SKEDULERINGSTATUS S2 20 en 40 tablette

S3 100 tablette

NS1 (Namibië)

EIENDOMSNAAM (EN DOSEERVORM)

Tensopyn Tablette

SAMESTELLING

Elke tablet bevat:

Parasetamol	450 mg
Kodeïenfosfaat	10 mg
Kafeïen anhidries	30 mg
Doksielamiensuksinaat	5 mg

FARMAKOLOGIESE KLASSIFIKASIE

A 2.9 Ander analgetika.

FARMAKOLOGIESE WERKING

TENSOPYN TABLETTE het 'n pynstillende, koorswerende en antihistamiene werking.

INDIKASIES

Vir ligte tot matige pyn wat met spanning gepaard gaan.

KONTRA-INDIKASIES

Pasiënte met verswakte lewer- of nierfunksie.
Hipersensitiwiteit vir enige van die bestanddele.
Die gebruik van monoamienoksidaseremmers, of binne 10 dae nadat sodanige behandeling gestaak is.

WAARSKUWINGS

Oorskryding van die voorgeskrewe dosis, tesame met langdurige en voortgesette gebruik van hierdie medikasie, kan tot afhanklikheid en verslawing lei.
Moenie nie langer as 10 dae aaneenlopend gebruik sonder om u dokter te raadpleeg nie. Raadpleeg u dokter ook indien geen verligting met die aanbevole dosis verkry word nie.
As gevolg van die parasetamolinhoud kan dosisse wat die aanbevole dosis oorskry, ernstige lewerskade veroorsaak. Pasiënte wat aan lewer- of niersiektes ly, behoort parasetamol onder mediese toesig te neem.
Daar behoort, wanneer hierdie preparaat gedurende die eerste trimester van swangerskap toegedien word, met sorg te werk gegaan word.
Hierdie medisyne kan tot lomerigheid en verswakte konsentrasie lei, wat deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel-depressante vererger kan word.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes en kinders bo 12 jaar: Een tot twee tablette elke 4 uur, met 'n maksimum van 8 tablette per dag.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Parasetamol:

Hematologiese reaksies is aangemeld. Veluitslae het ook al voorgekom.

Kodeïenfosfaat:

Hardlywigheid, naarheid en vomering, duiseligheid en lomerigheid. Droë mond, gesigsgloede, vertigo, bradikardie, hartkloppings, flouheid, kalmering, rusteloosheid, veranderings van gemoedstoestand, miose en verhoogde intrakraniale druk kan ook voorkom. Die depressiewe effekte daarvan word deur anestetika, hipnotika, kalmeermiddels en fenotiasiene verhoog. Dit behoort met versigtigheid geneem te word deur pasiënte met belemmerde lewerfunksie of prostaathipertrofie, bejaarde pasiënte en na operasies aan die galweë. As gevolg van die histamien-vrystellende effek kom allergiese reaksies soos urtikarie, pruritus en 'n gejeuk van die neus by sommige individue voor en idiosinkrasie tot kodeïen en ander narkotiese pynstillers is redelik algemeen.

Kafeïen:

Naarheid, hoofpyn en slaaploosheid. Kafeïen verhoog maag-uitskeidings en kan maagseervorming tot gevolg hê.

Doksielamiensuksinaat:

Kalmering wat wissel van geringe lomerigheid tot diep slaap, wat die onvermoë om te konsentreer, vermoeidheid, duiseligheid, hipotensie, spierswakheid en inkoördinasie insluit. Ander newe-effekte sluit gastro-intestinale versteurings soos naarheid, vomering, diarree of hardlywigheid, koliek en epigastriese pyn in. Dit kan ook lei tot hallusinasies, belemmerde gesigsvermoë, tinnitus, opgetoënheid of bedruktheid, prikkelbaarheid, anoreksie, moeilike urinering, droogheid van die mond, benoudheid van die bors en swakheid van die hande. Groot dosisse antihistamiene kan aanvalle by epilepsielyers veroorsaak. Alhoewel dit selde die geval is, is bloeddiskrasies, insluitend agranulositose, hemolitiese anemie en trombositopeniese purpura al aangemeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Parasetamol:

Lewerskade wat noodlottig kan wees, kan eers na 'n paar dae verskyn. Simptome van oordosering sluit naarheid en vomering in. Akute intoksikasie kan nierversaking veroorsaak.

Kodeïenfosfaat:

Veroorsaak sentrale stimulering met opgewondenheid en, by kinders, stuiptrekkings, wat gevolg word deur vomering, lomerigheid, respiratoriese depressie en sianose, en koma.

Kafeïen:

Groot dosisse kan rusteloosheid, opgewondenheid, spierbewing, tinnitus, flikkerskotoom, tagikardie en ekstrasistole veroorsaak.

