

SCHEDULING STATUS: [S2]

ADCO-SALTERPYN® SYRUP, SYRUP

Codeine/Promethazine/Paracetamol

Contains sugar (each 5 ml syrup contains 1,10 g sucrose, 2,0 g liquid glucose and 600 mg invert syrup)

Read all of this leaflet carefully because it contains important information for you and your child.

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

- Keep this leaflet. You may need to read it again.
- Do not share ADCO-SALTERPYN® 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 child's symptoms worsen or do not improve.

What is in this leaflet

1. What ADCO-SALTERPYN® SYRUP is and what it is used for
2. What you need to know before you give ADCO-SALTERPYN® SYRUP to your child
3. How to give ADCO-SALTERPYN® SYRUP to your child
4. Possible side effects
5. How to store ADCO-SALTERPYN® SYRUP
6. Contents of the pack and other information

1. What ADCO-SALTERPYN® is and what it is used for

ADCO-SALTERPYN® SYRUP contains three active ingredients namely, paracetamol, codeine phosphate and promethazine hydrochloride.

It is used to treat mild to moderate pain, associated with fever.

2. What you need to know before you give ADCO-SALTERPYN® SYRUP to your child

Do not give ADCO-SALTERPYN® to your child:

- if he / she is hypersensitive (allergic) to paracetamol, opiates or phenothiazines or any of the other ingredients of ADCO-SALTERPYN® SYRUP (listed in [section 6](#)).
- if he / she is younger than 2 years old.

Warnings and precautions

Take special care with ADCO-SALTERPYN® SYRUP:

- **do not give your child more than the recommended dose** (see [section 3: “How to give ADCO-SALTERPYN® SYRUP to your child”](#) for the dosing instructions).
 - giving too much ADCO-SALTERPYN® SYRUP to your child may cause serious liver problems (due to the paracetamol component of ADCO-SALTERPYN® SYRUP).
 - giving too much of ADCO-SALTERPYN® SYRUP to your child over a long period of time can lead to dependency and addiction (due to the codeine component of ADCO-SALTERPYN® SYRUP).
 - high doses of promethazine, a component of ADCO-SALTERPYN® SYRUP, may cause fits (seizures).
- if your child does not get better, talk to your child’s doctor.
- do not give your child ADCO-SALTERPYN® SYRUP continuously for more than 10 days without talking to your child’s doctor.
- ADCO-SALTERPYN® SYRUP may cause your child to feel drowsy and have decreased concentration. This may be worsened if taken with other medicines that contain alcohol or that are known as “central nervous system depressants”.
- your child’s skin and eye pigmentation (colour) should be checked regularly for changes. Speak to your doctor or pharmacist if you are not sure.
- if your child has liver or kidney problems, you should not give ADCO-SALTERPYN® SYRUP to him or her.

Children

Do not give ADCO-SALTERPYN® SYRUP to children younger than 2 years, as it can cause serious and life-threatening breathing problems.

Other medicines and ADCO-SALTERPYN® SYRUP

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

ADCO-SALTERPYN® SYRUP with alcohol

ADCO-SALTERPYN® SYRUP may cause your child to feel drowsy and have decreased concentration. This may be worsened if taken with other medicines that contain alcohol.

Pregnancy and breastfeeding

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-SALTERPYN® SYRUP may cause your child to feel drowsy and have decreased concentration. He / She should not perform any task, or take part in any activities, that require mental alertness (e.g., riding a bike, climbing).

It is not always possible to predict to what extent ADCO-SALTERPYN® SYRUP may interfere with your child's daily activities. Your child should not engage in any activities that may require mental concentration or alertness until you are aware of the measure to which ADCO-SALTERPYN® SYRUP affects him / her.

ADCO-SALTERPYN® SYRUP contains methyl hydroxybenzoate and propyl hydroxybenzoate

ADCO-SALTERPYN® SYRUP contains methyl hydroxybenzoate (0,10 % m/v) and propyl hydroxybenzoate (0,01 % m/v) as preservatives, which may cause allergic reactions (which can possibly be delayed).

