SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ADCO-SALTERPYN® SYRUP,

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains:

Codeine phosphate 5 mg

Promethazine hydrochloride 6,5 mg

Paracetamol 120 mg

Preservatives:

Methyl hydroxybenzoate 0,10 % *m/v*

Propyl hydroxybenzoate 0,01 % *m/v*

Contains alcohol: 12,5 % *v/v*

Contains sugar:

Sucrose 1,10 g

Liquid glucose 2,0 g

Invert syrup 600 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

Mauve to maroon-coloured, clear syrup with a distinctive flavour of blackcurrant.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ADCO-SALTERPYN® SYRUP is indicated for the relief of mild to moderate pain, associated with fever.

4.2 Posology and method of administration

DO NOT EXCEED THE RECOMMENDED DOSE.

2 to 5 years: One medicine-measure (5 ml) three times a day.

6 to 12 years: One to two medicine-measures (5 to 10 ml) three times a day.
SHAKE THE BOTTLE WELL BEFORE USE

4.3 Contraindications

- Sensitivity to paracetamol, opiates or phenothiazines.
- Contraindicated in children under 2 years of age.
- Patients with liver and/or kidney damage

4.4 Special warnings and precautions for use

This product 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 Centre must be contacted immediately.

Dosages in excess of those recommended may cause severe liver damage.

If the patient does not respond, a doctor should be consulted.
Do not use continuously for more than 10 days without consulting a doctor.

This medicine may cause drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.

Pigments should be examined periodically for abnormal skin pigmentation or eye changes.

Codeine: Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.

Do not administer to patients with liver or kidney damage. If taken in excess, this medicine may cause liver damage which may be fatal.
Large doses of promethazine may precipitate fits in epileptics.

Serious life-threatening cases of respiratory depression, including fatalities have been reported with promethazine use in paediatric patients less than 2 years of age

Excipients

ADCO-SALTERPYN® SYRUP contains sucrose and glucose which may have an effect on the

glycaemic control of patients with diabetes mellitus.
ADCO-SALTERPYN® SYRUP contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take ADCO-SALTERPYN® SYRUP.

4.5 Interaction with other medicines and other forms of interaction

No information available.

4.6 Fertility, pregnancy and lactation

No information available.

4.7 Effects on ability to drive and use machines

This medicine may cause drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.

4.8 Undesirable effects

Tabulated list of adverse reactions

Codeine

System Organ Class	**Frequent**	**Less frequent**	**Frequency not known**
Immune system disorders		Urticaria.	
Psychiatric disorders			Mental clouding and dysphoria.
Vascular disorders		Dizziness.	
Gastrointestinal disorders	Constipation.	Nausea and vomiting.	
Hepatobiliary disorders			Increased pressure in the biliary tract.
Skin and subcutaneous tissue disorders		Skin rash.	

Promethazine

System Organ Class	**Frequent**	**Less frequent**	**Frequency not known**
Blood and lymphatic system disorders		Blood dyscrasias and haemolytic anaemia.	Thrombocytopenia purpura and agranulocytosis.
Immune system disorders			Allergic reactions, idiosyncrasy and lupus erythematous-like syndrome.
Metabolism and nutrition disorders		Anorexia.	
Psychiatric disorders		Irritability and restlessness.	Depression, elation, hallucinations and insomnia.
Nervous system disorders		Blurred vision.	Muscular weakness, headache, tinnitus, extrapyramidal dysfunction and incoordination.
Eye disorders			Deposition of pigment in the eyes, corneal and lens opacities.
Cardiac disorders		Increase in heart rate.	
Vascular disorders		Hypotension and dizziness.	
Respiratory, thoracic and mediastinal			Tightness of chest.

System Organ Class	Frequent	Less frequent	Frequency not known
disorders			
Gastrointestinal disorders		Dryness of the mouth.	Nausea, vomiting, colic or epigastric pain and diarrhoea or constipation.
Hepatobiliary disorders			Jaundice of the obstructive type.
Skin and subcutaneous tissue disorders		Photosensitivity and skin rash.	
Musculoskeletal and connective tissue disorders			Weakness of hands.
Renal and urinary disorders		Difficulty in micturition.	Polyuria.
General disorders and administration site conditions			Lassitude, tiredness, weakness, lowering of blood temperature and pyrexia.

Paracetamol

System Organ Class	Frequent	Less frequent	Frequency not known
Blood and lymphatic system disorders			Leucopenia, pancytopenia and neutropenia.
Immune system disorders		Allergic reactions.	

System Organ Class	Frequent	Less frequent	Frequency not known
Gastrointestinal disorders			Pancreatitis.
Skin and subcutaneous tissue disorders		Skin rash (usually erythematous or urticarial).	Mucosal lesions.
General disorders and administration site conditions			Drug fever.

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. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Codeine:

Symptoms of overdosage with codeine phosphate include nausea, vomiting and drowsiness or coma and respiratory collapse.

In acute poisoning with codeine phosphate, the stomach should be emptied by aspiration and lavage.

