PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
S2

ASTRAPAIN SYRUP (Syrup)
Paracetamol 120 mg, Codeine phosphate 5 mg, Promethazine hydrochloride 6,5 mg.
Contains sugar:
Sucrose 2.0 g / 5 ml
Liquid glucose 2.0 g / 5 ml
Invert syrup 600 mg / 5 ml
Contains sweetener:
Sodium saccharin: 1,5 mg / 5 ml
Sodium cyclamate: 30 mg / 5 ml

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

- Keep this leaflet. You may need to read it again.
- Do not share **ASTRAPAIN 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 a few days.

What is in this leaflet

6. Contents of the pack and other information.

1. What ASTRAPAIN SYRUP is and what it is used for

ASTRAPAIN SYRUP is used for the relief of mild to moderate pain, associated with fever.

2. What you need to know before you take ASTRAPAIN SYRUP

Do not take ASTRAPAIN SYRUP :

- if you are hypersensitive (allergic) to paracetamol, codeine phosphate, promethazine hydrochloride or any other ingredients of **ASTRAPAIN SYRUP** (listed in section 6).
- if you are hypersensitive (allergic) to opiates or phenothiazines
- if you are sensitive to one antihistamine and may be sensitive to others
- if you suffer from kidney or liver problems
- if you have an attack of bronchial asthma, respiratory depression, especially in the presence of cyanosis (bluish discolouration of skin due to lack of oxygen) and excessive bronchial (relating to air passages in the lungs) secretion.
- If you are an alcoholic.
- If you have heart failure secondary to chronic lung disease, head injuries where the intracranial pressure (pressure inside the skull) is raised.
- do not give to children under the age of 2 years or to comatose-patients.
- If you are pregnant.
- If you are breastfeeding.
- If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment

Warnings and precautions

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.

Take special care with ASTRAPAIN SYRUP:

- if you take more than the recommended dose as it can cause severe liver damage.
- If no symptomatic improvement results, a doctor should be consulted.
- Do not drive or operate any tools or machines because this medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents.
- Pigments should be examined periodically for abnormal skin pigmentation or eye changes.
- Do not exceed the prescribed dose because exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.
- The use of promethazine may be associated with the sudden infant death syndrome.

Paracetamol:

Other products that contain paracetamol should not be taken at the same time as **ASTRAPAIN SYRUP**.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systematic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR, treatment with ASTRAPAIN SYRUP must immediately be discontinued and appropriate treatment instituted.

Codeine:

- Should be used with caution or in reduced doses in patient with adrenocortical insufficiency (failure of a part of the adrenal gland to produce adequate steroid hormones).
- Should be used with caution or reduced doses in patients with obstructive bowel disorders.
- Dosage should be reduced in debilitated patients.
- Should be used with caution or reduced doses in patients with hypothyroidism (underactive thyroid gland).
- Should be used with caution in patients with myasthenia gravis (muscle disorder causing weakness) or impaired function or shock.
- Prolonged use of high doses of codeine has produced dependence.

Promethazine:

- Promethazine has anticholinergic (a substance to stop the passage of certain nerve impulses involving acetyl choline) properties and should be used with care in conditions such as glaucoma (raised pressure in the eye) and prostatic hypertrophy (enlargement of prostate gland).
- Care should be taken when administering promethazine during the first trimester of pregnancy.
- Promethazine should be used cautiously in patients with cardiac failure, hypertension (high blood pressure), peripheral oedema (swelling of hands and feet due to retained fluid) and pulmonary oedema (excessive fluid accumulation in lungs) and in toxaemia (spread of bacterial products (toxins) by the bloodstream) or pregnancy. In young children, spasm of the glottis (the vocal apparatus of the larynx) may occur.

Children/ and adolescents

Do not give to children under the age of 2 years or to comatose-patients.

