PROFESSIONAL INFORMATION

SCHEDULING STATUS S2

1. NAME OF THE MEDICINE
ASTRAPAIN SYRUP

2. QUALITIVE AND QUANTITIVE COMPOSITION

Each 5 ml contains:	Paracetamol	120 mg
	Codeine Phosphate	5 mg
	Promethazine hydrochloride	6,5 mg
Preservatives:	Methylparaben	0,10 % *m/v*
	Propylparaben	0,01 % *m/v*
Contains alcohol:	Alcohol content	12,5 % *v/v*
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

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
For the relief of mild to moderate pain, associated with fever.

4.2 Posology and method of administration
Posology

DO NOT EXCEED THE RECOMMENDED DOSE

2 to 5 years: One medicine measure full (5 ml) three times a day.
6 to 12 years: One to two medicine measure full (5 to 10 ml) three times a day.
Do not use continuously for more than 5 days for pain and 3 days for fever.

Paediatric population
Not recommended for children under the age of 2 years.

Method of administration
For oral use.

4.3 Contraindications
- Hypersensitivity to the active substance or to any of the excipients.
- Sensitivity to paracetamol, opiates or phenothiazines.
- Patients sensitive to one antihistamine may be sensitive to others.
- During an attack of bronchial asthma, patients with obstructive airway disease, respiratory depression, especially in the presences of cyanosis and excessive bronchial secretion.
- Heart failure secondary to chronic lung disease and after operations on the biliary tract.
- Patients with severe liver or kidney complications.
- Head injuries and where intracranial pressure is raised.
- Acute alcoholism.
- Convulsive disorder.
- Premature infants or neonates.
- Children under the age of two years.
- Pregnancy and lactation
- Patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- ASTRAPAIN SYRUP should not be given during an attack of bronchial asthma or in heart disease secondary to chronic lung disease.
- Promethazine and codeine phosphate, as contained in ASTRAPAIN SYRUP, should not be given to comatosed patients.

4.4 Special warnings and precautions for use
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.
- This medicine may cause drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against performing potentially hazardous activities where loss of concentration may lead to accidents.
- Patients should be examined periodically for abnormal skin pigmentation or eye changes.
- Dosages of paracetamol in excess of those recommended may cause severe liver damage.
- The use of promethazine may be associated with the sudden infant death syndrome.
- Exceeding the described dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.
- Should be used in caution or in reduced doses in patients with adrenocortical insufficiency and hypothyroidism.
- Should be used with caution in patients with obstructive bowel disorders and myasthenia gravis.

Promethazine hydrochloride
ASTRAPAIN SYRUP may lead to drowsiness and impaired concentration, that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

Caution should be used when the following medical conditions exist: prostatic hypertrophy, narrow angle glaucoma, emphysema or chronic bronchitis and porphyria.

Paradoxical hyperexcitability, nervousness and insomnia, may occur in children and the elderly taking antihistamines. Elderly patients are especially susceptible to dizziness, sedation, confusion, hypotension and to anticholinergic effects such as dry mouth and urinary retention.

Promethazine should not be used in patients with pre-existing central nervous system depression, bone marrow depression, phaeochromocytoma or Reye's syndrome. Use with care in patients with epilepsy, jaundice, Parkinsonism, diabetes mellitus, hypothyroidism, and myasthenia gravis.

Risk of severe constipation if used with antidiarrhoeal agents such as diphenoxylate. Increased risk of constipation and urinary retention if used with other anticholinergic agents. Use with caution in patients with obstructive bowel disorders and prostatic hypertrophy.

Promethazine should be used with caution in patients with cardiovascular disease, closed angle glaucoma, asthma and urinary retention. The positive results of skin allergy tests may be suppressed.

Paracetamol
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.

ASTRAPAIN SYRUP contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdosage 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 function damage. Patients suffering from hepatitis or alcoholism, or recovering from any form of liver disease, should not take paracetamol.

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

Potentiates the effect of alcohol and other sedatives.

Prolonged use of high doses of codeine may lead to dependence.

There is a risk of severe constipation if used with antidiarrhoeal agents such as diphenoxylate. There is also an increased risk of constipation and urinary retention if used with other anticholinergic agents.

Codeine phosphate, as contained in ASTRAPAIN SYRUP, should be given with caution or in reduced doses to patients with hypotension, hypothyroidism, compromised respiratory function, adrenocortical insufficiency, prostatic hypertrophy, shock or head injury. It should be used with caution in patients with inflammatory or obstructive bowel syndrome. It should be given with caution to patients with myasthenia gravis. The administration during labour may cause respiratory depression in the newborn infant.

The dosage should be reduced in elderly and debilitated patients.

ASTRAPAIN SYRUP contains sucrose:
Patients with rare hereditary problems such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take this medicine.

