PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS **S5**

PROPRIETARY NAME (and dosage form)

WHAT ASTRAPAIN FORTE TABLETS CONTAINS

- The active substances are (per tablet):

  Paracetamol ……320 mg

  Codeine Phosphate…….8 mg

  Caffeine anhydrous……32 mg

  Meprobamate……150 mg

- The other ingredients are: Apple Green (CI 19140, CI 44090) Colloidal Silicone Dioxide (Aerosil 200), Magnesium Stearate, Nipastat (as preservative) - 0,025% (m/m), Povidone K90, Powdered Acacia, Purified Talc, Starch Maize.

Contains Tartrazine

Contains no sugar.

WHAT ASTRAPAIN FORTE TABLETS IS USED FOR

Pain and pain associated with tension.

Short term use in mild to moderate pain associated with anxiety or tension.

BEFORE YOU TAKE ASTRAPAIN FORTE TABLETS

Do not take ASTRAPAIN FORTE TABLETS:

- if you are hypersensitive (allergic) to paracetamol, codeine phosphate, caffeine, meprobamate or any of the other ingredients of **ASTRAPAIN FORTE TABLETS** as listed above.

i) Contra-indications

ASTRAPAIN FORTE TABLETS should not be used by patients with:

- acute intermittent porphyria (inherited disorder of blood pigment metabolism).
- by patients with kidney or liver insufficiency.
- Safety of **ASTRAPAIN FORTE TABLETS** during pregnancy has not been established.

- Asthma, respiratory depression especially in the presence of cyanosis and excessive bronchial (relating to air passages in lungs) secretion.
- head injuries and conditions in which intracranial pressure (pressure inside the skull) is raised.
- heart failure secondary to chronic lung disease, a history of heart disease, recurrent fits and all convulsive states.
- Patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Porphyria (inherited disorder of blood pigment metabolism).

ii) Warnings

Take special care with ASTRAPAIN FORTE TABLETS:

Paracetamol administration in excess of the recommended dosage may cause severe liver damage.

In the event of overdosage or suspected overdosage and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison control centre must be contacted immediately.

Driving and using machinery:

It is dangerous to drive a vehicle because using this medicine may cause drowsiness.

It is dangerous to operate any tools or machines because using this medicine may cause drowsiness.

This product contains Tartrazine which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of Tartrazine sensitivity in the general population is currently thought to be low, it is frequently seen in patients who also have aspirin sensitivity.

Prolonged use of high doses of codeine may lead to dependency and addiction.

iii) Pregnancy and Breastfeeding

Safety and efficacy in pregnancy and lactation have not been established.

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

iv) Precautions

Codeine should be used with caution or in reduced doses in patients with adrenocortical insufficiency (failure of a part of the adrenal gland to produce adequate steroid hormones). Should be used with caution in patients with obstructive bowel disorders. Dosage should be reduced in debilitated and in elderly patients. Should be used with caution or reduced doses in patients with hypothyroidism. Should be used with caution in patients with liver impairment, myasthenia gravis (muscle disorder causing weakness), prostatic hypertrophy (enlargement of prostate gland), impaired kidney function or shock. Prolonged use of high doses of codeine may lead to dependence.

Caffeine should be taken with care by patients with a history of peptic ulceration (stomach and duodenal ulcers) or hyperacidity (heartburn; excess stomach acid).

With prolonged use some degree of tolerance and psychic dependence may occur.

Due to the dependence potential meprobamate should be gradually withdrawn after long term treatment. Meprobamate may lower the tolerance to alcohol and other central nervous system depressants.

v) Interactions when taking other medicines

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

Due to codeine, **ASTRAPAIN FORTE TABLETS** may affect the activity of other medicines by delaying the absorption. The depressant effects are aggravated by alcohol, anaesthetics, hypnotics sedatives, tricyclic antidepressants and phenothiazines.

Hepatotoxic medicines – Increased risk of hepatoxicity.

Enzyme inducing medicines – Increased risk of hepatoxicity.

Possible decrease in therapeutic effects of **ASTRAPAIN FORTE TABLETS.**

Metoclopramide – Absorption of **ASTRAPAIN FORTE TABLETS** may be accelerated.

Cholestyramine – Absorption of **ASTRAPAIN FORTE TABLETS** is reduced if given within one hour of cholestyramine.

Prolonged concurrent use of **ASTRAPAIN FORTE TABLETS** with salicylates increases the risk of adverse renal effects.

