SCHEDULING STATUS: S1
NS1 (Namibia)

PROPRIETARY NAME AND DOSAGE FORM:

TENSOPYN PAEDIATRIC SYRUP

COMPOSITION:
Each 5 ml syrup contains:

Paracetamol	150,0 mg
Codeine phosphate	4,0 mg
Preservatives:	
Sodium benzoate	0,1 % m/v
Potassium sorbate	0,2 % m/v

The other ingredients are: Propylene glycol, glycerine, macrogol, sodium cyclamate, acesulfame-K, butylated hydroxytoluene, sodium chloride, blackcurrent flavour, cherry flavour, purified water.
SUGAR FREE.

PHARMACOLOGICAL CLASSIFICATION:
A.2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:
Pharmacodynamics:
Paracetamol has analgesic and antipyretic properties.
Codeine phosphate has analgesic properties.
Pharmacokinetics:
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is presented in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours. Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucoronide and sulphate conjugates. Less than 5 % is excreted as unchanged paracetamol. A minor hydroxylated metabolite (*N*-acetyl-p-benzoquinoneimine) is usually produced in very small amounts by cytochrome P450 iso-enzymes in the liver and kidneys. It is usually detoxified by conjugation with glutathione but may accumulate following paracetamol overdosage and cause tissue damage.
Codeine phosphate is absorbed from the gastrointestinal tract. Ingestion of codeine phosphate produces peak plasma-codeine concentrations in about one hour. Codeine is metabolized by *O*- and *N*- demethylation in the liver to morphine, norcodeine, and other metabolites including normorphine and hydrocodone. Codeine and its metabolites are excreted almost entirely by the kidneys, mainly as conjugates with glucuronic acids. The plasma half-life has been reported to be between 3 and 4 hours after an oral dose.

INDICATIONS:
TENSOPYN PAEDIATRIC SYRUP is indicated for the symptomatic relief of mild to moderate pain and fever in children.

CONTRA-INDICATIONS:
Hypersensitivity to paracetamol, opiates or any of the other ingredients in **TENSOPYN PAEDIATRIC SYRUP**.
During an attack of bronchial asthma, respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, heart failure secondary to chronic lung disease, liver or kidney damage, head injuries and where intracranial pressure is raised.
Should be used with extreme caution in patients receiving monoamine-oxidase inhibitors.
Premature infants or neonates.
TENSOPYN PAEDIATRIC SYRUP is contra-indicated in patients receiving monoamine oxidase inhibitors or within 10 days of stopping such treatment.

WARNINGS:

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.

If the patient does not respond, a doctor should be consulted.
Do not take continuously for more than 10 days without consulting a doctor.
Patients should be examined periodically for abnormal skin pigmentation or eye changes.
Dosages in excess of those recommended may cause severe liver damage.
Overdosage is very dangerous in young children.

INTERACTIONS:
Refer to section **"CONTRA-INDICATIONS"** and **"SIDE EFFECTS AND SPECIAL PRECAUTIONS"**.
Paracetamol: The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic medicines or medicines that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by medicines such as metoclopramide. Excretion may be affected and plasma concentrations altered when administered with probenecid. Cholestyramine reduces the absorption of paracetamol if given within one hour of paracetamol administration. Paracetamol must be given with caution if concomitantly used with antibacterials, anticoagulants, antiepileptics, antivirals and probenecid.
Codeine phosphate: The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives and phenothiazines.

PREGNANCY AND LACTATION:
The safety of **TENSOPYN PAEDIATRIC SYRUP** in pregnancy and lactation has not been established. Paracetamol crosses the placenta and is presented in breast milk.

DOSAGE AND DIRECTIONS FOR USE:
DO NOT EXCEED THE RECOMMENDED DOSE.

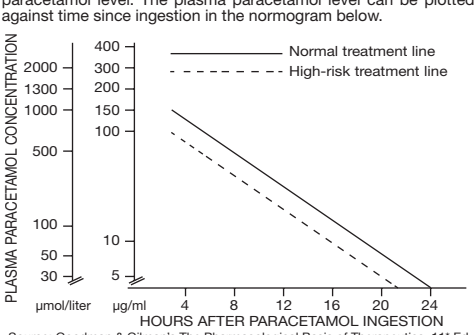
Infants: 6 months to 1 year:	2,5 ml (half a medicine measure) every four hours.
Children 1 – 5 years:	5,0 ml (one medicine measure) every four hours.
Children 6 – 12 years:	5 ml to 10 ml (one to two medicine measures) every four hours.