ASTRAPAIN SYRUP contains liquid glucose:
Patients with rare glucose-galactose malabsorption should not take this medicine.

ASTRAPAIN SYRUP contains invert syrup:
Patients with rare hereditary problems of fructose intolerance or glucose-galactose malabsorption should not take this medicine.

ASTRAPAIN SYRUP contains propylene glycol:
Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.
While propylene glycol has not been shown to cause reproductive or development toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case to case basis.
Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

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

4.5 Interaction with other medicines and other forms of interaction
The anticholinergic effects of agents with anticholinergic properties may be enhanced. The depressant effects are aggravated by alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants, maprotiline and phenothiazines. Monoamine oxidase inhibitors may enhance the anticholinergic effects.

The warning signs of damage caused by ototoxic agents may be masked. May affect the activity of the other medicines by delaying their absorption.

Promethazine may potentiate the hypotensive effect of some antihypertensives. False negative and positive results have been reported with some pregnancy tests.

All sedatives, including alcohol, will potentiate depressant effects on the central nervous system if taken with antihistamines. The antiparkinsonian effects of levodopa may be inhibited

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

4.6 Fertility, pregnancy and lactation
Women of childbearing potential / Contraception in males and females
No information available.

Pregnancy
ASTRAPAIN SYRUP is contraindicated in pregnancy (see section 4.3)

Breastfeeding
ASTRAPAIN SYRUP is contraindicated in lactation (see section 4.3).

Fertility
No information available.

4.7 Effects on ability to drive and use machines
This medicine may cause drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against performing potentially hazardous activities where loss of concentration may lead to accidents.

4.8 Undesirable effects
Tabulated list of adverse reactions

Body System	**Undesirable effect**		
	Frequent	Less frequent	Frequency not known
PARACETAMOL			
Blood and the lymphatic system disorders:		Neutropenia Pancytopenia Leucopenia Thrombocytopenia Agranulocytosis Anaemia	
Skin and subcutaneous tissue disorders:		Skin rashes and other allergic reactions may occur. This rash is usually erythematous or urticarial, but sometimes more serious and may be accompanied by fever and mucosal lesions. The use of paracetamol has been associated with the occurrence of dermatitis.	Fixed dug eruptions (FDE) Drug-induced hypersensitivity syndrome (DIHS) have been reported in patients treated with paracetamol containing medicines.
Psychiatric disorders	Confusion Hallucinations A central effect include euphoria.		
Nervous system disorders	Sedation (varying from slight drowsiness to deep sleep, including dizziness and incoordination) Paradoxical central nervous system stimulation may occur especially in children, with insomnia, nervousness, tachycardia, tremors, ataxia, irritability and consvulsions. A central effect includes occasional headache.		
Ear and labyrinth disorder		Tinnitus	
Vascular disorders		Hypotension	
Gastrointestinal disorders		Side effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite, and epigastric pain. Pancreatitis may occur.	
Hepato-biliary disorders		This medicine can cause liver damage which may be fatal, if taken in excess.	The use of paracetamol has been associated with the occurrence of hepatitis.
Musculoskeletal, connective tissue and bone disorders		Other central effects include muscular weakness.	
Renal and urinary disorders		Prolonged excessive use may cause irreversible kidney damage. The use of paracetamol has been associated with the occurrence of renal colic, renal failure, sterile pyuria.	
General disorders and administrative site conditions	Lassitude		
CODEINE			
Cardiac disorders		Hypotension Orthostatic hypotension Circulatory failure	Bradycardia Palpitation
Gastrointestinal disorders	Constipation Nausea Vomiting		Dry mouth
Nervous system disorders:	Drowsiness Confusion	Hypothermia Deepening coma Euphoria Muscle rigidity Dry mouth Sweating Facial flushing Dizziness Restlessness Changes of mood	Raised intracranial pressure occurs in some patients.
Skin and subcutaneous tissue disorders			Pruritis Urticaria Contact dermatitis
PROMETHAZINE HYDROCHLORIDE			
Nervous system disorders	Sedation Lassitude Dizziness Hypertension Muscular weakness and in-coordination	Headache Tinnitus Elation or depression Irritability Halluciantion Dryness of the mouth Tightness of the chest and tingling Dissiness and weakness of the hands may occur. In infants and children it may act as a cerebral stimulant. Symptoms of stimulation include insomnia, nervoursness, tachycardia, tremors, muscle twitching and convulsions. Large doses may precipitate fits in epileptics.	Extrapyramidal dysfunction
Cardiac disorders		Increase in heart rate.	Hypotension In high doses, transient bradycardia followed by tachycardia with palpitations and dysrhythmias can occur.
Gastrointestinal disorders:		Nausea Vomiting Constipation Diarrhoea Colic Epigastric pain	
Blood and lymphatic system disorders		Blood dyscrasias including, Agranulocytosis, Leucopenia, Haemolytic anaemia Thrombocytopenic purpura	
Eye disorders			Blurred vision Depostiton of pigment in the eyes, corneal and lens opacities.
Renal and urinary disorders:		Difficulty in micturition and dysuria.	Polyuria
Immune system disorders			Idiosyncrasy Angioedema Lupus erythematous-like syndrome
Metabolism and nutrition disorders		Anorexia, or increased appetite.	
General disorders and administration site conditions			Lowering of blood temperature (occasionally pyrexia)
Psychiatric disorders		Irritability and restlessness.	Depression Hallucinations Insomnia
Vascular disorder		Dizziness	May also produce antimuscurinic effects including flushing.
Respiratory, thoracic and mediastinal disorders			May also produce antimuscarinic effects including thickened respiratory tract secretions, dryness of the nose, tightness of the chest.
Hepato-biliary disorders			Jaundice of the obstructive type.
Skin and subcutaneous tissue disorders		Photosensitivity reactions and skin rash may ocuur.	Allergic dermatitis and thrombocytopaenic purpura have also been reported.
Musculoskeletal and connective tissue disorders			Weakness of hands

