition that causes your heart to beat too fast or irregularly.
- If your child is taking a medicine called ephedrine (used for asthma), do not use this syrup together with it.

Warnings and precautions

Take special care with ADCO-DIATUSSIN SYRUP:

- ADCO-DIATUSSIN SYRUP contains theophylline, and if the dose is too high, it could cause harmful effects. Make sure to follow the recommended dosage closely or speak to your healthcare provider if you are still unsure.
- If you have diabetes, please consult your healthcare provider before taking this medicine.
- If you have epilepsy,as large doses of one of the diphenhydramine hydrochloride, as contained in ADCO-DIATUSSIN SYRUP could trigger seizures.
- If you have eye problems (like glaucoma), prostate issues, or certain other conditions , you should use ADCO-DIATUSSIN SYRUP carefully as it may make them worse.
- Diphenhydramine hydrochloride, as contained in ADCO-DIATUSSIN SYRUP may interfere with skin allergy tests, so let your doctor know if you’re having one done
- If you have a history of alcohol use, heart or lung problems, or certain lung diseases, you should be extra careful when using ADCO-DIATUSSIN SYRUP.
- If you're switching from another medicine to ADCO-DIATUSSIN SYRUP, your doctor may want to monitor the levels of theophylline in your blood to make sure they are safe.
- Theophylline, as contained in ADCO-DIATUSSIN SYRUP should be used carefully if you have stomach ulcers, thyroid problems, heart disease, or irregular heartbeats, as it could make these conditions worse.
- If you have heart failure, high blood pressure, or fluid buildup or toxaemia of pregnancy (a serious condition during pregnancy, where there’s high blood pressure and signs of damage to organs like the kidneys) use ADCO-DIATUSSIN SYRUP cautiously.
- If your cough lasts more than a week, keeps coming back, or is accompanied by a high fever, rash, or headache, consult your doctor. It may be a sign of a serious illness.

- Diphenhydramine hydrochloride could trigger seizures, especially in people with certain brain conditions.
- If you have conditions like narrow-angle glaucoma (a type of eye problem) or difficulty urinating
- Taking too much diphenhydramine, as contained in ADCO-DIATUSSIN SYRUP, can cause serious side effects, including heart problems, seizures, and even death.
- If you have heart failure, kidney problems, liver cirrhosis, high blood pressure, or are taking corticosteroids, talk to your doctor before using ADCO-DIATUSSIN SYRUP, as it contains sodium citrate.
- Some people may have allergic reactions to menthol, which is an ingredient in ADCO-DIATUSSIN SYRUP.

Children

- ADCO-DIATUSSIN SYRUP may make children more energetic or cause nervous system stimulation. In newborns, the body may take longer to clear the theophylline, a component of ADCO-DIATUSSIN SYRUP, so it should be used carefully.

Elderly

- Older patients are more likely to experience side effects like dizziness, confusion, sedation, and low blood pressure. They may also be more sensitive to the effects of ADCO-DIATUSSIN SYRUP, so dosages should be carefully adjusted, and the medicine should be monitored closely.
- Their bodies may also not be able to get rid of the medicine as efficiently.

Other medicines and ADCO-DIATUSSIN SYRUP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Diphenhydramine hydrochloride, as contained in ADCO-DIATUSSIN SYRUP, may increase the sedative (sleepy) effects of other medicines that also make you drowsy, like alcohol, sleeping pills, painkillers, and tranquilizers.

- If you are taking other medicines that affect your body in a similar way, like atropine (used for eye conditions) or certain antidepressants, ADCO-DIATUSSIN SYRUP could make those effects stronger.
- If you're taking certain types of antidepressants (called monoamine oxidase inhibitors), they may increase the effects of diphenhydramine hydrochloride, as contained in ADCO-DIATUSSIN SYRUP, especially those related to drying up body fluids (like mouth dryness and constipation).
- The syrup contains theophylline, which is used to treat breathing problems. Taking it with other medicines that open up airways (like bronchodilators) or stimulants could increase side effects.
- The following medicines can affect how your body breaks down theophylline, a component of ADCO-DIATUSSIN SYRUP causing it to stay in your body longer:
    - Allopurinol – used for gout (a type of arthritis).
    - Cimetidine – used for stomach acid problems like ulcers or heartburn.
    - Influenza vaccine – used to prevent the flu.
    - Propranolol – used for high blood pressure or heart problems.
    - Erythromycin and other similar antibiotics (macrolides) – used to treat infections.
    - Disulfiram – used to help people stop drinking alcohol.
    - Fluvoxamine – used to treat anxiety or depression.
    - Interferon alfa – used to treat certain viral infections or cancers.
    - Tetracycline – used for bacterial infections.
    - Quinolones – a type of antibiotic used for infections.
    - Oral contraceptives (birth control pills) – used to prevent pregnancy.
    - Caffeine – found in coffee, tea, or some medicines.
    - Verapamil – used for high blood pressure or heart problems.
    - Zileuton – used for asthma.
    - Tacrine – used for Alzheimer’s disease.
    - Thiabendazole – used to treat parasitic infections.
    - Viloxazine – used for attention-deficit hyperactivity disorder (ADHD).
    - BCG vaccination – a vaccine used to protect against tuberculosis (TB).

