SKEDULERINGSTATUS S2

NS1 (Namibië)

EIENDOMSNAAM (EN DOSEERVORM)

Tensopyn Bruistablette

SAMESTELLING

Elke tablet bevat:

Parasetamol	450 mg
Doksielamiensuksinaat	5 mg
Kafeïenanhidries	50 mg
Kodeïenfosfaat	10 mg

Preserveermiddel:

Natrium bensoaat: 0,001 % *m/m*

FARMAKOLOGIESE KLASSIFIKASIE

A 2.8 Analgetiese kombinasies.

FARMAKOLOGIESE WERKING

TENSOPYN BRUISTABLETTE het pynstillende, koorswerende en antihistaminiese eienskappe.

INDIKASIES

TENSOPYN BRUISTABLETTE word aangedui vir die verligting van geringe tot matige pyn wat met spanning geassosieer word.

KONTRA-INDIKASIES

Hipersensitiwiteit vir enige van die bestanddele. Erge inkorting van lewerfunksie. Akute terugkerende porfirie.

Word teenaangedui tydens asemhalingsonderdrukking, veral in die teenwoordigheid van sianose en oormatige brongiale afskeiding, na 'n galbuisoperasie, akute alkoholisme, hoofbeserings en toestande waar die intrakraniale druk verhoog is. Dit moet nie tydens 'n brongiale asma aanval of by hartversaking sekondêr tot chroniese longsiekte toegedien word nie. Word teenaangedui by pasiënte wat behandeling met monoamienoksidaseremmers ontvang, of binne 14 dae na die staking van sulke behandeling. Veilige gebruik tydens swangerskap en borsvoeding is nog nie vasgestel nie.

WAARSKUWINGS

Moenie langer as 10 dae aaneen neem sonder om u geneesheer te raadpleeg nie. Hierdie medisyne kan tot lomerigheid en verswakte konsentrasie lei, wat deur die gelyktydige inname van alkohol of ander sentrale senuweestelselonderdrukkers vererger kan word. Pasiënte behoort gewaarsku te word om nie in beheer van voertuie of masjinerie te wees, of om gevaarlike take te verrig waar 'n verlies aan konsentrasie tot ongelukke aanleiding kan gee nie.

Dosisse groter as die aanbevole dosis kan ernstige lewerskade veroorsaak. Die dosering moet verminder word indien nierfunksie ingekort is. Asmalyers moet middel met sorg neem.

Raadpleeg 'n geneesheer indien geen verligting met die aanbevole dosering verkry word nie. Gebruik met sorg in geval van niersiekte.

INTERAKSIES

Verwys na die afdelings "KONTRA-INDIKASIES" en "NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS".

SWANGERSKAP EN BORSVOEDING

Die veiligheid van hierdie preparaat is nie bewys vir gebruik tydens swangerskap en borsvoeding nie.

DOSIS EN GEBRUIKSAANWYSINGS

Moenie die aanbevole dosis oorskry nie.

Volwassenes en kinders 12 jaar en ouer: 1 tot 2 tablette opgelos in ongeveer 200 ml water elke 4 uur soos nodig. Moenie meer as 8 tablette per dag neem nie. Moenie langer as 10 dae aaneen neem sonder om u geneesheer te raadpleeg nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Parasetamol:

Sensitiwiteitsreaksies wat tot omkeerbare veluitslae in bloedaandoeninge aanleiding kan gee, mag voorkom. Hierdie veluitslag is gewoonlik eriteem- of roosagtig, maar kan soms ernstig wees en gepaard gaan met geneesmiddel geïnduseerde koors en slymvliesletsels. Pankreatitis mag voorkom. Die gebruik van parasetamol is al geassosieer met die voorkoms van trombositopenie, neutropenie, pansitopenie, leukopenie en agranulositose.

Pasiënte met nier- en lewersiektes behoort parasetamol onder mediese toesig te neem.

Kodeïenfosfaat:

Kodeïen kan naarheid, braking, hardlywigheid, lomerigheid, verwarring, droë mond, sweet, gesigsgloede, vertigo, asemhalingsonderdrukking, bradikardie, hartkloppings, hipotensie, ortostatiese hipotensie, omloopstelselversaking, hipertermie, rusteloosheid, verdiepende koma, 'n gevoel van welsyn, verandering in gemoedstoestand en miose, spierstyfheid, gejeuk, galbulte en sweet veroorsaak. Urinering kan moeilik wees en daar kan ureter- of galspasmas voorkom met 'n diuretiese effek. Verhoogde intrakraniale druk mag voorkom.