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 (see section 4.4).

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
Paracetamol:
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, and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage.

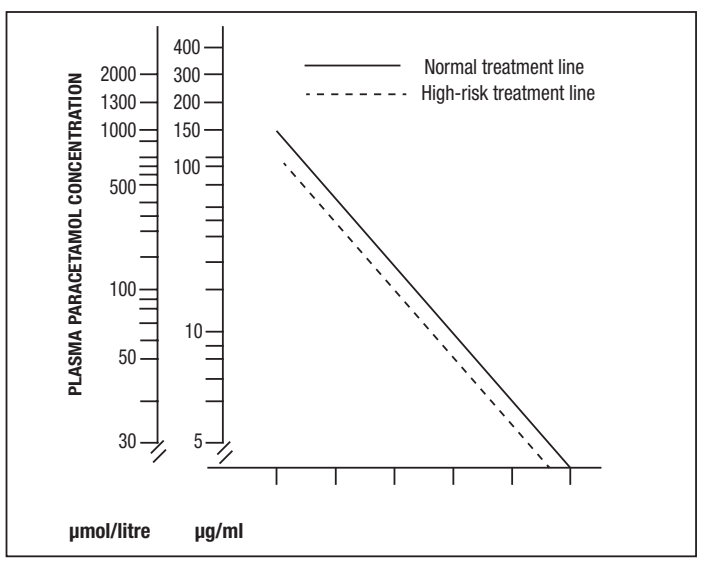
Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may lead to encephalopathy, coma and death.

Acute 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:
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 1000 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 as a 5 % solution may be administered initially, followed by 70 mg/kg every 4 hours for 17 doses.

A plasma paracetamol level should be determined 4 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.

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, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia, respiratory collapse. Children and the elderly are more likely to exhibit anticholinergic and central nervous system stimulant effects. The elderly are prone to hypotension. Death may occur from respiratory failure. Drowsiness and hypotension may occur.

There is no specific antidote and treatment is symptomatic and supportive. It may be necessary to treat extrapyramidal reactions with barbiturates or diphenhydramine.

Codeine:
Symptoms of overdosage that may arise include excitement, consulsions and respiratory failure. Respiratory depression is the most important feature of overdosage with codeine containing preparations and it occurs with circulatory failure and a deepening coma. Pinpoint pupils, hypotension and hypothermia, excitement and convulsions, especially in children, and non-cardiogenic pulmonary oedema occur. Immediate attention should be given to maintaining adequate respiration.

Death may occur from respiratory failure. Naloxone should be given intravenously in a dose of 0,4 mg to 2 mg every 2 to 3 minutes until improvement occurs to a maximum of 10 mg. Children may be given 0,01 mg/kg initially followed by a dose of 0,1 mg/kg.

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

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: A 2.8 Analgesic combinations

ASTRAPAIN SYRUP has analgesic (relief of pain), antipyretic (reduces fever) and antihistaminic (prevention or relief of symptoms associated with some types of allergies such as hayfever and runny nose) properties.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
- Blackcurrant colour
- Citric Acid
- Essence Blackcurrant
- Ethanol 96 % *v/v*
- Invert Syrup
- Liquid Glucose
- Methylparaben
- Propylparaben
- Propylene Glycol
- Raspberry Red
- Sodium Cyclamate
- Sodium Saccharin
- Sucrose
- Vanilla Flavour

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at or below 25 °C
Protect from light.
Store in the original container.