ADCO-SALTERPYN® SYRUP contains alcohol

ADCO-SALTERPYN® SYRUP contains 0,625 ml of alcohol (ethanol) in each 5 ml of syrup which is equivalent to 12,5 % v/v. This is about the same amount of alcohol in 5 ml of wine. The small amount of alcohol in this medicine should not have any noticeable effects.

ADCO-SALTERPYN® SYRUP contains sugar

Each 5 ml syrup contains 1,10 g sucrose, 2,0 g liquid glucose and 600 mg invert syrup; all of which contributes to the sugar content of ADCO-SALTERPYN® SYRUP.

The sugar content of ADCO-SALTERPYN® SYRUP should be taken into account if your child is diabetic (has blood sugar problems).

If you have been told by your child's doctor that he / she has an intolerance to some sugars, contact the doctor before giving ADCO-SALTERPYN® SYRUP to your child.

ADCO-SALTERPYN® SYRUP contains propylene glycol

Each 5 ml syrup contains 0,26 ml propylene glycol. 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.

3. How to give ADCO-SALTERPYN® SYRUP to your child

Do not share medicines prescribed for you, or your child, with any other person.

Always give ADCO-SALTERPYN® SYRUP exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose:

- for children 2 to 5 years: 5 ml three times a day.
- for children 6 to 12 years: 5 to 10 ml three times a day.

Do not give ADCO-SALTERPYN® SYRUP continuously for more than 10 days without consulting a doctor.

If you give more ADCO-SALTERPYN® SYRUP to your child than you should

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

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Take this medicine with you to show the doctor.

Paracetamol

ADCO-SALTERPYN® SYRUP contains paracetamol which may be fatal (cause death) in overdose. If you have given your child too much of this medicine, think you might have given your child too much ADCO-SALTERPYN® SYRUP or if your child has accidentally swallowed some of this medicine (or you think he / she might have), contact the nearest doctor, hospital or poison control centre immediately. Do this even if your child is not showing or experiencing any symptoms. Prompt specialised treatment is essential as soon as possible.

The initial symptoms of paracetamol overdose (taking too much paracetamol), within the first 24 hours, may include pale appearance, nausea (feeling sick), vomiting (being sick), loss of appetite and abdominal pain.

Even though these initial symptoms may appear mild, paracetamol overdose is a serious condition, and liver damage may only become apparent 12 to 48 hours after the paracetamol overdose. Other serious adverse effects which may occur include kidney problems (and failure), abnormal heart rhythm, abnormal glucose metabolism and metabolic acidosis (abnormal increase in the acidity of the body's fluids).

Due to the seriousness of paracetamol overdose, and the risk for serious adverse reactions (including death), your child may be treated for such even if their symptoms appear mild.

Codeine

ADCO-SALTERPYN® SYRUP contains codeine. Symptoms of codeine overdose (taking too much codeine) include nausea (feeling sick), vomiting (being sick), drowsiness and breathing problems.

Promethazine

ADCO-SALTERPYN® SYRUP contains promethazine. Overdose with promethazine is serious and can be fatal (cause death), especially in infants and children. Symptoms of promethazine overdose in children include excitation, moving unsteadily or stumbling, uncontrolled wriggling movements/tremor (especially of the hands or feet), dilated pupils, dry mouth, flushed face, hyperpyrexia (abnormally high body temperature), hallucinations (seeing, hearing, smelling or feeling things that are not there), drowsiness, fits (seizures) and breathing problems. Specialised

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treatment of overdose is essential and the patient should be moved to a hospital as soon as possible.

If you forget to give ADCO-SALTERPYN® SYRUP

DO NOT EXCEED THE RECOMMENDED DOSE. Do not give your child a double dose to make up for forgotten individual doses.

4. Possible side effects

ADCO-SALTERPYN® SYRUP can have side effects.