Should not be administered more than four times daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
The following side-effects may occur with **TENSOPYN PAEDIATRIC SYRUP:**
- Skin and appendages disorders
  Less frequent – Yellow eyes or skin, pinpoint red spots on skin, allergic reactions, hives or itching, sores, ulcers, or white spots on lips or in the mouth, skin eruptions, skin rash. This rash is usually erythromatous or urticarial, but sometimes more serious and may be accompanied by drug fever and mucosal lesions. Redness or flushing of face
- Musculoskeletal system disorders
  Less frequent – Trembling or uncontrolled muscle movements or muscle rigidity
- Central and peripheral nervous system disorders
  Frequent – Dizziness, drowsiness, confusion, dry mouth, sweating, facial flushing, faintness, sedation, vertigo
- Vision disorders
  Less frequent – Miosis
- Hearing and vestibular disorders
  Less frequent – Ringing or buzzing in the ears
- Psychiatric disorders
  Less frequent – Feelings of unreality, hallucinations, mental depression or other mood or mental changes, restlessness, deepening coma, euphoria
- Gastro-intestinal disorders
  Frequent – Nausea, vomiting, constipation
  Less frequent – Bloody or black, tarry stools, sore throat, biliary spasms
- Endocrine disorders
  Frequency not known – Pancreatitis
- Heart rate and rhythm disorders
  Less frequent – Fast, slow, or pounding heartbeat, bradycardia, palpitations
- Vascular (extracardiac) disorders
  Less frequent – Swelling of face, hypotension, orthostatic hypotension, circulatory failure, hyperthermia
- Respiratory system disorders
  Less frequent – Increased sweating, irregular breathing, shortness of breath, wheezing or troubled breathing, respiratory depression
- Platelet, bleeding and clotting disorders
  Less frequent – Unusual bleeding or bruising
  Frequency not known – Haematological reactions, thrombocytopenia, neutropenia, pancytopenia, leucopenia and agranulocytosis
- Urinary system disorders
  Less frequent – Bloody or cloudy urine, sudden decrease in amount of urine, difficult micturition, ureteric spasms, antidiuretic effect
- Body as a whole – general disorders
  Less frequent: Unusual tiredness or weakness, raised intracranial pressure

Special precautions:
Patients suffering from kidney or liver disease should take **TENSOPYN PAEDIATRIC SYRUP** under medical supervision.
TENSOPYN PAEDIATRIC SYRUP 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, prostatic hypertrophy, elderly patients and after operations on the biliary tract. The dosage should be reduced in elderly and debilitated patients.
TENSOPYN PAEDIATRIC SYRUP should be taken with caution by patients with impaired liver function. 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 are fairly common.
Breathing problems may be especially likely to occur in children younger than 2 years of age.
Unusual excitement or restlessness may be more likely to occur in children receiving **TENSOPYN PAEDIATRIC SYRUP.**
The depressant effects of codeine are enhanced by depressants of the central nervous system such as anaesthetics, hypnotics and sedatives, and phenothiazines.
The prolonged use of high doses of codeine has produced dependence.
Consult a doctor if no relief is obtained with the recommended dosage.
Do not use continuously for longer than ten days without consulting a doctor.
Store in a safe place, out of reach of children.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
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 the 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 drugs that induce 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 the prothrombin time. 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:
Although evidence is limited it is recommended that any adult person who has ingested 5 – 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.
N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight 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 four hours, and then 100 mg/kg in 1000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children.**
Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.
A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four 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 below.



Source: Goodman & Gilman's The Pharmacological Basis of Therapeutics, 11* Ed.

Those whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen 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 ingestions for at least ninety six hours.
Codeine:
Larger doses of codeine produce respiratory depression and hypotension, with circulatory failure and deepening coma. Convulsions may occur in infants and children. Death may occur from respiratory failure.
Get emergency help immediately if any of the following symptoms occur:
Cold, clammy skin, confusion, convulsions, severe dizziness, low blood pressure, severe nervousness or restlessness, pinpoint pupils of eyes, slow heartbeat, slow or troubled breathing, severe weakness.
In acute poisoning the stomach should be emptied by aspiration and lavage. Intensive supportive therapy may be necessary to correct respiratory failure and shock. The specific antagonist naloxone may be used to counteract severe respiratory depression.

IDENTIFICATION:
A clear, colourless syrup, with an odour and taste of fresh cherries.

PRESENTATION:
Amber glass bottle of 100 ml, fitted with a white plastic cap with a tamper-evident break ring, packed into an outer carton.

STORAGE INSTRUCTIONS:
Store at or below 25 ºC. Protect from light. Keep the bottle well closed until ready for use. Store the bottle in the original container until ready for use.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:
W/2.8/23
12/21.2/0109 (Namibia)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Mirren (Pty) Ltd
18 Golden Drive
Morehill
Benoni
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
16 February 2011

TPP-PI-BP-14/04

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **TENSOPYN PAEDIATRIC SYRUP** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your or your child's symptoms worsen or do not improve after 5 days.

SCHEDULING STATUS: S1
NS1 (Namibia)

PROPRIETARY NAME AND DOSAGE FORM:

TENSOPYN PAEDIATRIC SYRUP

150,0 mg paracetamol and 4,0 mg codeine phosphate per 5 ml.

WHAT TENSOPYN PAEDIATRIC SYRUP CONTAINS:
Each 5 ml syrup contains:

Paracetamol	150,0 mg
Codeine phosphate	4,0 mg
Preservatives:	
Sodium benzoate	0,1 % m/v
Potassium sorbate	0,2 % m/v

The other ingredients are: Propylene glycol, glycerine, macrogol, sodium cyclamate, acesulfame-K, butylated hydroxytoluene, sodium chloride, blackcurrent flavour, cherry flavour, purified water.
SUGAR FREE.

WHAT TENSOPYN PAEDIATRIC SYRUP IS USED FOR:
TENSOPYN PAEDIATRIC SYRUP is used for the relief of mild to moderate pain and fever in children.