Kodeïen moet met versigtigheid toegedien word aan pasiënte met hipotiroïdisme, bynier ontoereikendheid, lewer- of nierwanfunksie, miastenie gravis, hipertrofie van die prostaat of skok. Dit moet met versigtigheid gebruik word by pasiënte met inflammasie of obstruksie van die ingewande. Die dosis moet by bejaarde of verswakte pasiënt verminder word. Die onderdrukkende effekte van kodeïen word verhoog deur sentrale senuweestelselonderdrukkers soos alkohol, anestetika, slaap- en kalmeermiddels en fenotiasiene.

Langdurige gebruik van hoë dosisse kodeïen kan gewoontevormend word.

Kafeïen:

Newe-effekte van kafeïen sluit naarheid, hoofpyn en slapeloosheid in. Groot dosisse kan rusteloosheid, opgewondenheid, spiertrillings, tinnitus, flikkerende skotoom, tagikardie en ekstrasistolie veroorsaak. Kafeïen verhoog maagsapafskeiding en kan maagulkusse veroorsaak. Kafeïen moet met versigtigheid toegedien word aan pasiënte met 'n geskiedenis van maagsere. Met langdurige gebruik kan 'n mate van verdraagsaamheid en psigiese afhanklikheid voorkom. Gee met sorg aan pasiënte met hipotiroïdisme, hartaritmieë of ander kardiovaskulêre siektes of epilepsie, aangesien hierdie toestande vererger kan word.

Doksielamiensuksinaat:

'n Algemene newe-effek van doksielamiensuksinaat is sedasie (sien "WAARSKUWINGS"). Ander newe-effekte sluit in maagdermversteurings, hoofpyn, dowwe visie, tinnitus, uitgelatenheid of depressie, irriteerbaarheid, nagmerries, anoreksie, moeilike urinering, droë mond, toe bors en suising, swaarheid en swakheid van die hande, naarheid, braking, diarree en parestesie.

Simptome van paradoksale sentrale senuweestelsel stimulasie by volwassenes sluit in slapeloosheid, senuweeagtigheid, tagikardie, hipotensie, spierbewing, spiertrilling en konvulsies.

Hipersensitiwiteitsreaksies soos veluitslae, galbulte, purpura, angioedeem, brongospasma of anurie kan voorkom. Groot dosisse kan aanvalle by epilepsie-lyers veroorsaak. Allergie en anafilakse kan voorkom. Veelvoudige eriteem en afskilferende of blasige dermatitis kan voorkom. Simptome van porfirie kan vererger word.

Bloedafwykings, insluitend agranulositose, eosinofilie, leukopenie, trombositopenie en hemolitiese bloedarmoede kan voorkom. Doksielamiensuksinaat het anticholinergiese eienskappe en behoort met sorg gebruik te word in toestande soos gloukoom en hipertrofie van die prostaat. Die effek van atropien en trisikliese antidepressante kan versterk word deur doksielamiensuksinaat. Doksielamiensuksinaat kan die waarskuwende simptome van beskadiging deur ototoksiese geneesmiddels masker en kan ook die metabolisme van geneesmiddels in die lewer beïnvloed.

Doksielamiensuksinaat kan ook die sedatiewe effekte van sentrale senuweestelselonderdrukkers soos onder andere alkohol, barbiturate, hipnotika, narkotiese analgetika, slaapmiddels en kalmeermiddels versterk.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Antihistamiene (doksielamiensuksinaat):

Oordosering met doksielamiensuksinaat veroorsaak sedasie. Oordosering kan fataal wees, veral by babas en kinders by wie die hoof simptome sentrale senuwee stimulasie en antimuskariene effekte is, insluitend ataksie, opgewondenheid, hallusinasies, spierbewing, konvulsies, pupilverwyding, droë mond, gesigsgloede en hiperpireksie. Verdiepende koma, kardiorespiratoriese verval en dood kan binne 18 uur voorkom. By volwassenes is die simptome wat gewoonlik voorkom sentrale senuwee onderdrukking met lomerigheid, koma en konvulsies. Hipotensie mag ook voorkom. Behandeling van antihistamien-oordosering is simptomaties en ondersteunend.

Parasetamol:

Simptome van parasetamol oordosering in die eerste 24 uur is bleekheid, naarheid, braking, anoreksie, en buikpyn. Lewerskade mag 12 tot 48 uur na inname waarneembaar word. Abnormale metabolisme van glukose en metaboliese asidose kan voorkom. Akute nierversaking met akute tubulêre nekrose kan selfs in die afwesigheid van ernstige lewerbeskadiging, ontwikkel. Hartaritmieë is ook al aangemeld.