Other medicines and ASTRAPAIN SYRUP

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

Care should be taken if concomitantly taking with:

- Nervous system depressants such as alcohol, barbiturates, hypnotics (causes sleep), narcotic analgesics (dependence producing substances used for the relief of pain), sedatives (for calming) and tranquillisers (medicines used for calming nerves) and
- Anticholinergic medicines (a substance used to stop the release of certain nerve impulses involving acetylcholine),
- Tricyclic antidepressants and phenothiazines as their effects may be enhanced by promethazine
- Antidepressants such as Monoamine-oxidase inhibitors (MAOI's) will potentiate both the drowsiness effect and the anticholinergic effects of promethazine, therefore, ASTRAPAIN SYRUP should not be taken concurrently with patients taking MAOI's or within 14 days of stopping therapy with MAOI's
- The effects of the medicines with anticholinergic activity such as tricyclic antidepressants or phenothiazine will be potentiated.
- Ototoxic medicines (medicines that causes damage to the ear) may be masked.
- Promethazine may increase the hypotensive (lowering of blood pressure) effect of antihypertensives.
- The antiparkinson's effect of levodopa may be inhibited.
- Antihistamines may suppress positive skin test results and should be stopped several days before the test.

Pregnancy and breastfeeding and fertility

You should not take ASTRAPAIN SYRUP if you are pregnant or breastfeeding your baby.

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 machinery

Do not drive or operate any tools or machines because this medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents.

ASTRAPAIN SYRUP contains:

ASTRAPAIN SYRUP contains sucrose, liquid glucose, invert syrup
If you have been told by your doctor that you have an intolerance to some sugars, contact you doctor before taking this medicinal product.

ASTRAPAIN SYRUP contains propylene glycol
If your child is less thant 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.
If you suffer from a liver or kidney disease, do not take this medicine.

ASTRAPAIN SYRUP contains ethanol.
Co-administration (administration of two medicines) with medicines containing e.g. propylene glycol or ethanol may lead to accumulation (collection) of ethanol and induce (bring on) adversed effects, in particular in young children with low or immature metabolic capacity.

3. How to take ASTRAPAIN SYRUP

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

Always take ASTRAPAIN SYRUP exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

DO NOT EXCEED THE RECOMMENDED DOSAGE

Not recommended for children under 2 years of age.

Children 2 to 5 years: 5 ml three times a day.

Children 6 years and older: 5 to 10 ml three times a day.

Do not use continuously for more than 5 days for pain and 3 days for fever.

Shake the bottle before use.

If you have the impression that the effect of **ASTRAPAIN SYRUP** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ASTRAPAIN SYRUP than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Paracetamol:

If you take too much **ASTRAPAIN SYRUP**, prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly. 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 medicines that include 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 (lack of appetite), 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 dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may lead to encephalopathy, coma and death.

Acute kidney failure with acute tubular necrosis (death of tissue) may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis (abnormal increase in the acidity of the body's fluids) may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage:

N-acetylcysteine should be administered to all cases of suspected overdosage as soon as possible, preferably within 8 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 4 hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next 16 hours. **The volume of intravenous fluids 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 4 hours for seventeen doses.

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

Those whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over 16 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 ingestion for at least 96 hours.

Codeine Phosphate:

Symptoms of overdosage of codeine include excitement, convulsions and respiratory failure. 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:

Overdosage of promethazine may be fatal, especially in infants and children in whom main symptoms are nervous system stimulation and antimuscarinic effects including ataxia (loss of muscle co-ordination), excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face, hyperpyrexia (high fever state; abnormally high body temperature) and respiratory collapse (breathing collapse). Specialised treatment of overdosage is essential and the patient should be moved to a hospital as soon as possible. Treatment of overdosage is symptomatic and supportive.

If you forget to take a dose of ASTRAPAIN SYRUP

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

4. Possible side effects

ASTRAPAIN SYRUP can have side effects.
Not all side effects reported for ASTRAPAIN SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASTRAPAIN SYRUP, please consult your healthcare professional for advice.