BEFORE YOU TAKE TENSOPYN PAEDIATRIC SYRUP:
Do not give TENSOPYN PAEDIATRIC SYRUP to your child if:
- your child has had an allergic or unusual reaction to any of the ingredients in **TENSOPYN PAEDIATRIC SYRUP**
- your child has an allergy to any of the ingredients in **TENSOPYN PAEDIATRIC SYRUP**
- your child has severe kidney disease
- your child has jaundice or any other liver disease

Take special care with TENSOPYN PAEDIATRIC SYRUP if your child is taking other medicines which have calming effects such as medicines containing alcohol or medicines which cause sleepiness or drowsiness as **TENSOPYN PAEDIATRIC SYRUP** may enhance these symptoms. (Refer "Taking other medicines with **TENSOPYN PAEDIATRIC SYRUP"**).
Taking TENSOPYN PAEDIATRIC SYRUP with food and drink:
TENSOPYN PAEDIATRIC SYRUP may be taken without regard for food or drink.

PREGNANCY AND BREAST-FEEDING:
The safety of **TENSOPYN PAEDIATRIC SYRUP** in pregnancy and lactation has not been established. Paracetamol crosses the placenta and is presented in breast milk.
If you are pregnant or breast feeding your baby while taking **TENSOPYN PAEDIATRIC SYRUP**, or you are giving **TENSOPYN PAEDIATRIC SYRUP** to your baby, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:
TENSOPYN PAEDIATRIC SYRUP is indicated for use by children. As **TENSOPYN PAEDIATRIC SYRUP** can lead to drowsiness and dizziness it is recommended that no tools or machines are used while taking **TENSOPYN PAEDIATRIC SYRUP**.

Taking other medicines with TENSOPYN PAEDIATRIC SYRUP:
If you or your child is taking **TENSOPYN PAEDIATRIC SYRUP** with other medicines which have calming effects such as medicines containing alcohol or medicines which cause sleepiness or drowsiness. **TENSOPYN PAEDIATRIC SYRUP** may enhance these symptoms. (Refer **"INSTRUCTION BEFORE TAKING TENSOPYN PAEDIATRIC SYRUP"**).
If you or your child are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TENSOPYN PAEDIATRIC SYRUP** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE TENSOPYN PAEDIATRIC SYRUP:
Always take **TENSOPYN PAEDIATRIC SYRUP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is:

Infants: 6 months to 1 year:	2,5 ml (half a medicine measure) every four hours.
Children 1 – 5 years:	5,0 ml (one medicine measure) every four hours.
Children 6 – 12 years:	5 to 10 ml (one to two medicine measures) every four hours.

TENSOPYN PAEDIATRIC SYRUP should not be administered more than four times daily.
If you have the impression that the effect of **TENSOPYN PAEDIATRIC SYRUP** is too strong or too weak, talk to your doctor or pharmacist.

DO NOT EXCEED THE STATED DOSE.

If you or your child take more TENSOPYN PAEDIATRIC SYRUP than you should:
If you or your child, accidentally take more **TENSOPYN PAEDIATRIC SYRUP** than you should, or someone else takes your medicine, you should tell your doctor or pharmacist at once. If neither is available, contact the nearest hospital or poison control centre immediately. Show any left-over medicines or the empty bottle or carton to the doctor.

If you forget to take TENSOPYN PAEDIATRIC SYRUP:
If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:
TENSOPYN PAEDIATRIC SYRUP can have side-effects.
Not all side-effects reported for **TENSOPYN PAEDIATRIC SYRUP** are included in this leaflet. Should your child's general health worsen while taking **TENSOPYN PAEDIATRIC SYRUP**, please consult your doctor, pharmacist or other health care professional for advice.
Stop taking **TENSOPYN PAEDIATRIC SYRUP** and contact your doctor or pharmacist if your child begins to itch, becomes short of breath or wheezy, develops swelling of the face, hands, feet, mouth, throat and eyes. These are allergic reactions. Your child may be allergic to **TENSOPYN PAEDIATRIC SYRUP**.
Paracetamol:
Skin rashes may occur. Patients suffering from kidney or liver disease should take **TENSOPYN PAEDIATRIC SYRUP** under medical supervision.
Codeine phosphate:
Codeine may cause nausea, vomiting, dizziness, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, faintness, sleepiness and difficult breathing.
TENSOPYN PAEDIATRIC SYRUP should be taken with caution by patients with liver problems.
The effects of **TENSOPYN PAEDIATRIC SYRUP** may be enhanced by medicines containing alcohol and by other medicines which cause drowsiness and sleepiness.
Breathing problems may be especially likely to occur in children younger than 2 years of age.
Unusual excitement or restlessness may occur in children receiving **TENSOPYN PAEDIATRIC SYRUP.**
Prolonged use of high doses of codeine has led to dependence.

If your child takes more TENSOPYN PAEDIATRIC SYRUP than he or she should:

TENSOPYN PAEDIATRIC SYRUP contains paracetamol and codeine which may be fatal in overdose. 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.

Prompt treatment is essential. If you or your child, take an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Liver damage is possible if effective treatment is not given immediately.
Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest Poison Centre.
Dosages in excess of those recommended may cause severe liver damage.
Overdosage is very dangerous in young children.

STORING AND DISPOSING OF TENSOPYN PAEDIATRIC SYRUP:
Store at or below 25 ºC. Protect from light. Keep the container in the outer carton. Keep the container tightly closed.
Do not use after the expiry date stated on the label.
Keep all medicine out of the reach and sight of children.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF TENSOPYN PAEDIATRIC SYRUP:
Amber glass bottle of 100 ml, fitted with a white plastic cap with a tamper-evident break ring, packed into an outer carton.