6.5 Nature and contents of container
Amber, plastic or glass bottles containing 100 ml of syrup.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product
No special requirements.

7. THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Astral Pharma (Pty) Ltd
49 Riboville Road
Randjiesfontein
Midrand
1683
South Africa

8. REGISTRATION NUMBER
27/2.8/0139

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
14 January 1995

10. DATE OF REVISION OF TEXT
31 December 2023

PASIËNTINLIGTINGPAMFLET

SKEDULERINGSTATUS S2

ASTRAPAIN SYRUP (Stroop)
Parasetamol 120 mg, Kodeïenfosfaat 5 mg en Prometasienhidrochloried 6,5 mg.

Bevat suiker:
Sukrose 2.0 g / 5 ml
Vloeibare glukose 2.0 g / 5 ml
Versoeter stroop 600 mg / 5 ml

Bevat versoeter:
Natriumsakkarien: 1,5 mg / 5 ml
Natrium Siklamaat: 30 mg / 5 ml

ASTRAPAIN SYRUP is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n ligte siekte te behandel. Nietemin moet jy **ASTRAPAIN SYRUP** steeds versigtig gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie **ASTRAPAIN SYRUP** met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter sien as jou simptome vererger of nie na 'n paar dae verbeter nie.

Wat is in hierdie pamflet

1. Wat **ASTRAPAIN SYRUP** is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy **ASTRAPAIN SYRUP** gebruik.
3. Hoe om **ASTRAPAIN SYRUP** te gebruik.
4. Moontlike newe-effekte.
5. Hoe om **ASTRAPAIN SYRUP** te stoor.
6. Inhoud van die houer en ander inligting.

1. Wat ASTRAPAIN SYRUP is en waarvoor dit gebruik word

ASTRAPAIN SYRUP word gebruik vir die verligting van ligte tot matige pyn wat verband hou met koors.

2. Wat jy moet weet voordat jy ASTRAPAIN SYRUP neem.

Moenie ASTRAPAIN SYRUP neem:
- indien jy hipersensitief (allergies) is vir parasetamol, kodeïenfosfaat, prometasienhidrochloried of vir enige van die ander bestanddele (gelys in afdeling 6).
- indien jy hipersensitief (allergies) is vir opiate of fenotiasien.
- indien jy sensitief is vir een anthihistamien en mag dalk sensitief wees vir ander.
- indien jy aan nier- of lewersiekte ly.
- indien jy 'n brongiale asma aanval, respiratoriese onderdrukking, veral in die teenwoordigheid van sianose (blou verkleuring van die vel as gevolg van 'n gebrek aan suurstof) en oormatige brongiale (met betrekking tot luggange in die longe) afskeiding.
- indien jy 'n alkolis is.
- indien jy hartversaking sekondêr tot chroniese longsiekte het, kopbeserings waar die intrakraniale druk (druk binne die skedel) verhoog word.
- moenie aan kinders onder die ouderdom van 2 jaar of aan komateuse pasiënte gegee word nie.
- indien jy swanger is.
- indien jy borsvoed.
- indien jy monamienoksidase-inhibeerders neem of binne 14 dae nadat jy so behandeling gestaak het.

Waarskuwings en voorsorgmaatreëls
In die geval van oordosering of vermoedelike oordosering, al mag die persoon asimptomaties wees, moet die naaste dokter, hospitaal of gifbeheersentrum onmiddellik gekontak word.

Neem spesiale sorg met ASTRAPAIN SYRUP:
- Indien jy meer as die aanbevole dosis neem, aangesien dit ernstige lewerskade kan veroorsaak.
- Indien daar geen verbetering in die simptome is nie, moet 'n dokter geraadpleeg word.
- Moenie enige gereedskap of masjiene bestuur of gebruik nie, want hierdie medisyne kan lei tot lomerigheid en verswakte konsentrasie, wat vererger kan word deur gelyktydige inname van alkohol of ander sentrale senuweestelselonderdrukkers.
- Pasiënte moet van tyd tot tyd ondersoek word vir abnormale velpigmentasie of oogveranderinge.
- Moenie die voorgeskrewe dosis oorskry nie, oorskryding van die voorgeskrewe dosis, tesame met verlengde en aanhoudende gebruik van hierdie medikasie, kan lei tot afhanklikheid en verslawing.
- Die gebruik van prometasien kan geassosieer word met die skielike babadood-sindroom.

Parasetamol:
Ander produkte wat parasetamol bevat, moet nie gelyktydig saam met **ASTRAPAIN SYRUP** geneem word nie.

