

Applicant: Astral Pharma (Pty) Ltd

Product name: ASTRAPAIN FORTE TABLETS

Dosage form and strength: Tablets, Paracetamol 320 mg, Codeine Phosphate 8 mg, Caffeine anhydrous 32 mg, Meprobamate 150 mg.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ASTRAPAIN FORTE TABLETS

Paracetamol 320 mg, Codeine Phosphate 8 mg, Caffeine anhydrous 32 mg , Meprobamate 150mg

Contains Tartrazine.

Sugar free.

Read all of this leaflet carefully before you start taking ASTRAPAIN FORTE TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **ASTRAPAIN FORTE TABLETS** 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.

What is in this leaflet

1. What **ASTRAPAIN FORTE TABLETS** is and what it is used for.
2. What you need to know before you take **ASTRAPAIN FORTE TABLETS**.
3. How to use **ASTRAPAIN FORTE TABLETS**
4. Possible side effects.
5. How to store **ASTRAPAIN FORTE TABLETS**.
6. Contents of the pack and other information.

1. What **ASTRAPAIN FORTE** is and what it is used for

ASTRAPAIN FORTE TABLETS belongs to a group of medicines called analgesic combinations.

It is used for pain and fever, and pain associated with tension.

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

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2. What you need to know before you take ASTRAPAIN FORTE TABLETS

Do not take ASTRAPAIN FORTE TABLETS:

- if you are hypersensitive (allergic) to paracetamol, codeine phosphate, caffeine anhydrous, meprobamate or any of the other ingredients of **ASTRAPAIN FORTE TABLETS** (listed in section 6).

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 (lung/airways) depression especially in the presence of cyanosis (condition where your skin or lips turn blue due to an insufficient level of oxygen in the blood) and excessive bronchial (mucus and fluid) secretion in the airways
- if you had an operation on the biliary tract (liver, gall bladder and bile ducts)
- if you suffer from acute alcoholism (alcohol poisoning due to rapid and excessive alcohol intake);
- head injuries and conditions in which intracranial pressure (a rise in the pressure around your brain) is raised;
- heart failure secondary to chronic lung disease, a history of heart disease, recurrent fits (epilepsy) and all convulsive states.
- Patients taking an antidepressant in the class called monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Porphyria (inherited disorder of blood pigment metabolism).
- If you are under 12 years old
- If you are breastfeeding
- If you are pregnant, do not take codeine containing products, including **ASTRAPAIN FORTE TABLETS** later in your pregnancy because these medicines may cause problems in your unborn baby.
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

Take special care with ASTRAPAIN FORTE TABLETS:

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

- 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.

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- Should be used with caution in patients with, myasthenia gravis (muscle disorder causing weakness) and prostatic hypertrophy (enlargement of prostate gland),
- 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.
- If you are taking flucloxacillin (used to treat bacterial infections). If taken together with **ASTRAPAIN FORTE TABLETS**, it may cause build up of acid in your body.
- If you experience any serious skin reactions, often together with flu-like symptoms after you start taking **ASTRAPAIN FORTE TABLETS**. Stop taking **ASTRAPAIN FORTE TABLETS** and seek urgent advice from your doctor. The skin reactions such as swelling, itching, red severe rash especially those covering the whole body (as allergic wheals) may progress to widespread blistering or peeling of the skin and can be a serious reaction to **ASTRAPAIN FORTE TABLETS**, called severe cutaneous adverse reactions (SCARs) (see section 4, Possible side effects).
- Children with conditions associated with respiratory problems should not use **ASTRAPAIN FORTE TABLETS**, due to the codeine content.
- If you have a personal or family history of substance abuse or mental health issues.
- *Opioid-induced Hyperalgesia*

Taking high doses of opioid medication can paradoxically induce or sensitise patients to acute pain, this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).

Children and adolescents

Not recommended for children under the age of 12 years.

Other medicines and ASTRAPAIN FORTE

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

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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 hepatotoxicity.

Enzyme inducing medicines – Increased risk of hepatotoxicity.

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

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

Medicines used to treat gout and high blood levels or uric acid, such as probenecid, can decrease the elimination of **ASTRAPAIN FORTE TABLETS** from the body.

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 kidney effects.