IDENTIFICATION OF TENSOPYN PAEDIATRIC SYRUP:
A clear, colourless syrup, with an odour and taste of fresh cherries.

REGISTRATION NUMBER/REFERENCE NUMBER:
W/2.8/23
12/21.2/0109 (Namibia)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Mirren (Pty) Ltd.
18 Golden Drive
Morehill
Benoni
South Africa
Tel No: (+2711) 425-4026

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:
16 February 2011

TPP-PI-BP-14/04

SKEDULERINGSTATUS: S1
NS1 (Namibië)

EIENDOMSNAAM EN DOSEERVORM:

TENSOPYN PAEDIATRIESE STROOP

SAMESTELLING:
Elke 5 ml stroop bevat:

Parasetamol	150,0 mg
Kodeïenfosfaat	4,0 mg
Preserveermiddels:	
Natriumbensoaat	0,1 % m/v
Kaliumsorbaat	0,2 % m/v

Die ander bestanddele is: Propileen glikol, gliserine, makrogol, natrium siklomaat, akesulfaam-K, gebutileerde hidroksietolueen, natrium chloried, swartbessiegeursel, kersiegeursel, gesuiwerde water.
BEVAT GEEN SUIKER.

FARMAKOLOGIESE KLASSIFIKASIE:
A.2.8 Analgetiese kombinasies

FARMAKOLOGIESE WERKING:
Pharmakodinamika:
Parasetamol het pynstillende en koorsverlagende eienskappe.
Kodeïenfosfaat het pynstillende eienskappe.
Pharmakokinetika:
Parasetamol word geredelik opgeneem vanuit die maagdermkanaal met piek plasmakonsentrasies wat bereik word na omtrent 10 tot 60 minute na dosering.
Parasetamol word versprei deur meeste van die liggaamsweefsels. Dit oorkruis die plasenta en is teenwoordig in borsmelk. Plasma-proteïen binding is weglaatbaar klein by gewone terapeutiese konsentrasies, maar verhoog met verhoogde konsentrasies. Die eliminasie half-lewe van parasetamol wissel tussen omtrent 1 tot 3 uur. Parasetamol word hoofsaaklik afgebreek in die lewer en uitgeskei in die urine hoofsaaklik as die glukoronied en sulfaat verbindings. Minder as 5 % word as onveranderde parasetamol uitgeskei.
'n Onbeduidende gehidroksieleerde metaboliet (*N*-asetiel-p-bensokwinonimie) word soms gevorm in klein hoeveelhede deur sitokroom P450 iso-ensieme in die lewer en niere.
Dit word gewoonlik ontgiftig deur die verbinding met glutatioon maar kan ophoop na parasetamol oordosering en kan weefsel skade veroorsaak.
Kodeïen fosfaat word uit die gastro-intestinale kanaal opgeneem. Na inname van kodeïen fosfaat word piek plasma-kodeïen konsentrasies verkry na omtrent een uur.
Kodeïen word afgebreek deur *O*- en *N*- demetilase in die lewer na morfien, norkodeïen, en ander metaboliete insluitend normorfien and hidrokodon.
Kodeïen en sy metaboliete word omtrent uitsluitlik uitgeskei deur die niere hoofsaaklik as verbindings met glukonsuur.
Die plasma half-lewe word aangegee om tussen 3 en 4 uur na orale dosis te wees.

INDIKASIES:
TENSOPYN PAEDIATRIESE STROOP word aangedui vir die simptomatiese verligting van ligte of matige pyn en koors by kinders.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir parasetamol, opiate of enige van die ander bestanddele.
Gedurende 'n brongiale asma aanval, asemhalingsonderdrukking, veral in die teenwoordigheid van sianose en oormatige brongiale afskeiding, hartversaking as gevolg van kroniese long siekte, lewer- of nierskade, kopbeserings en in gevalle waar interkraniale drukking verhoog is.
Moet met uiterste versigtigheid gebruik word in pasiënte wat mono-amien-oksidase inhibeerders gebruik.
Prematuur babas en pasgebore babas.
TENSOPYN PAEDIATRIESE STROOP is gekontra-indikeer by pasiënte wat mono-amien okidase inhibeerders ontvang of binne 10 dae nadat behandeling met hierdie middels, gestaak is.

WAARSKUWINGS:

In die geval van oordosering of as 'n oordosering vermoed word, al het die pasiënt geen simptome nie, moet die naaste dokter, hospitaal, of gifhulpsentrum onmiddelik geraadpleeg word.

As die pasiënt nie na wense reageer nie moet 'n dokter geraadpleeg word.
Moenie langer as 10 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.
Pasiënte behoort gereeld ondersoek te word vir abnormale vel pigmentasie of oog veranderings.
Dosisse van parasetamol groter as die aanbevole dosis kan ernstige lewerskade veroorsaak.
Oordosering is baie gevaarlik by jong kinders.