If any of the following happens, stop taking ASTRAPAIN 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;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASTRAPAIN 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:

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea
- Vomiting
- Constipation
- Drowsiness and confusion
- Sedation (which can vary from slight drowsiness to deep sleep and including inability to concentrate)
- Lassitude (lack of energy, fatigue, lethargy)
- Dizziness
- Hypertension (high blood pressure)
- Muscular weakness and in-coordination

Less frequent side effects:

- Neutropenia (too few white blood cells)
- Pancytopenia (too few blood cells of all types)
- Leucopenia (too few white blood cells)
- If taken in excess, this medicine may casuse liver damage which may be fatal
- Skin rashes and other allergic reactions may occur. The rash is usually erythematous (red skin rash) or urticaria (allergic skin reaction / nettle-rash) but sometimes more serious and may be accompanied by fever and mucosal (tissues that produce mucus) lesions (deterioration of tissue due to injury or disease).
- Dryness of mouth
- Sweating
- Facial flushing
- Dizziness
- Restlessness
- Changes of mood may occur
- Difficulty in passing urine
- Ureteric spasm (Colic/spasm of the ureter/kidney duct)
- Biliary spasm (spasm of bile duct)

- Bradycardia (abnormally slow pulse rate)
- Palpitations (rapid irregular action heart)
- Respiratory depression (abnormally slow and/or shallow breathing)
- Orthostatic hypotension (drop in blood pressure when standing up)
- Hypothermia (abnormally low body temperature)
- Miosis (Contraction of the pupil of eye) may occur
- Raised intracranial pressure (pressure inside the skull) may occur
- Due to the histamine releasing effect, reactions sus a urticaria (allergic skin reaction / nettle-rash) and pruritis (itching) may occur in infants and children.
- Blood dyscrasias (serious blood disorder)
- Agranulocytosis (severe decrease in a particular type of white blood cells)
- Leucopenia (too few white blood cells)
- Haemolytic anaemia (lack of red blood cells due to destruction of circulation cells).
- Epigastric pain (pain in upper, middle region of stomach).
- Headache
- Tinnitus (ringing in the ears)
- Elation of depression
- Irritability
- Nightmares
- Dryness of the mouth
- Tightness of the chest and tingling
- Dizziness and weakness of the hands may occur
- In infants and children it may act as a cerebral stimulant . Symptoms of stimulation include insomnia (inability to sleep), nervousness, tachycardia (increased rate of heart beat_ tremors, musclce twitching and convulsions.
- Large doses may preciptitate fits in epileptics.
- Photosensitivity reactions (increase in the reactivity of the skin to light) may occur.
- Allergic reactions anaphylaxis (sudden, life threatening severe allergic reaction) may occur.
- Anorexia (loss of appetite), or increased appetite
- Difficulty in passing urine may also occur.
- Extrapyramidal symptoms may develop.

Frequency unknown side effects:

- Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicine.

Post Marketing Experience:

Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicine. If a patient develops SCAR (Severe cutaneous adverse reactions), treatment with ASTRAPAIN SYRUP must immediately be discontinued and appropriate treatment instituted.

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. This includes any possible side effects not listed in this leafltet. 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/. By reporting side effects, you can help provide more information on the safety of **AstraPain Syrup.**

5. How to store ASTRAPAIN SYRUP

- Store in well closed containers, at or below 25°C.
- Protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in the original container.
- 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).

6. Contents of the pack and other information

What ASTRAPAIN SYRUP contains:

- The active substances are

Paracetamol 120 mg / 5 ml

Codeine Phosphate 5 mg / 5 ml

Promethazine Hydrochloride 6.5 mg / 5 ml

- The other ingredients are

Blackcurrant colour

Citric Acid

Essence Blackcurrant

Ethanol 96% v/v

Invert Syrup

Liquid Glucose

Methylparaben

Propylene Glycol

Propylparaben

Raspberry Red

Sodium Cyclamate

Sodium Saccharin

Sucrose

Vanilla Flavour

What ASTRAPAIN SYRUP looks like and contents of the pack

Mauve to maroon coloured clear syrup with a distinctive flavour of blackcurrant.
Amber, plastic PVC or glass bottles containing 100 ml of syrup.

Holder of Certificate of Registration and Manufacturer

Astral Pharma (Pty) Ltd
125 Meade Street
George
6529
South Africa

This leaflet was last revised in

Date of registration: 14 January 1995
Date of revision of text: 31 December 2023

Registration number

27/2.8/0139

Access to the corresponding Professional Information
Can be obtained on the SAHPRA website