Ernstige kutane nadelige reaksies (SCARs)
Ernstige kutane nadelige reaksies (SCARs) soos toksiese epidermale nekrolise (TEN), Steven-Johnson-sindroom (SJS), akute veralgemeende eksantematiese pustulose (AGEP), eosinofilie en sistematiese (DRESS)/Dwelm-geïnduseerde hipersensitiwiteitsindroom (DIHS) en vaste middels uitbarstings (FDE) is aangemeld by pasiënte wat behandel is met medisyne wat parasetamol bevat. Indien 'n pasiënt SCAR ontwikkel, moet behandeling met **ASTRAPAIN SYRUP** onmiddellik gestaak word en toepaslike behandeling ingestel word.

Kodeïen:
- Moet versigtig gebruik word of in verlaagde dosisse in pasiënt met adrenokortikale ontoereikendheid (mislukking van 'n deel van die bynier om voldoende steroïde hormone te produseer).
- Moet versigtig gebruik word of in verlaagde dosisse by pasiënte met obstruktiewe dermkwale.
- Dosis moet verlaag word in verswakte pasiënte.
- Moet versigtig gebruik word of in verlaagde dosisse by pasiënte met hipotireose (onderaktiewe skildklier).
- Moet versigtig gebruik word by pasiënte met lewerinkorting, myasthenia gravis (spierversteuring wat swakheid veroorsaak), verswakte funksie of skok.
- Verlengde gebruik van hoë dosisse kodeïenfosfaat kan lei tot afhanklikheid.

Prometasien:
- Prometasien het anticholinergiese ('n stof om die verloop van sekere senuwee-impulse te stop waarby asetielcholien betrokke is) en moet met sorg gebruik word in toestande soos gloukoom (verhoogde druk in die oog) en prostatiese hipertrofie (vergroting van prostaatklier).
- Sorg moet geneem word wanneer prometasien toegedien word gedurende die eerste trimester van swangerskap.
- Prometasien moet versigtig gebruik word by pasiënte met hartversaking, hipertensie (hoë bloeddruk), verswakte nierfunksie, lewerafwykings perifere edeem (swelling van hande en voete as gevolg van behoue vloeistof) en pulmonale edeem (oormatige vloeistofophoping in longe) en in toksemie (verspreiding van bakteriese produkte (gifstowwe) deur die bloedstroom) of swangerskap. By jong kinders kan spasma van die glottis (die vokale apparaat van die larinks) voorkom.

Kinders en adolessente
Moenie aan kinders onder die ouderdom van 2 jaar of aan komateuse pasiënte gegee word nie.

Ander medisyne en ASTRAPAIN SYRUP
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in).
Sorg moet gedra word indien dit gelyktydig geneem word met:
- Senuweestelseldepressante soos alkohol, barbiturate, hipnotika (veroorsaak slaap), narkotiese analgetika (afhanklikheidproduserende stowwe wat gebruik word vir die verligting van pyn) en kalmeermiddels (medisyne wat gebruik word om senuwees te kalmeer),
- Anticholinergiese medisyne ('n stof wat gebruik word om die vrystelling van sekere senuwee-impulse wat asetielcholien insluit, te stop),
- Trisikliese antidepressante en fenotiasiene aangesien hul effekte deur prometasien versterk kan word
- Antidepressante soos monoamienoksidase-inhibeerders (MAOI's) sal beide die lomerigheidseffek en die anticholinergiese effekte van prometasien versterk, daarom moet **ASTRAPAIN SYRUP** nie gelyktydig geneem word met pasiënte wat MAOI's neem of binne 14 dae nadat terapie met MAOI's gestaak is.
- Die effekte van die medisyne met anticholinergiese aktiwiteit soos trisikliese antidepressante of fenotiasien sal versterk word.
- Ototoksiese medisyne (medisyne wat skade aan die oor veroorsaak) kan gemasker word.
- Prometasien kan die hipotensiewe (verlaging van bloeddruk) effek van antihipertensiewe middels verhoog.
- Die antiparkinson-effek van levodopa kan geïnhibeer word.
- Antihistamiene kan positiewe veltoetsresultate onderdruk en moet 'n paar dae voor die toets gestaak word.

Swangerskap, borsvoeding en fertiliteit
Jy moet nie **ASTRAPAIN SYRUP** neem as jy swanger is of jou baba borsvoed nie.
As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

Bestuur en gebruik van masjiene
Moenie bestuur of enige gereedskap of masjiene gebruik nie, want hierdie medisyne kan lei tot lomerigheid en verswakte konsentrasie, wat vererger kan word deur gelyktydige inname van alkohol of ander middels wat die sentrale senuweestelsel onderdruk.

ASTRAPAIN SYRUP bevat:
ASTRAPAIN SYRUP bevat sukrose, vloeibare glukose, versoeter stroop
Indien u dokter gesê het dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne gebruik.

