PATIENT INFORMATION LEAFLET

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

This medicine 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.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

S2

PROPRIETARY NAME (and dosage form)

ASTRAPAIN SYRUP

WHAT ASTRAPAIN SYRUP CONTAINS

- The active substances are Paracetamol, Codeine Phosphate and Promethazine hydrochloride.
- **ASTRAPAIN SYRUP** contains Methyl paraben and Propyl paraben as preservatives.
- Contains alcohol.
- Contains sugar.
- The other ingredients are: Propylene Glycol, Sodium Saccharin, Citric Acid, Liquid Glucose, Invert Syrup, Sodium Cyclamate, Raspberry Red H1277 (Cl 14720),

Blackcurrant Colour F1134 (CJ 14720 / 42090 / 15985), Vanilla Flavour No. 1, Essence of Blackcurrant, Purified water.

WHAT ASTRAPAIN SYRUP IS USED FOR

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

BEFORE YOU TAKE ASTRAPAIN SYRUP

Do not take ASTRAPAIN SYRUP:

- if you are hypersensitive (allergic) to paracetamol, opiates or phenothiazines
- 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 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.

Take special care with ASTRAPAIN SYRUP:

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.

- 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 use continuously for more than 10 days without consulting your doctor.
- 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.
- Should be used with extreme caution in patients receiving monoaminoxidase inhibitors.
- Pigments should be examined periodically for abnormal skin pigmentation or eye changes.
- Patients suffering from renal or liver diseases should take paracetamol under medical supervision.
- 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.

Pregnancy and Breast-feeding

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with ASTRAPAIN SYRUP:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ASTRAPAIN SYRUP** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

HOW TO TAKE ASTRAPAIN SYRUP

Always take **ASTRAPAIN SYRUP** exactly as instructed. You should check with your doctor or pharmacist if you are unsure

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.

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, seek help at the nearest hospital or poison control center.

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:

Although evidence is limited it is recommended that any adult person who has ingested about 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 (washing out of stomach) in order to avoid aspiration (sucking out).

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. In acute poisoning, the stomach should be emptied by aspiration and lavage (sucking out and washing). 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.

POSSIBLE SIDE EFFECTS

ASTRAPAIN SYRUP can have side effects.

Possible side-effects include the following:

SIDE-EFFECTS:

Paracetamol:

Blood disorders: *(Less frequent)*: Neutropenia (too few white blood cells), pancytopenia (too few blood cells of all types) and leucopenia (too few white blood cells).

Hepatic disorders: *(Less frequent)*: If taken in excess, this medicine may cause liver damage which may be fatal.

Skin disorders: *(Less frequent)*: Skin rashes and other allergic reactions may occur. The rash is usually erythematous (red skin rash) or urticarial (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).

Codeine:

Gastrointestinal disorders: *(Frequent):* Nausea, vomiting, and constipation.

Nervous system disorders: *(Frequent)*: Drowsiness and confusion.

(Less frequent): Dryness of the mouth, sweating, facial flushing, dizziness, restlessness, and changes of mood may occur.

Urinary disorders: *(Less frequent)*: Difficulty in passing of urine, ureteric spasm (colic/spasm of the ureter/kidney duct) or biliary spasm (spasm of bile duct).

Other disorders: *(Less frequent)*: Bradycardia (abnormally slow pulse rate), palpitations (rapid irregular action of heart), respiratory depression (abnormally slow and/or shallow breathing}, orthostatic hypotension (drop in blood pressure when standing up), hypothermia (abnormally low body temperature), and 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 such as urticaria (allergic skin reaction/nettle-rash) and pruritis (itching) may occur in infants and children.

Promethazine:

Blood disorders: *(Less frequent)*: Blood dyscrasias (serious blood disorder) including agranulocytosis (severe decrease in a particular type of white blood cells), leucopenia (too few white blood cells) and haemolytic anaemia (lack of red blood cells due to destruction of circulating cells).

Gastrointestinal disorders: *(Less frequent)*: Nausea, vomiting, diarrhoea or constipation and epigastric pain (pain in upper, middle region of stomach).

Nervous system disorders: *(Frequent)*: Sedation, which can vary from slight drowsiness to deep sleep and including inability to concentrate, lassitude (Jack of energy, fatigue, lethargy), dizziness, hypertension (high blood pressure), muscular weakness and in-coordination.

(Less frequent): Headache, tinnitus (ringing in the ears), elation or 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, muscle twitching and convulsions. Large doses may precipitate fits in epileptics.

Skin disorders: *(Less frequent)*: Photosensitivity reactions (increase in the reactivity of the skin to light) may occur.

Other disorders: *(Less frequent)*: Allergic reactions anaphylaxis (sudden, life-threatening severe allergic reaction) may occur. Anorexia (loss of appetite), or increased appetite, and difficulty in passing urine may also occur. Extrapyramidal symptoms may develop.

PRECAUTIONS:

Paracetamol:

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

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 liver

impairment, myasthenia gravis (muscle disorder causing weakness), 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), impaired kidney function, liver disorders 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.

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

STORING AND DISPOSING OF ASTRAPAIN SYRUP

Store in well closed containers, below 25°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

PRESENTATION OF ASTRAPAIN SYRUP

Amber, plastic PVC or glass bottles containing 100 ml of syrup.

IDENTIFICATION OF ASTRAPAIN SYRUP

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

REGISTRATION NUMBER

27/2.8/0139

NAME AND ADDRESS OF REGISTRATION HOLDER

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