- Due to the active caffeine, which undergoes extensive metabolism by hepatic microsomal cytochrome P450, **ASTRAPAIN FORTE TABLETS** is subject to numerous interactions with other medicines which enhance or reduce its metabolic clearance.
- **ASTRAPAIN FORTE TABLETS** may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesics.
- **ASTRAPAIN FORTE TABLETS** has an additive antimuscarinic action with other antimuscarinic medicines such as atropine and antidepressants (both tricyclic and monoamineoxidase inhibitors.)

ASTRAPAIN FORTE TABLETS may enhance the metabolism of oral contraceptives, corticosteroids, phenytoin, phenothiazines and tricyclic antidepressants.

HOW TO TAKE ASTRAPAIN FORTE TABLETS

Always take ASTRAPAIN FORTE TABLETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is:

Not recommended for children under the age of 12 years.

Adults: Two tablets every 6 to 8 hours as needed.

Not to be used for longer than 10 days.

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

If you take more ASTRAPAIN FORTE TABLETS 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 immediately. Take this leaflet or some tablets with you so your doctor will know what you have taken.

Symptoms of overdosage with *codeine phosphate* include the following: nausea, vomiting, restlessness, sensory disturbances, muscle tremor, diuresis (increased urine secretion), palpitations (rapid irregular action of heart), stupor, shock, central stimulation with excitement, convulsions, drowsiness, respiratory depression (abnormally slow and/or shallow breathing), hypotension (low blood pressure) with circulatory failure, respiratory collapse, cyanosis (bluish discoloration of skin due to lack of oxygen) and coma.

Symptoms of *paracetamol* overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia (lack of appetite) and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.

Symptoms of *meprobamate* overdosage include hypotension (low blood pressure) and symptoms mainly due to the depressant effect on the central nervous system.

POSSIBLE SIDE EFFECTS

ASTRAPAIN FORTE TABLETS can have side effects:

Paracetamol:

Less frequent: Neutropenia (too few white blood cells), pancytopenia (too few blood cells of all types) and leucopenia (too few white blood cells). Skin rashes and other allergic reactions may occur. This rash is usually erythematous (red skin rash) or urticarial (nettle-rash), but sometimes more serious and may be accompanied by fever and mucosal lesions (deterioration of tissue due to injury or disease).

Meprobamate:

Less frequent: Agranulocytosis (severe decrease in a particular type of white blood cells), eosinophilia (increased number of a certain type of white blood cells in blood), leucopenia (too few white blood cells), thrombocytopenia (too few blood platelets) and aplastic anaemia (serious reduction of blood cells, due to failure of the bone marrow). Low blood pressure, tachycardia (increased rate of hart beat), and irregular heart beat. Disturbances of vision. Nausea, vomiting, diarrhoea. Drowsiness, paraesthesia (numbness; tingling; pins & needles), weakness, headache, paradoxical excitement (excites instead of sedates), dizziness, loss of muscle co-ordination. Hypersensitivity reactions such as skin rashes, urticaria (nettle-rash), purpura, angioedema, erythema multiforme and exfoliative or bullous dermatitis may occur. Symptoms of porphyria (inherited disorder of blood pigment metabolism) may be exacerbated. Bronchospasm (constriction of air passages) or anuria (failure of kidneys to produce urine).

Codeine:

Less frequent: Bradycardia (abnormally slow pulse rate), palpitation (rapid irregular action of heart), hypotension (drop in blood pressure when standing up), orthostatic hypotension, circulatory failure. Nausea, vomiting, constipation. Dizziness, raised body temperature, restlessness, deepening coma, unrealistic feeling of well-being, changes of mood, muscle rigidity, drowsiness, confusion, dry mouth, sweating, facial flushing. Itching, nettle-rash. Urinating may be difficult and there may be ureteric or biliary spasms and antidiuretic effect. Respiratory

depression, raised intracranial pressure (pressure in the skull) and miosis (contraction of the pupil of the eye).

Caffeine:

Frequent: Nausea. Headache, inability to sleep, restlessness, excitement, muscle tremor.

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 FORTETABLETS

Store in a cool dry place below 25°C in the original package.

Protect from strong light.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Keep blisters in the carton until required for use.

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

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION

Packaged in Aluminium foil/PVC push-through blister packs of 10 tablets per strip (packed in 20's or 100's per unit carton), or in round amber PVC jars containing 500 or 1 000 tablets.

IDENTIFICATION OF ASTRAPAIN FORTE TABLETS

Green, round, biconvex tablet, bisected on the one side, and embossed "ASTRAL PAIN" on the other side.

REGISTRATION NUMBER/REFERENCE NUMBER

27/2.8/0137

NAME AND ADDRESS OF REGISTRATION HOLDER

Astral Pharma (Pty) Ltd

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