Not all side effects reported for ADCO-SALTERPYN® SYRUP are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking ADCO-SALTERPYN® SYRUP, please consult your health care provider for advice.

If any of the following happens, stop giving ADCO-SALTERPYN® SYRUP to your child, 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;
- muscle rigidity or spasms, rapid and shallow breathing, rapid heart rate, very high body temperature, sweating excessively, and patchy, irregular skin colour (mottled skin).

These are all very serious side effects. If your child has them, he / she may have had a serious allergic reaction to ADCO-SALTERPYN® SYRUP. Your child may need urgent medical attention or hospitalisation.

Stop giving ADCO-SALTERPYN® SYRUP and call your doctor at once if your child experience any of the following:

- nausea, vomiting, stomach pain, itching and loss of appetite;
- dark urine and jaundice (yellowing of the skin or eyes);
- tiredness or extreme drowsiness / sleepiness;
- nervousness/excitement, hallucinations (seeing, hearing, feeling or smelling things that are not there), tremors, muscle twitching, fits (seizures) and high fever.

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These are all serious side effects and may be due to liver problems or that your child has been given too much of this medicine. Your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- constipation.

Less frequent side effects:

- skin rash and / or redness, hives and skin sensitivity (increase in the reactivity to light known as photosensitivity);
- dizziness, low blood pressure (also known as hypotension which may cause dizziness) and blurred vision;
- nausea (feeling sick), vomiting (being sick), loss of appetite and dry mouth;
- changes in blood count (be picked up with a blood test) and a type of anaemia known as haemolytic anaemia (lack of red blood cells due to destruction of circulating cells);
- feeling irritable or restless;
- increase in heart rate;
- difficulty in passing urine.

Side effects with an unknown frequency:

- lack of concentration or confusion;
- generally feeling unhappy, restless, dissatisfied or depressed;
- feeling extremely happy or exhilarated;
- hallucinations (seeing, hearing, smelling or feeling things that are not there i.e., perception of a non-existent object or event);
- difficulty in sleeping (insomnia);
- lassitude (lack of energy, fatigue, lethargy), tiredness and weakness;
- muscular weakness (including of the hands) and in-coordination;
- headache;
- ringing in ears (tinnitus);
- changes to the eyes or vision;
- feeling tight chested;
- colic or upper stomach pain and diarrhoea;

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- passing of more than usual / excessive amounts of urine;
- increase (fever) or decrease of body temperature;
- mucosal skin lesions (which appear, for example, on soft skin tissue or inside the body, like the lips, mouth, skin around genitals);
- pancreatitis (which may include signs and symptoms like stomach pain that also radiates to the back, nausea and vomiting, fever, chills, tender and swollen stomach, diarrhoea and indigestion).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. 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 ADCO-SALTERPYN® SYRUP.

5. How to store ADCO-SALTERPYN® SYRUP

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light.
- 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).

6. Contents of the pack and other information

What ADCO-SALTERPYN® SYRUP contains

- The active substances are codeine phosphate, promethazine hydrochloride and paracetamol.
- Each 5 ml of ADCO-SALTERPYN® SYRUP contains 5 mg codeine phosphate, 6,5 mg promethazine hydrochloride and 120 mg paracetamol.
- The other ingredients are methyl hydroxybenzoate (0,10 % m/v), propyl hydroxybenzoate (0,01 % m/v), ethanol (12,5 % v/v), propylene glycol, sucrose, glycerol, citric acid (for pH adjustment), liquid glucose, invert syrup, raspberry red H1277 (CI 14720), blackcurrant

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colour F1134 (CI 14720/42090115985), vanilla flavour no. 1, essence blackcurrant and purified water.

What ADCO-SALTERPYN® SYRUP looks like and contents of the pack

ADCO-SALTERPYN® SYRUP is a mauve to maroon-coloured, clear syrup with a distinctive flavour of blackcurrant.

ADCO-SALTERPYN® SYRUP is packed in bottles containing 100 ml and 2,5 L of syrup.

Holder of Certificate of Registration

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