INTERAKSIES:
Verwys na **"KONTRA-INDIKASIES"** en **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS"**.
Parasetamol: Die risiko van parasetamol vergiftiging kan verhoog word by pasiënte wat ander potensieel lewertoksiese medisyne gebruik of medisyne wat lewermikrosoom ensieme veroorsaak.
Die opname van parasetamol kan versnel word deur medisyne soos metoklopramied. Uitskeiding kan geaffekteer en plasma konsentrasies kan verander word wanneer probenesied gelyktydig geneem word.
Cholestiramien verminder die opname van parasetamol wanneer dit binne een uur na parasetamol gegee word.
Parasetamol moet met versigtigheid gegee word wanneer dit saam met antibakteriële, antiepileptiese, antivirale middels, antikoagulante of probenesied toegedien word.
Kodeïenfosfaat: Die onderdrukkende eienskappe van kodeïen word versterk deur sentrale senuwee stelsel onderdrukkers soos alkohol, narkose, hipnotika, kalmeermiddels en fenotiasiene.

SWANGERSKAP EN BORSVOEDING:
Die veiligheid van **TENSOPYN PAEDIATRIESE STROOP** tydens swangerskap en borsvoeding, is nog nie vasgestel nie.
Parasetamol oorkruis die plasenta en is teenwoordig in bors melk.

DOSIS EN GEBRUIKSAANWYSINGS:
MOENIE DIE VOORGESKREWE DOSIS OORSKRY NIE.

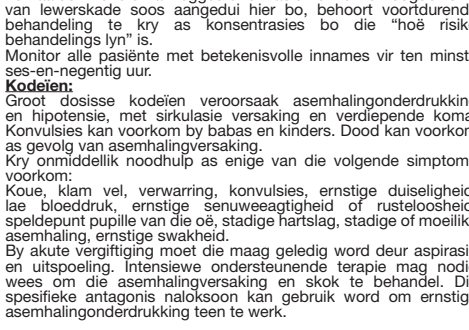
Babas: 6 maande tot 1 jaar:	2,5 ml ('n halwe medisyne maat vol) elke vier uur.
Kinders: 1 – 5 jaar:	5,0 ml (een medisyne maat vol) elke vier uur.
Kinders: 6 – 12 jaar:	5 ml tot 10 ml (een tot twee medisyne mate vol) elke vier uur.

Moenie meer as vier keer per dag toegedien word nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Die volgende newe-effekte kan voorkom met **TENSOPYN PAEDIATRIESE STROOP:**
- Vel en aanhangsel versteurings
  Minder dikwels – Geel oë of vel, klein rooi kolletjies op vel, allergiese reaksies, huiduitslag of jeukerigheid, sere, swere, wit kolle op lippe of in die mond en veluitslag. Die uitslag is gewoonlik oppervlakkig, maar soms kan dit meer ernstig wees en kan saam met koors en slymvlies sere voorkom. Rooiheid of blosing in die gesig
- Spier- en skelet-stelsel versteurings
  Minder dikwels – Bewing of onbeheersde spier bewegings of spier styfheid
- Sentrale en periferale senuweestelsel effekte
  Dikwels – Duiseligheid, slaperigheid, verwarring, droë mond, sweterigheid, blosing in die gesig, flouheid, verdowing, lighoofdigheid
- Gesig versteurings
  Minder dikwels – Miose
- Gehoor en vestibulêre versteurings
  Minder dikwels – Suis of tuit in die ore
- Psigiatriese versteurings
  Minder dikwels – Gevoel van onwerklikheid, hallusinasies, verstandelike onderdrukking, gemoed of geestes veranderinge, rusteloosheid, verdiepende koma of euforie
- Gastro-intestinale versteurings
  Dikwels – Naarheid, braking, hardlywigheid
  Selde – Bloederige of taai swart stoelgang, seerkeel, gal spasmas
- Endokrien versteurings
  Frekwensie onbekend – Pankreatitis
- Hart tempo en -ritme versteurings
  Minder dikwels – Vinnige, stadige, of bonsende hartslag, bradikardie, hartkloppings
- Vaskulêre (buite kardiale) versteurings
  Minder dikwels – Swelling van die gesig, laebloeddruk, duiseligheid, sirkulêre versaking, oorverhitting van die liggaam.
- Asemhaling stelsel versteurings
  Minder dikwels – Verhoging in sweet, onegalige asemhaling, kort asem, fluit asem of moeilike asemhaling, asemhaling onderdrukking
- Bloedplaatjie, bloeding en stolling versteurings
  Minder dikwels – Ongewone bloeding of kneusing
  Frekwensie onbekend – Bloedings reaksies, trombositopenie, neutropenie, pansitopenie, leukopenie en agranulositose
- Urinêre sisteem versteurings
  Minder dikwels – Bloederige of troebel urine, skielike afname in die hoeveelheid urine, moeilike urinering, ureteriese spasmas, antidiuretiese effek
- Liggaam as 'n geheel – Algemene versteurings
  Minder dikwels – Ongewone moegheid of swakheid, verhoogde intrakraniale drukking