  When taking these medications with theophylline, your doctor may need to adjust your dose to avoid potential side effects or complications.

- Phenytoin and other anticonvulsants (for seizures), ritonavir (for HIV), sulfinpyrazone (for gout), rifampicin (for tuberculosis and other infections), and cigarette smoking can increase the breakdown of theophylline in your body, which may require a higher dose or more frequent doses of theophylline.
- ADCO-DIATUSSIN SYRUP may increase the risk of low potassium levels in your blood when taken with medicines like asthma inhalers (beta-2- agonists), steroids, or water pills (diuretics).
- Combining ADCO-DIATUSSIN SYRUP with anaesthetics like halothane or ketamine could increase the risk of serious side effects.
- ADCO-DIATUSSIN SYRUP may interfere with how adenosine (used for certain heart problems) and muscle relaxants work.
- ADCO-DIATUSSIN SYRUP may help your body get rid of lithium (used for mood disorders) more quickly, possibly affecting how lithium works.
- Isoniazid (used to treat tuberculosis) may slow down how quickly your body gets rid of ADCO-DIATUSSIN SYRUP, so it might stay in your system longer.
- Diphenhydramine in ADCO-DIATUSSIN SYRUP could hide signs of ear damage caused by certain antibiotics (aminoglycosides).
- ADCO-DIATUSSIN SYRUP can increase the amount of aluminium your body absorbs, which could be a concern if you're taking certain medications that contain aluminium.

Pregnancy, breastfeeding and fertility

The safety of this medicine in fertility, pregnancy and breastfeeding
has not been established.

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 this medicine.

Driving and using machines

ADCO-DIATUSSIN SYRUP may make you sleepy and reduce your level of concentration or alertness. Do not drive or operate any tools or machines as this medicine may interfere with your ability to do these safely.

It is not always possible to predict to what extent ADCO-DIATUSSIN SYRUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in tasks or activities requiring mental alertness, judgement and / or sound coordination and vision until they are aware of the measure to which ADCO-DIATUSSIN SYRUP affects them. Persons operating machinery or driving cars should exercise caution after taking the medicine.

ADCO-DIATUSSIN SYRUP contains ethanol, propylen glycol, sucrose, parabens and sodium

- ADCO-DIATUSSIN SYRUP contains 0,00025 ml of alcohol (ethanol) in each 2,5 ml, or 0,079 mg of alcohol (ethanol) per mL, which is equivalent to 0,01 % v/v. The amount in 2,5 mL of this medicine is equivalent to less than 0,005 mL of beer or 0,002 mL of wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- ADCO-DIATUSSIN SYRUP contains 0,3 ml propylene glycol in each 2,5 ml which is equivalent to 12 % v/v.
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- If you are pregnant or breastfeeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- ADCO-DIATUSSIN SYRUP contains 1,45 g of sucrose per 2,5 mL. This should be taken into account in patients with diabetes mellitus.
- If you have been told by your doctor that you have an intolerance to some. sugars, contact your doctor before taking ADCO-DIATUSSIN SYRUP
- ADCO-DIATUSSIN SYRUP contains parabens which may cause allergic reactions (possibly delayed).
- ADCO-DIATUSSIN SYRUP contains 6,67 mg of sodium per 2,5 mL of syrup or 2,7 mg of sodium per mL of syrup. This is equivalent to 0,14% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take ADCO-DIATUSSIN SYRUP

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

Always take ADCO-DIATUSSIN SYRUP exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults: 10 mL (two medicine measures) every four hours.

Children 6 to 12 years: 2,5 mL to 5 mL (half to one medicine measure) every four hours.

Should not be given to children under 6 years.

Shake well before use.