ASTRAPAIN SYRUP bevat propileenglikol
As u kind jonger as 5 jaar oud is, praat met u dokter of apteker voordat u hierdie medisyne aan hulle gee, veral as hulle ander medisyne gebruik wat propileenglikol of alkohol bevat.
As jy swanger is of borsvoed, moenie hierdie medisyne neem nie.
As jy aan 'n lewer- of niersiekte ly, moenie hierdie medisyne gebruik nie.

ASTRAPAIN SYRUP bevat etanol.
Gesamentlike toediening (toediening van twee medisyne) met medisyne wat bv. propileenglikol of etanol kan lei tot ophoping (versameling) van etanol en kan nadelige effekte veroorsaak, veral by jong kinders met 'n lae of onvolwasse metaboliese kapasiteit.

3. Hoe om ASTRAPAIN SYRUP te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **ASTRAPAIN SYRUP** presies soos beskryf in hierdie pamflet of soos jou dokter of apteker of verpleegster vir jou gesê het. Gaan gesels met jou dokter of apteker of verpleegster as jy nie seker is nie.

Die gewone dosering is:
MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.
Nie aanbeveelbaar vir kinders onder 2 jaar nie.
Kinders 2 tot 5 jaar: 5 ml drie keer per dag.
Kinders 6 jaar en ouer: 5 tot 10 ml drie keer per dag.
Moet nie langer as 5 dae aaneenlopend vir pyn en 3 dae vir koors gebruik nie.
Skud die bottel voordat jy dit gebruik.

Indien jy onder die indruk het dat die effek van **ASTRAPAIN SYRUP** te sterk of te swak is, praat met jou dokter of apteker.

As jy meer ASTRAPAIN SYRUP neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker onmiddelik. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Parasetamol:

Indien jy te veel **ASTRAPAIN SYRUP** neem, is vinnige behandeling noodsaaklik. In die geval van 'n oordosering, raadpleeg dadelik 'n dokter of neem die persoon direk na 'n hospitaal. 'n Vertraging in die aanvang van behandeling kan beteken dat die teenmiddel te laat gegee word om effektief te wees. Bewyse van lewerskade word dikwels vertraag tot nadat die tyd vir effektiewe behandeling verstryk het.

Vatbaarheid vir parasetamol toksisiteit word verhoog by pasiënte wat herhaalde hoë dosisse (meer as 5 - 10 g/dag) parasetamol vir 'n paar dae geneem het, in chroniese alkoholisme, chroniese lewersiekte, VIGS, wanvoeding en met die gebruik van medisyne wat lewer mikrosomale oksidasie induseer, soos barbiturate, isoniasied, rifampisien, fenitoïen en karbamasepien insluit.

Simptome van parasetamol oordosering in die eerste 24 uur sluit bleekheid, naarheid, braking, anoreksie (gebrek aan eetlus) en moontlik abdominale pyn in. Matige simptome gedurende die eerste twee dae van akute vergiftiging weerspieël nie die potensiële erns van die oordosering nie.

Lewerskade kan binne 12 tot 48 uur of later na inname van parasetamol voorkom, aanvanklik deur die verhoging van die serumtransaminase en laktiese dehidrogenase aktiwiteit, verhoogde serumbilirubien konsentrasie en verlenging van protombientyd. Lewerskade kan lei tot enkefalopatie, koma en sterfte.

Akute nierversaking met akute tubulêre nekrose (dood van weefsel) kan ontwikkel in die afwesigheid van ernstige lewerskade. Abnormaliteite van glukose metabolisme en metaboliese asidose (abnormale toename in die suurheid van die liggaam se vloeistowwe) kan voorkom. Hartdisritmïee is aangemeld.

Behandeling vir parasetamol oordosering:

N-asetielsisteïen moet so gou as moontlik in alle gevalle van vermoedelike oordosis toegedien word, verkieslik binne 8 uur na oordosering, alhoewel behandeling tot en met 36 uur na inname steeds voordelig kan wees, veral indien meer as 150 mg/kg parasetamol geneem is. 'n Aanvanklike dosis van 150 mg/kg N-asetielsisteïen in 200 ml dekstrose inspuiting, intraveneus gegee oor 15 minute, gevolg deur 'n infusie van 50 mg/kg in 'n 500 ml dekstrose inspuiting oor die volgende 4 uur, en dan 100 mg/kg in 1 000 ml dekstrose inspuiting oor die volgende 16 uur. **Die volume intraveneuse vloeistof moet aangepas word vir kinders.**

Alhoewel die mondelikse formulasie nie die eerste keuse van behandeling is nie, kan 140 mg/kg opgelos in water as 'n 5 % oplossing aanvanklik toegedien word, gevolg deur 70 mg/kg elke 4 uur vir 17 dosisse.