Spesiale voorsorgmaatreëls:
Pasiënte wat aan nier- of lewer siektes ly moet **TENSOPYN PAEDIATRIESE STROOP** slegs onder mediese toesig neem.
TENSOPYN PAEDIATRIESE STROOP moet met versigtigheid gegee word aan pasiënte wat hipotiroïdisme, adrenokortikale onvoldoendheid, verswakte nier- of lewer funksie, Erb se siekte, prostatiese hipertrofie of skok het. Dit moet met versigtigheid gebruik word in pasiënte met inflammasie of obstruktiewe ingewand versteurings, bejaarde pasiënte en na operasies aan die galkanaal. Die dosis moet verminder word in bejaarde en verswakte pasiënte.
As gevolg van die histamien-vrystellende effek is allergiese reaksies, soos veluitslag en jeukerigheid van die neus by sommige mense, en die idiosinkrasie vir kodeïne en ander narkoties pynstillers taamlik algemeen.
Asemhalings probleme kan veral voorkom by kinders jonger as twee jaar.
Ongewone opgewondenheid of rusteloosheid kom meer geredelike voor in kinders wat **TENSOPYN PEDIATRIESE STROOP** gebruik.
Die onderdrukkende effekte van kodeïen word verhoog deur onderdrukkers van die sentrale senuwee stelsel soos narkotika, hipnotika, kalmeermiddels en fenotiasiene.
Aanhoudende gebruik van hoë dosisse kodeïen kan verslawing tot gevolg hê.
Raadpleeg 'n dokter as geen verligting verkry word met die voorgeskrewe dosis nie.
Moenie langer as tien dae aanhoudend gebruik sonder om 'n dokter te raadpleeg nie.
Berg op 'n veilige plek buite bereik van kinders.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Onmiddellike behandeling is noodsaaklik. In die geval van oordosering raadpleeg dadelik 'n dokter of neem die pasiënt na die naaste hospitaal toe.
Die uitstel in die aanvang van behandeling kan beteken dat die teenmiddel te laat gegee word om effektief te wees. Bewyse van lewerskade word dikwels eers duidelik nadat die tyd vir doeltreffende behandeling verstryk het.
Die risiko vir parasetamol vergiftiging word vererger in pasiënte wat herhaaldelik hoë dosisse (meer as 5 – 10 gram per dag) parasetamol geneem het vir 'n paar dae, by kroniese alkoholisme, kroniese lewer siekte, VIGS, ondervoeding en die gebruik van medisyne wat lewer mikrosomale oksidasie induseer soos barbiturate, isoniasied, rifampisien, fenitoïn en karbamasepien.
Simptome van parasetamol oordosering in die eerste 24 uur sluit in, bleekheid, naarheid, braking, anoreksie en moontlik abdominale pyn. Die geringe simptome gedurende die eerste twee dae van akute vergiftiging reflekteer nie die potensieel ernstig aard van die oordosering nie.
Lewerskade mag eers duidelik word na 12 tot 48 huur of langer na inname, aanvanklik deur die verhoging van serum transaminase en laktiese dehidrogenase aktiwiteit, verhoogde serum bilirubien konsentrasie en verlenging van die protrombien tyd. Lewerskade mag ensefalopatie, koma en dood tot gevolg hê.
Akute nierversaking met akute tubulêre nekrose kan ontwikkel, selfs in die afwesigheid van ernstige lewerskade. Abnormaliteite van glukose metabolisme en metaboliese asidose kan voorkom. Kardiale aritmieë is aangemeld.
Behandeling van parasetamol oordosering:
Alhoewel bewyse beperk is, word aanbeveel dat 'n volwasse persoon wat 5 tot 10 gram of meer parasetamol (of 'n kind wat meer as 140 mg/kg) binne die voorafgaande vier uur ingeneem het, se maag geledig moet word deur uitspoeling (opgooi mag voldoende wees by kinders) en 'n enkel dosis van 50 gram geaktiveerde houtskool gegee word deur die uitspoelbuis. Die inname van kleiner hoeveelhede parasetamol mag behandeling benodig by pasiënte wat vatbaar is vir parasetamol vergiftiging (sien bogenoemde). By pasiënte wat bewusteloos of in 'n koma is moet endotrageale inkubasie die maagspoeling voorafgaan om aspirasie te voorkom.
N-asetielsisteïen moet so gou moontlik toegedien word in alle gevalle van vermoedelike oordosering, verkieslik binne agt uur na die oordosis, behandeling kan tot 36 uur na inname nog voordelig wees, veral as meer as 150 mg/kg parasetamol ingeneem is. 'n Aanvanklike dosis van 150 mg/kg N-asetielsisteïen in 200 ml dekstrose inspuiting moet **intraveneus** toegedien word gedurende 15 minute, gevolg deur 'n infusie van 50 mg/kg in 500 ml dekstrose gedurende die volgende vier uur en dan 100 mg/kg in 1000 ml dekstrose inspuiting gedurende die volgende sestien uur. **Die volume intraveneuse vloeistof moet aangepas word vir kinders.**
Alhoewel orale dosering nie die behandeling van keuse is nie, kan 140 mg/kg opgelos in water aanvanklik toegedien word, gevolg deur 70 mg/kg elke vier uur vir sewentien dosisse.
'n Plasma parasetamol vlak moet bepaal word vier uur na inname in alle gevalle van vermoedelike oordosering. Vlakke wat geneem word voor vier ure kan misleidend wees, behalwe as dit hoog is. Pasiënte wat 'n risiko loop van lewerskade en dus voortdurende behandeling met N-asetielsisteïen moet kry, kan geïdentifiseer word volgens hulle plasma parasetamol vlak. Die plasma parasetamol vlak kan in 'n grafiek aangedui word teen tyd vanaf die tyd van inname in die normogram hier onder.



Source: Goodman & Gilman's The Pharmacological Basis of Therapeutics, 11° Ed.