Doksielamiensuksinaat:

By die jong kind is die oorheersende uitwerking opgewondenheid, wat hallusinasies, ataksie, inkoördinering, atetose en stuiptrekkings insluit. Starre, verwyde kykers met 'n blosende gesig en koors is algemeen. By die volwassene is koors en gesigsgloede gewoonlik nie te bespeur nie en die fase van opgewondenheid wat tot stuiptrekkings en postiktale bedruktheid lei, word dikwels deur lomerigheid en koma voorafgegaan.
In die geval van oordosering, raadpleeg 'n dokter of neem die pasiënt onmiddellik na die naaste hospitaal. Respiratoriese depressie sal reageer op toediening van naloksoon.
Gespesialiseerde behandeling is noodsaaklik so gou as moontlik. Die nuutste inligting in verband met die behandeling van oordosering kan by die naaste gifhulpsentrum verkry word.

IDENTIFIKASIE

Oranje, effens gespikkelde, feitlik reuklose, ronde tablette met plat oppervlaktes en skuins kante met 'n driehoekmonogram gedruk op die een kant.

AANBIEDING

Pakkies van 20 tablette in stolpverpakking, en houers met 40 en 100 tablette.

BERGINGSINSTRUKSIES

Bewaar op 'n koel (benede 25 °C), droë plek.
Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

T/2.9/79
11/2.9/0039 (Namibië)

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Mirren (Edms) Bpk
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

18 November 1985

TPT-PI-PR-16/06
Pro-Print

SCHEDULING STATUS S2 20 and 40 tablets

S3 100 tablets

NS1 (Namibia)

PROPRIETARY NAME (AND DOSAGE FORM)

Tensopyn Tablets

COMPOSITION

Each tablet contains:

Paracetamol	450 mg
Codeine phosphate	10 mg
Caffeine anhydrous	30 mg
Doxylamine succinate	5 mg

PHARMACOLOGICAL CLASSIFICATION

A 2.9 Other analgesics.

PHARMACOLOGICAL ACTION

TENSOPYN TABLETS have analgesic, antipyretic and antihistaminic action.

INDICATIONS

For mild to moderate pain associated with tension.

CONTRA-INDICATIONS

Patients with impaired liver or kidney function.
Hypersensitivity to any of the ingredients.
The use of monoamine oxidase inhibitors or within 10 days of stopping such treatment.

WARNINGS

Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.
Do not use continuously for more than 10 days without consulting your doctor. Also consult your doctor if no relief is obtained with the recommended dosage.
Due to the paracetamol content, dosage in excess of that recommended may cause severe liver damage. Patients suffering from liver or kidney disease should take paracetamol under medical supervision. Care should be taken when administering this preparation during the first trimester of pregnancy.
This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years: One to two tablets every 4 hours, with a maximum of 8 tablets daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Paracetamol:

Haematological reactions have been reported. Skin eruptions have also occurred.

Codeine phosphate:

Constipation, nausea and vomiting, dizziness and drowsiness. Dry mouth, facial flushing, vertigo, bradycardia, palpitations, faintness, sedation, restlessness, changes of mood, miosis and raised intracranial pressure may also occur. Its depressant effects are enhanced by anaesthetics, hypnotics, sedatives and phenothiazines. It should be taken with caution by patients with impaired liver function or prostatic hypertrophy, elderly patients and after operations on the biliary tract. Due to the histamine-releasing effect allergic reactions such as urticaria, pruritus and itching of the nose occur in some individuals and idiosyncrasy to codeine and other narcotic analgesics is fairly common.

Caffeine:

Nausea, headache and insomnia. Caffeine increases gastric secretion and may cause gastric ulceration.

Doxylamine succinate:

Sedation varying from slight drowsiness to deep sleep including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and in-coordination. Other side-effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, colic and epigastric pain. It may also produce hallucinations, blurred vision, tinnitus, elation or depression, irritability, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and weakness of the hands. Large doses of antihistamines may precipitate fits in epileptics.
Blood dyscrasias, including agranulocytosis, haemolytic anaemia and thrombocytopenic purpura, though rare, have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Paracetamol:

Liver damage which may be fatal may only appear after a few days. Symptoms of overdosage include nausea and vomiting. Acute intoxication may cause kidney failure.

Codeine phosphate:

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

Caffeine:

Large doses may cause restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystoles.

Doxylamine succinate:

In the small child the dominant effect is excitement including hallucinations, ataxia, incoordination, athetosis and convulsions. Fixed dilated pupils with a flushed face and fever are common. In the adult, fever and flushing are not usually in evidence, the phase of excitement leading to convulsions and postictal depression is not uncommonly preceded by drowsiness and coma.
In the event of overdosage, consult a doctor or take the patient to the nearest hospital immediately. Respiratory depression will respond to naloxone administration.
Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest Poison Centre.

IDENTIFICATION

Orange, slightly mottled, practically odourless, flat faced, bevelled edged, round tablets embossed with a triangle on one side.

PRESENTATION

Packs of 20 blistered tablets, and containers of 40 and 100 tablets.

STORAGE INSTRUCTIONS

Store in a cool (below 25 °C), dry place.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

T/2.9/79
11/2.9/0039 (Namibia)

NAME AND BUSINESS ADDRESS OF APPLICANT

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

18 November 1985

TPT-PI-PR-16/06