'n Plasma parasetamolvlak moet 4 uur na inname bepaal word met alle gevalle van vermoedelike oordosering. Vlakke wat voor 4 ure geneem word, behalwe as dit hoog is, kan misleidend wees. Pasiënte wat 'n risiko loop vir lewerskade, en dus wat volgehoue behandeling met N-asetielsisteïen vereis, kan geïdentifiseer word volgens hul plasma parasetamolvlak. Die plasma parasetamolvlak kan gestip word teenoor die tyd vanaf inname in die behandelingsnomogram. Die nomogram moet slegs gebruik word in verhoudung tot 'n enkele akute inname.

Diegene wie se plasma parasetamolvlakke bokant die "normale behandelingslyn" is, moet aanhou met die N-asetielsisteïen behandeling met 100 mg/kg IV herhaaldelik oor 16 uur tot herstel. Pasiënte met verhoogde vatbaarheid vir lewerskade soos hierbo geïdentifiseer, moet behandeling voortsit indien konsentrasies bokant die "hoë risiko behandelingslyn" is. Protrombien indeks korreleer die beste met oorlewing.

Moniteer alle pasiënte met betekenisvolle innames vir ten minste 96 uur.

Kodeïenfosfaat:
Simptome van oordosering met kodeïen sluit opgewondenheid, konvulsies en respiratoriese versaking in. Onmiddelike ondersteunende behandeling mag nodig wees om respiratoriese versaking en skok te herstel. Die spesifieke teenmiddel naloxone kan gebruik word om ernstige respiratoriese onderdrukking teen te werk.

Prometasien:
Oordosering kan dodelik wees. Kinders en babas is meer geneig om anticholinergiese en sentrale senuweestelsel stimulerende effekte te toon. Simptome sluit in ataksie (verlies aan spierkoördinasie), opgewondenheid, hallusinasies, bewing, konvulsies, stipkykyende pupille, droë mond, blooisende gesig, hiperpireksie (hoë koorstoestand; abnormale hoë liggaamstemperatuur) en respiratoriese versaking (asemhalingsineenstorting). Spesiale behandeling van oordosering is noodsaaklik en die pasiënt moet so gou as moontlik na 'n hospitaal verskuif word. Behandeling van oordosering is simptomaties en ondersteunend.

Indien jy vergeet om 'n dosis ASTRAPAIN SYRUP te neem
Moenie 'n dubbele dosis neem om vir die oorgeslane dosis op te maak nie.

4. Moontlike newe-effekte

ASTRAPAIN SYRUP kan newe-effekte hê.
Nie alle newe-effekte wat vir **ASTRAPAIN SYRUP** gerapporteer is, is ingesluit in die voubiljet nie. Indien u algemene gesondheid verswak of indien u enige ongewensde effek ondervind tydens die gebruik van hierdie medikasie, raadpleeg asseblief u dokter, apteker of ander gesondheidsdeskundige.

As enige van die volgende gebeur, hou op om **ASTRAPAIN SYRUP** te gebruik en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal',
- uitslag of jeuk,
- floute.

Dit is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie met **ASTRAPAIN SYRUP** gehad. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
Dit is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Naarheid
- Braking
- Hardlywigheid
- Lomerigheid en verwarring
- Sedasie (wat kan wissel van effense lomerigheid tot diep slaap en insluitend onvermoë om te konsentreer)
- Losheid (gebrek aan energie, moegheid, lusteloosheid)
- Duiseligheid
- Hipertensie (hoë bloeddruk)
- Spierswakheid en in-koördinasie