Chronic use of isoniazid and/or rifampicin, antibiotic medicines often prescribed for tuberculosis – These medicines may increase the risk of liver damage when combined with **ASTRAPAIN FORTE TABLETS**, even at recommended doses.

Warfarin (used to prevent blood clots from forming): **ASTRAPAIN FORTE TABLETS** may increase the anticoagulant effect and there is an increased risk of bleeding if you take regular or high doses of paracetamol while on an oral anticoagulant.

Zidovudine used to treat viral infections and co-trimoxazole used to treat bacterial infections – These medicines together with **ASTRAPAIN FORTE TABLETS** can cause damage to the liver.

The effect of interferon alfa used to treat cancers and viral infections, can be increased when used together with **ASTRAPAIN FORTE TABLETS** and your doctor might change the dose.

Flucloxacillin, due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily dose of paracetamol are used.

Monoamine oxidase inhibitors (used to treat depression) – if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers.

Pregnancy and breastfeeding and fertility

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.

ASTRAPAIN FORTE TABLETS is, however, not recommended for use by pregnant or breastfeeding women. If you use **ASTRAPAIN FORTE TABLETS** during pregnancy, your baby may become dependent and experience withdrawal syndrome after birth which may need to be treated.

Do not take **ASTRAPAIN FORTE TABLETS** while you are breastfeeding. Codeine and Morphine passes into breast milk and will affect your baby.

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.

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ASTRAPAIN FORTE TABLETS contains:

- Tartrazine: 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.

3. How to take ASTRAPAIN FORTE TABLETS

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

Always take ASTRAPAIN FORTE TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

Your doctor will tell you how long your treatment with **ASTRAPAIN FORTE TABLETS** will last. If you have the impression that the effect of ASTRAPAIN FORTE TABLETS is too strong or too weak, tell 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, contact the nearest hospital or poison centre. 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.

If you forget to take a dose of ASTRAPAIN FORTE TABLETS

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

4. Possible side effects

ASTRAPAIN FORTE TABLETS can have side effects.

Not all side effects reported for **ASTRAPAIN FORTE TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ASTRAPAIN FORTE TABLETS**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **ASTRAPAIN FORTE TABLETS** 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;
- serious skin reactions called severe cutaneous adverse reactions (SCARs). SCARs are a group of potentially very serious adverse drug reactions that can be fatal and involve the skin and mucous membranes (the moist, inner lining of some organs and body openings, such as the nose, mouth, lungs and stomach). Examples of SCARs includes toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS) / drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruption (FDE) (see also section 2, Warnings and precautions).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASTRAPAIN FORTE TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common/Frequent side effects:

Caffeine:

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

Uncommon/Less frequent side effects:

Paracetamol:

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).

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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 heart 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).

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. This includes any possible side effects not listed in this leaflet. 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 this medicine.

5. How to store ASTRAPAIN FORTE TABLETS

Store all medicines out of reach of children.

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

Protect from strong light.

Keep blisters in the carton until required for use.

Do not store in a bathroom.

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).

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6. Contents of the pack and other information

What ASTRAPAIN FORTE TABLETS contains:

- The active substances are:

Each tablet contains:

- Paracetamol 320 mg
- Caffeine anhydrous 32 mg
- Codeine Phosphate 8 mg
- Meprobamate 150 mg

The other ingredients are

- Deep Apple Green (CI 19140/44090)
- Colloidal silicone dioxide (Aerosil 200)
- Magnesium stearate
- Nipastat
- Povidone 90 F
- Powdered Acacia
- Purified talc
- Starch, Maize

What ASTRAPAIN FORTE TABLETS looks like and contents of the pack

Green, round, flat tablet, bisected on the one side.

- *Blister pack*
 - 10 tablets per blister (Aluminium foil/PVC push-through) packed in outer carton as 30 tablets.
 - 20 tablets per blister (Aluminium foil/PVC push-through) packed in outer carton as 20, 40 or 100 tablets.
- *PVC jars*
 - 500 tablets in a round white PVC jar.
 - 1000 tablets in a round white PVC jar.

Not all pack sizes may be marketed.

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Holder of Certificate of Registration

Astral Pharma (Pty) Ltd
49 Riboville Road
Randjiesfontein
Midrand
1683
South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website (Professional Information only) or by scanning the QR code below.

Email: info@astralpharma.co.za or medical@astralpharma.co.za

Telephone: 010 021 0750