Diegene wie se plasma parasetamol vlak hoër is as die "normale behandelings lyn", behoort aan te hou met asetielsisteïen behandeling met 100 mg/kg intraveneus oor sestien uur herhaaldelik tot die vlak reggestel is. Pasiënte met verhoogde risiko van lewerskade soos aangedui hier bo, behoort voortdurende behandeling te kry as konsentrasies bo die "hoë risiko behandelings lyn" is.
Monitor alle pasiënte met betekenisvolle innames vir ten minste ses-en-negentig uur.
Kodeïen:
Groot dosisse kodeïen veroorsaak asemhalingonderdrukking en hipotensie, met sirkulasie versaking en verdiepende koma. Konvulsies kan voorkom by babas en kinders. Dood kan voorkom as gevolg van asemhalingversaking.
Kry onmiddellik noodhulp as enige van die volgende simptome voorkom:
Koue, klam vel, verwarring, konvulsies, ernstige duiseligheid, lae bloeddruk, ernstige senuweeagtigheid of rusteloosheid, speldepunt pupille van die oë, stadige hartslag, stadige of moeilike asemhaling, ernstige swakheid.
By akute vergiftiging moet die maag geledig word deur aspirasie en uitspoeling. Intensiewe ondersteunende terapie mag nodig wees om die asemhalingversaking en skok te behandel. Die spesifieke antagonis naloksoon kan gebruik word om ernstige asemhalingonderdrukking teen te werk.

IDENTIFIKASIE:
'n Helder, kleurlose stroop met 'n reuk en smaak van vars kersies.

AANBIEDING:
'n 100 ml amber glas bottel, met 'n wit plastiese prop met 'n ring wat dui op die verseëling, verpak in 'n karton.

BERGINGSINSTRUKSIES:
Bewaar benede 25 °C, op 'n koel plek en beskerm teen lig. Hou die bottel dig toe tot gereed vir gebruik. Berg die medisyne in die oorspronklike houer tot gereed vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
W/2.8/23
12/21.2/0109 (Namibië)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT:
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET: 04/2014
16 Februarie 2011 BRITEPAK

PASIËNT INLIGTINGSBLAD

Lees die hele blaadjie noukeurig deur voordat u begin om TENSOPYN PAEDIATRIESE STROOP te gebruik.
Hierdie medisyne is verkrygbaar sonder 'n dokter se voorskrif, om 'n matige siektetoestand te behandel. Dit is steeds nodig om **TENSOPYN PAEDIATRIESE STROOP** met die nodige sorg te gebruik, om die beste resultate daaruit te verkry.
- Hou hierdie blaadjie. U mag dit nodig vind om dit weer te lees.
- Indien u enige verdere vrae het, vra u dokter of apteker.
- U moet 'n dokter raadpleeg as u simptome vererger of as dit nie verbeter binne 5 dae nie.

SKEDULERINGSTATUS: S1
NS1 (Namibië)

EIENDOMSNAAM EN DOSEERVORM:

TENSOPYN PAEDIATRIESE STROOP

150,0 mg parasetamol and 4,0 mg kodeïen fosfaat per 5 ml.

WAT TENSOPYN PAEDIATRIESE STROOP BEVAT:
Elke 5 ml stroop bevat:

Parasetamol	150,0 mg
Kodeïenfosfaat	4,0 mg
Preserveermiddels:	
Natriumbensoaat	0,1 % m/v
Kaliumsorbaat	0,2 % m/v

Die ander bestanddele is: Propileen glikol, gliserine, makrogol, natrium siklomaat, akesulfaam-K, gebutileerde hidroksietolueen, natrium chloried, swartbessiegeursel, kersiegeursel, gesuiwerde water.
BEVAT GEEN SUIKER.

WAARVOOR TENSOPYN PAEDIATRIESE STROOP GEBRUIK WORD:
TENSOPYN PAEDIATRIESE STROOP word gebruik vir die simptomatiese verligting van ligte of matige pyn en koors by kinders.

VOOR TENSOPYN PAEDIATRIESE STROOP GEBRUIK WORD:
Moenie TENSOPYN PAEDIATRIESE STROOP vir u kind gee nie indien:
- U kind 'n allergie of ongewone reaksie getoon het vir enige van die bestanddele in **TENSOPYN PAEDIATRIESE STROOP**
- U kind 'n allergie het vir enige van die bestanddele in **TENSOPYN PAEDIATRIESE STROOP**
- U kind ernstige nier siekte het
- U kind geelsug of enige ander lewer siekte gehad het.

Neem spesiale voorsorg met TENSOPYN PAEDIATRIESE STROOP indien u kind ook ander medisyne neem wat 'n kalmerende invloed kan hê, soos medisyne wat alkohol bevat of medisyne wat slaperigheid of lomerigheid veroorsaak omdat **TENSOPYN PAEDIATRIESE STROOP** hierdie simptome kan vererger (sien "Ander medisyne met **TENSOPYN PAEDIATRIESE STROOP"**).
Die neem van TENSOPYN PAEDIATRIESE STROOP saam met kos en vloeistowwe:
TENSOPYN PAEDIATRIESE STROOP kan geneem word sonder enige voorsorg saam met kos en vloeistowwe.

SWANGERSKAP EN BORSVOEDING:
Die veiligheid van **TENSOPYN PAEDIATRIESE STROOP** tydens swangerskap en borsvoeding, is nog nie vasgestel nie.
Parasetamol oorkruis die plasenta en is teenwoordig in bors melk.
As u swanger is of u baba borsvoed, terwyl u **TENSOPYN PAEDIATRIESE STROOP** gebruik, of u gee **TENSOPYN PAEDIATRIESE STROOP** vir u baba, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies.