Simptome binne die eerste 2 dae van akute vergiftiging reflekteer nie die potensiële ernstigheid van die oordosering nie. Naarheid, braking, anoreksie en abdominale pyn mag vir 'n week of langer voortduur. Lewerskade mag op die tweede dag (of eers later) verskyn, aanvanklik met verhoging in serum transaminase- en melksuurdehidrogenase-aktiwiteit, verhoogde serumbilirubienkonsentrasies en verlenging van protrombientyd. Die lewerskade kan ontwikkel in breinsiekte, koma en dood. Serebrale edeem en nie-spesifieke miokardiale onderdrukking kan ook voorkom.

In geval van 'n oordosering moet 'n dokter geraadpleeg word of die pasiënt moet onmiddellik na die naaste hospitaal geneem word.

Gespesialiseerde behandeling so gou as moontlik is nodig. Vinnige behandeling is noodsaaklik. Enige pasiënt wat ongeveer 7,5 g parasetamol in die voorafgaande 4 uur geneem het se maag moet gespoel word. Spesifieke behandeling met 'n teenmiddel soos asetielsisteïen behoort so gou as moontlik IV toegedien te word.

Vatbaarheid vir parasetamol vergiftiging is verhoog by pasiënte wat herhaalde doserings (7,5 – 10 g/dag) parasetamol vir verskeie dae geneem het, in chroniese alkoholisme, chroniese lewersiekte, VIGS, wanvoeding, en met die gebruik van medikasie wat lewer mikrosomale oksidasie induseer, soos barbiturate, isoniasied, rifampisien, fenitoïen en karbamasepien.

Asetielsisteïen:

Asetielsisteïen behoort so gou moontlik toegedien te word, verkieslik binne 8 uur na die oordosering.

IV: 'n Aanvanklike dosis van 150 mg/kg in 200 ml glukose inspuiting, toegedien intraveneus oor 'n tydperk van 15 minute, gevolg deur 'n intraveneuse infusie van 50 mg/kg in 'n 500 ml glukose inspuiting tydens die volgende 4 uur, en dan 100 mg/kg in 1 000 ml oor die volgende 16 uur. Die volume van intraveneuse vloeistowwe behoort aangepas te word vir kinders.

Oraal: Aanvanklik 140 mg/kg as 'n 5 % oplossing, gevolg deur 'n 70 mg/kg oplossing elke 4 uur vir 17 dosisse.

Asetielsisteïen is effektief indien toegedien binne 8 uur na die oordosering. Indien N-asetielsisteïen nie beskikbaar is nie kan 2,5 g metionien onmiddelik gegee word, met 2,5 g elke vier ure vir drie doserings daarna. Pasiënte moet egter verkieslik verskuif word na 'n fasiliteit waar N-asetielsisteïen gegee kan word.

Kodeïenfosfaat:

Vergiftiging met kodeïen veroorsaak sentrale stimulasie met opgewondenheid en, in kinders, konvulsies wat gevolg word deur braking, lomerigheid, asemhalingsonderdrukking en sianose en koma.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

'n Ronde wit tot afwit tablet, met skerp kante en 'n kersie geur en smaak.

AANBIEDING

Wit polipropileen buisie wat 18 tablette elk bevat.

BERGINGSINSTRUKSIES

Berg benede 25 °C in 'n droë plek. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

33/2.8/0380
11/2.8/0040 (Namibië)

NAAM EN ADRES VAN DIE APPLIKANT

Mirren (Edms) Bpk
Goldenrylaan 18
Morehill
Benoni
Suid-Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

4 Maart 2005

TPE-PI-PR-14/11
Pro-Print

SCHEDULING STATUS S2

NS1 (Namibia)

PROPRIETARY NAME (AND DOSAGE FORM)

Tensopyn Effervescent Tablets

COMPOSITION

Each tablet contains:

Paracetamol	450 mg
Doxylamine succinate	5 mg
Caffeine anhydrous	50 mg
Codeine phosphate	10 mg

Preservative:

Sodium benzoate	0,001 % *m/m*

PHARMACOLOGICAL CLASSIFICATION

A 2.8 Analgesic combinations.

PHARMACOLOGICAL ACTION

TENSOPYN EFFERVESCENT TABLETS have analgesic, antipyretic and antihistaminic properties.

INDICATIONS

TENSOPYN EFFERVESCENT TABLETS are indicated for the relief of mild to moderate pain associated with tension.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients. Severe liver function impairment. Acute intermittent porphyria.

Contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operation on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease. Contra-indicated in patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment. Safety in pregnancy and lactation has not been established.

WARNINGS

Do not use continuously for longer than 10 days without consulting your doctor. 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. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Dosage in excess of those recommended may cause severe liver damage. The dosage in renal functional impairment must be reduced. Should be taken with caution by asthmatics.

Consult a doctor if no relief is obtained from the recommended dosage. Use with caution in renal disease.