Minder gereelde newe-effekte:
- Neutropenie (te min witbloedselle)
- Pancytopenie (te min bloedselle van alle soorte)
- Leukopenie (te min witbloedselle)
- As dit in oormaat geneem word, kan hierdie medisyne lewerskade veroorsaak wat dodelik kan wees
- Veluitslag en ander allergiese reaksies kan voorkom. Die uitslag is gewoonlik eritemateus (rooi veluitslag) of urtikaria (allergiese velreaksie / brandneteluitslag), maar soms ernstiger en kan gepaard gaan met koors en slymvlies (weefsels wat slym produseer) letsels (agteruitgang van weefsel as gevolg van besering of siekte).
- Droogheid van die mond
- Sweet
- Gesigspoeling
- Duiseligheid
- Rusteloosheid
- Gemoedsveranderinge kan voorkom
- Moeilik urineer
- Ureteriese spasma (Kolik/spasma van die ureter/nierkanaal)
- Galspasma (spasma van galbuis)
- Bradykardie (abnormaal stadige polsslag)
- Hartkloppings (vinnige onreëlmatige werking van die hart)
- Respiratoriese depressie (abnormaal stadige en/of vlak asemhaling)
- Ortostatiese hipotensie (verlaging in bloeddruk wanneer jy opstaan)
- Hipotermie (abnormaal lae liggaamstemperatuur)
- Miose (sametrekking van die pupil van die oog) kan voorkom
- Verhoogde intrakraniale druk (druk binne die skedel) kan voorkom
- As gevolg van die histamienvrystellende effek kan reaksies soos 'n urtikaria (allergiese velreaksie / brandneteluitslag) en pruritis (jeuk) by babas en kinders voorkom
- Bloeddyskrasieë (ernstige bloedversteuring)
- Agranulositose (ernstige afname in 'n spesifieke tipe witbloedselle)
- Leukopenie (te min witbloedselle)
- Hemolitiese anemie (gebrek aan rooibloedselle as gevolg van vernietiging van sirkulasieselle)
- Epigastriese pyn (pyn in die boonste, middelste deel van die maag)
- Hoofpyn
- Tinnitus (geluide in die ore)
- Verheuging van depressie
- Prikkelbaarheid
- Nagmerries
- Droogheid van die mond
- Beklemtoonheid van die bors en tinteling
- Duiseligheid en swakheid van die hande kan voorkom
- By babas en kinders kan dit as 'n serebrale stimulant optree. Simptome van stimulasie sluit slapeloosheid (onvermoë om te slaap), senuweeagtigheid, tagikardie (verhoogde tempo van hartklop) bewing, spiertrekkings en stuiptrekkings in.
- Groot dosisse kan aanvalle by epilepsie veroorsaak.
- Fotosensitiwiteitsreaksies (toename in die reaktiwiteit van die vel tot lig) kan voorkom.
- Allergiese reaksies anafilakse (skielike, lewensbedreigende ernstige allergiese reaksie) kan voorkom.
- Anoreksie (verlies aan eetlus), of verhoogde eetlus
- Moeilik urineer kan ook voorkom.
- Ekstrapiramidale simptome kan ontwikkel.

Frekwensie onbekende newe-effekte:
- Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (DIHS) en vaste dwelm-uitbarstings (FDE) is aangemeld by pasiënte wat met parasetamolbevattende medisyne behandel is.

Postbemarkingservaring:
Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (DIHS) en vaste dwelm-uitbarstings (FDE) is aangemeld by pasiënte wat met parasetamolbevattende medisyne behandel is. Indien 'n pasiënt SCAR (Ernstige kutane newe-reaksies) ontwikkel, moet behandeling met **ASTRAPAIN SYRUP** onmiddellik gestaak word en toepaslike behandeling ingestel word.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem is nie, stel asseblief jou dokter of apteker in kennis.

Rapportering van vermoedelike ongewenste effekte:
Rapportering van vermoedelike ongewenste effekte na die magtiging van die mesdisyne is belangrik. Dit help met die monitoring van die voordele/risiko balans van die medisyne. Gesondheidsorgkundiges word gevra om enige vermoedelike ongewenste effekte aan SAHPRA te rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van ASTRAPAIN SYRUP te verskaf.

5. Hoe om ASTRAPAIN SYRUP te stoor

- Berg in goed geslote houers, by of benede 25°C.
- Beskerm teen lig.
- BERG ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Berg in die oorspronklike verpakking totdat jy dit benodig vir gebruik.
- Moet dit nie in die badkamer stoor nie.
- Moenie na die vervaldatum wat op die verpakking aangedui word, gebruik nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die houer en ander inligting

Wat **ASTRAPAIN SYRUP** bevat:
Die aktiewe bestanddele is
Parasetamol 120 mg / 5 ml
Kodeïenfosfaat 5 mg / 5 ml
Prometasienhidrochloried 6.5 mg / 5 ml

Die ander bestannddele is
Essensie van Swartbessie
Etanol 9 6% *v/v*
Framboos Rooi
Metielparabeen
Natriumsakkarien
Natrium Siklamaat
Propielparabeen
Propileenglikol
Sitroensuur
Sukrose
Swartbessie kleur
Vanielje geursel No. 1
Versoeter Stroop
Vloeibare glukose

Hoe lyk ASTRAPAIN SYRUP en inhoud van die verpakking
Donker rooierige-pers tot maroen stroperige vloeistof met 'n kenmerkende swartbessie geur.
Amber, plastiek PVC of glasbottels wat 100 ml stroop bevat.

Houer van sertifikaat van registrasie
Astral Pharma (Pty) Ltd
49 Riboville Road
Randjiesfontein
Midrand
1683
South Africa

Hierdie pamflet was laas hersien in
Datum van registrasie: 14 Januarie 1995
Datum van hersiening van teks: 31 Desember 2023

Registrasienommer
27/2.8/0139

Toegang tot die toepaslike Professionele Inligting
Kan verkry word op die SAHPRA webwerf of deur die QR-kode te skandeer.
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