If you take more ADCO-DIATUSSIN SYRUP than you should

- Taking too much theophylline, as contained in ADCO-DIATUSSIN SYRUP, can cause nausea, vomiting, diarrhoea, agitation, shakiness, muscle tightness, fast breathing, irregular heartbeat, low blood pressure, or seizures (fits). Other issues include low potassium, high blood sugar, and electrolyte imbalances. If these occur, seek medical help immediately, as treatment may include activated charcoal or other measures to speed up elimination.
- Overdosing on diphenhydramine hydrochloride, as contained in ADCO-DIATUSSIN SYRUP, may be fatal, especially when being administered to children. It may cause excitement, hallucinations, muscle tremors, dry mouth, dilated pupils, high fever, drowsiness, low blood pressure and difficulty breathing, which could lead to coma or death.
- Symptoms of too much sodium citrate, as contained in ADCO-DIATUSSIN SYRUP, include swelling or fluid retention, restlessness, weakness, thirst, swollen tongue, reduced saliva or tear production, dry mouth, headache, feeling flushed, fever, low blood pressure, dizziness, confusion, fast heartbeat, difficulty breathing, decreased urine production and severe vomiting. Seek medical attention immediately if you notice these signs, as severe cases may cause electrolyte imbalances and respiratory distress.
- Taking too much ammonium chloride,as contained in ADCO-DIATUSSIN SYRUP, can lead

to nausea, vomiting, headache, thirst, fast breathing, drowsiness, and confusion. In severe cases, it can cause acid buildup and weakness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ADCO-DIATUSSIN SYRUP

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

4. Possible side effects

ADCO-DIATUSSIN SYRUP can have side effects.

Not all side effects reported for ADCO-DIATUSSIN SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-DIATUSSIN SYRUP, please consult your health care provider for advice.

If any of the following happens, stop taking ADCO-DIATUSSIN SYRUP 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 ADCO-DIATUSSIN 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:

- Seizures (convulsions)
- Sudden irregular or rapid heartbeats
- Chest tightness

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-DIATUSSIN SYRUP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling thirsty
- feeling overly happy or sad
- irritable, restless, agitated
- feeling anxious or nervous
- having nightmares
- feeling confused
- headache
- drowsiness
- trouble concentrating
- feeling tired
- dizziness
- difficulty sleeping
- shaking, feeling tingling sensations
- seizures (fits)
- nausea, vomiting
- diarrhoea, constipation
- stomach pain or reactivation of an old stomach ulcer
- dry mouth
- heartburn

Less frequent side effects:

- Low red blood cells, white blood cells, and platelets
- anorexia
- feeling hungrier than usual,
- increased acid in the body,
- low potassium levels,
- high sodium levels

- blurred vision.
- ringing in the ears (tinnitus).
- vertigo (feeling dizzy or light headed)
- extra heartbeats or skipped beats.
- feeling your heart pounding, fluttering, or racing in your chest.
- skin sensitivity to sunlight.

Side effects of unknown frequency

- High blood sugar or low magnesium levels
- weakness, muscle twitching, or difficulty with coordination and hand movements
- difficulty urinating or painful urination
- hair loss
- increased urine output
- blood or protein in the urine
- changes in hormone levels affecting fluid balance
- risk of reacting to other related drugs.

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 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. By reporting these side effects, you can help provide more information on the safety of ADCO-DIATUSSIN SYRUP.

5. How to store ADCO-DIATUSSIN SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C, in a cool dry place.

Do not use after the expiry date stated on the label / carton / bottle.

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 ADCO-DIATUSSIN SYRUP contains

The active substances are:

Theophylline	56,31 mg
Diphenhydramine hydrochloride	28,15 mg
Sodium citrate	113,83 mg
Menthol	2,28 mg
Ammonium chloride	273,86 mg

The other ingredients are:

- Ethanol 96,5 %
- Flavour wild Cherry
- Caramel
- Raspberry essence
- Propylene glycol (E1520)
- Sucrose
- Methylhydroxybenzoate
- Propylhydroxybenzoate
- Purified water

What ADCO-DIATUSSIN SYRUP looks like and contents of the pack

ADCO-DIATUSSIN SYRUP is a Clear amber syrup with a raspberry-cherry odour.

ADCO-DIATUSSIN SYRUP is packed in amber PVC bottles of 100 mL, amber glass bottles of 150 mL or 2.5 L amber HDPE container.

Not all pack types and pack sizes may be marketed.

Holder of Certificate of Registration

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