INTERACTIONS

Refer to section "CONTRA-INDICATIONS" and "SIDE EFFECTS AND SPECIAL PRECAUTIONS".

PREGNANCY AND LACTATION

The safety of this preparation in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Do not exceed the stated dose.

Adults and children 12 years and older: 1 to 2 tablets dissolved in approximately 200 ml water every 4 hours as needed. Do not exceed 8 tablets per day. Do not use continuously for longer than 10 days without consulting your doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Paracetamol:

Sensitivity reactions resulting in reversible skin rashes or blood disorders may occur. This rash is usually erythematous or urticarial, but sometimes more serious and may be accompanied by drug fever and mucosal lesions. Pancreatitis may occur. The use of paracetamol has been associated with the occurrence of thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis.

Patients suffering from kidney or liver disease should take paracetamol under medical supervision.

Codeine phosphate:

Codeine may cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, respiratory depression, bradycardia, palpitation, hypotension, orthostatic hypotension, circulatory failure, hyperthermia, restlessness, deepening coma, euphoria, changes of mood and miosis, muscle rigidity, pruritus, urticaria and sweating. Micturition may be difficult and there may be ureteric or biliary spasms and a diuretic effect. Raised intracranial pressure may occur.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, myasthenia gravis, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients. The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives and phenothiazines.

Prolonged use of high doses of codeine has produced dependence.

Caffeine:

Side-effects of caffeine include nausea, headache and insomnia. Large doses may cause restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystole. Caffeine increases gastric secretion and may cause gastric ulceration. Caffeine should be given with care to patients with a history of peptic ulceration. With prolonged use some degree of tolerance and psychic dependence may occur. Give with caution to patients with hyperthyroidism, cardiac arrhythmias or other cardiovascular disease or epilepsy as these conditions may be exacerbated.

Doxylamine succinate:

A common side-effect of doxylamine succinate is sedation (see "WARNINGS"). Other side-effects include gastrointestinal disturbances, headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands, nausea, vomiting, diarrhoea and paraesthesia.

Symptoms of paradoxical central nervous system stimulation in adults include insomnia, nervousness, tachycardia, hypotension, tremors, muscle twitching and convulsions.

Hypersensitivity reactions such as skin rashes, urticaria, purpura, angioedema, bronchospasm or anuria may occur. Large doses may precipitate fits in epileptics. Allergy and anaphylaxis may occur. Erythema multiforme and exfoliative or bullous dermatitis may occur. Symptoms of porphyria may be exacerbated.

Blood discrasias, including agranulocytosis, eosinophilia, leukopenia, thrombocytopenia and haemolytical anaemia may occur. Doxylamine succinate has anticholinergic properties and should be used with care in conditions such as glaucoma and prostatic hypertrophy. The effects of atropine and tricyclic antidepressants may be enhanced by doxylamine succinate. Doxylamine succinate may mask the symptoms of damage caused by ototoxic medicine and may affect metabolism of medicine in the liver.

Doxylamine succinate may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Antihistamines (doxylamine succinate):

Overdosage of doxylamine succinate causes sedation. Overdosage may be fatal, especially in infants and children in whom the main symptoms are central nervous stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur within 18 hours. In adults the usual symptoms are central nervous depression with drowsiness, coma and convulsions. Hypotension may also occur. Treatment of antihistamine overdose is symptomatic and supportive.

Paracetamol:

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported.

Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day (or later), initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and nonspecific myocardial depression have also occurred.

In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately.

Specialised treatment is essential as soon as possible. Prompt treatment is essential. Any patient who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine should be administered IV as soon as possible.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (7,5 – 10 g/day) paracetamol for several days in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of medicines that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Acetylcysteine:

Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.

Acetylcysteine is effective if administered within 8 hours of overdosage.

If N-acetylcysteine is not available, methionine 2,5 g may be given immediately, followed by 2,5 g every four hours for the three doses. Patients should however preferably be transferred to a facility where N-acetylcysteine can be given.

Codeine phosphate:

Poisoning with codeine produces central stimulation with exhilaration and, in children, convulsions followed by vomiting, drowsiness, respiratory depression and cyanosis and coma.

Treatment is symptomatic and supportive.

IDENTIFICATION

Round white to off-white tablet, with sharp edges and a cherry odour and taste.

PRESENTATION

White polypropylene tubes containing 18 tablets each.

STORAGE INSTRUCTIONS

Store below 25 °C in a dry place. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

33/2.8/0380

11/2.8/0040 (Namibia)

NAME AND ADDRESS OF THE APPLICANT

Mirren (Pty) Ltd
18 Golden Drive
Morehill
Benoni
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT

4 March 2005

TPE-PI-PR-14/11