Intensive supportive therapy may be necessary to correct respiratory failure and shock. The specific antagonist naloxone may be used to counteract severe respiratory depression.

Promethazine:

Promethazine overdosage may be fatal, especially in infants and children in whom main symptoms are central nervous system stimulation and antimuscarinic effects including ataxia, excitement, hallucinations, hyperpyrexia and respiratory collapse. Death may occur from

respiratory failure.

Drowsiness and hypotension may occur. Treatment is symptomatic and supportive.

Paracetamol:

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 – 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenaseactivity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage: Although evidence is limited it is recommended that any adult person who has ingested 5 – 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube.

Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given **intravenously** over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four

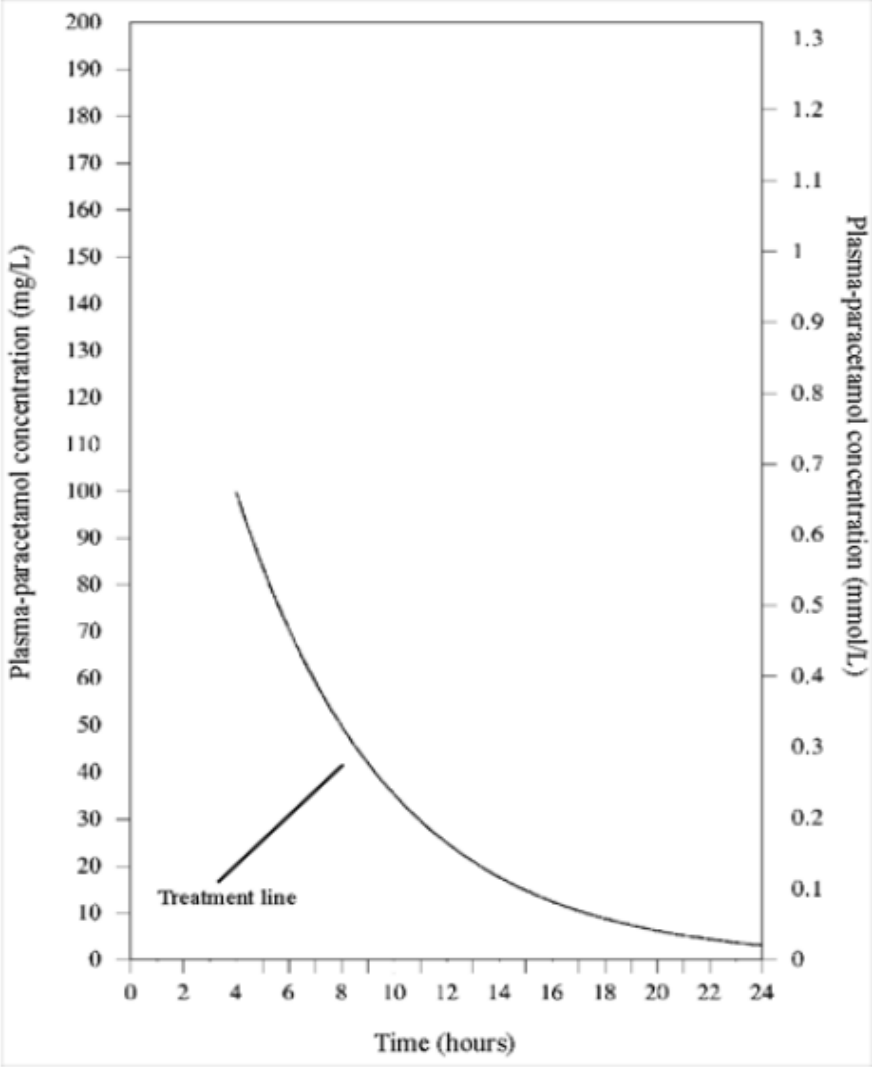
hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children.**

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram. The nomogram should be used only in relation to a single acute ingestion.

Those whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line". Prothrombin index correlates best with survival.

Monitor all patients with significant ingestions for at least ninety-six hours.



(Reference: Martindale)

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Classification: A 2.8 Special analgesic combinations.

ADCO-SALTERPYN® SYRUP has analgesic, antipyretic and antihistaminic properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate

Propyl hydroxybenzoate

Ethanol (96 % v/v)
Propylene glycol
Sucrose
Glycerol
Citric Acid (for pH adjustment)
Liquid glucose
Invert syrup
Raspberry Red H1277 (CI 14720)
Blackcurrant colour F1134 (CI 14720/42090/15985)
Vanilla flavour No. 1
Essence blackcurrant
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Bottles containing 100 ml and 2,5 L of syrup.
100 ml PVC long round amber bottle with a 24 mm LLDPE white snap on cap (not lined).
2,5 L HDPE rectangular amber bottle with a white polypropylene screw-on cap containing a built in polypropylene frustum as sealer.

Not all pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicine or waste material should be disposed of in accordance with local

requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)

27/2.8/0575

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 November 1993

10. DATE OF REVISION OF THE TEXT

14 October 2022

Namibia NS1: 05/2.8/0255

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PI 31594 04/2023