Bestuur en gebruik van masjinerie:
TENSOPYN PAEDIATRIESE STROOP word voorgeskryf vir gebruik deur kinders. Omdat **TENSOPYN PAEDIATRIESE STROOP** lomerigheid of dronkerigheid kan veroorsaak word aanbeveel dat geen gereedskap of masjinerie gebruik word wanneer **TENSOPYN PAEDIATRIESE STROOP** gebruik word nie.

Die gebruik van ander medisyne saam met TENSOPYN PAEDIATRIESE STROOP:
Indien u of u kind **TENSOPYN PAEDIATRIESE STROOP** saam met ander medisyne gebruik wat 'n kalmerende effek het of medisyne wat slaperigheid of lomerigheid veroorsaak, kan dit die effek van **TENSOPYN PAEDIATRIESE STROOP** vererger.
Indien u of u kind enige ander medisyne op 'n gereelde grondslag gebruik, insluitend komplementêre of tradisionele medisyne, kan die gelyktydige gebruik van **TENSOPYN PAEDIATRIESE STROOP** saam met die ander medisyne ongewensde interaksies veroorsaak. Raadpleeg u dokter, apteker of ander gesondheidsorgkundige.

HOE OM TENSOPYN PAEDIATRIESE STROOP TE GEBRUIK:
Neem altyd **TENSOPYN PAEDIATRIESE STROOP** presies soos die dokter voorgeskryf het of soos die aanwysigings op die etiket aandui. Raadpleeg u dokter of apteker as u onseker is van die dosering.
Die gewone dosis is:

Babas: 6 maande tot 1 jaar:	2,5 ml ('n halwe medisyne maat vol) elke vier uur.
Kinders: 1 – 5 jaar:	5,0 ml (een medisyne maat vol) elke vier uur.
Kinders: 6 – 12 jaar:	5,0 ml tot 10,0 ml (een tot twee medisyne mate vol) elke vier uur.

TENSOPYN PAEDIATRIESE STROOP moenie meer as vier keer per dag toegedien word nie.
As u onder die indruk is dat die effek van **TENSOPYN PAEDIATRIESE STROOP** te sterk of te swak is raadpleeg u dokter of apteker.
MOENIE DIE VOORGESTELDE DOSIS OORSKRY NIE.

Indien u of u kind meer TENSOPYN PAEDIATRIESE STROOP neem as wat aanbeveel word:
Indien u of u kind per ongeluk meer **TENSOPYN PAEDIATRIESE STROOP** neem as wat aanbeveel word, of iemand anders neem die medisyne, moet u dadelik u dokter of apteker ingelig. As nie een beskikbaar is nie moet u dadelik die naaste hospitaal of gifhulpsentrum om raad vra. Wys enige oorblywende medisyne of die leë houer of karton vir die dokter.

Indien u vergeet om TENSOPYN PAEDIATRIESE STROOP te neem:
Indien u vergeet om 'n dosis te neem, neem dit so gou as moontlik, tensy dit amper tyd is vir die volgende dosis. Gaan dan voort soos voorheen. Moenie die dosis verdubbel om op te maak vir die dosis wat oorgeslaan is nie.

NEWE-EFFEKTE:
TENSOPYN PAEDIATRIESE STROOP kan newe-effekte hê.
Nie alle newe-effekte wat vir **TENSOPYN PAEDIATRIESE STROOP** aangemeld is, word in hierdie biljet genoem nie. Indien u kind se algemene gesondheid verswak terwyl **TENSOPYN PAEDIATRIESE STROOP** gebruik word, moet u asseblief u dokter, apteker of 'n ander gesondheidsorgkundige raadpleeg.
Staak **TENSOPYN PAEDIATRIESE STROOP** dadelik en raadpleeg u dokter of apteker as u kind begin jeuk en krap, kortasem is of die asemhaling fluit, die gesig, hande, voete, mond, keel en oë geswel raak. Hierdie is seldsame allergiese reaksies. U kind mag dalk allergies wees vir **TENSOPYN PAEDIATRIESE STROOP.**
Parasetamol:
Vel uitslag mag voorkom.
Pasiënte wat nier- of lewer siektes het moet **TENSOPYN PAEDIATRIESE STROOP** slegs onder mediese toesig gebruik.
Kodeïenfosfaat:
Kodeïen kan naarheid en braking, duiseligheid, hardlywigheid, slaperigheid, verwarring, droë mond oormatige sweet, rooi gesig, flouheid en asemhalings onderdrukking veroorsaak.
TENSOPYN PAEDIATRIESE STROOP moet met versigtigheid toegedien word aan pasiënte wat lewerversaking het.
Die onderdrukkende effekte van **TENSOPYN PAEDIATRIESE STROOP** kan vererger word wanneer ander medisyne soos kalmeermiddels, narkose en fenotiasiene gelyktydig toegedien word.
Asemhalings probleme kom veral voor by kinders jonger as 2 jaar oud.
Ongewone opgewondenheid of rusteloosheid kan voorkom by kinders wat **TENSOPYN PAEDIATRIESE STROOP** gebruik.
Verlengde gebruik van hoe dosisse kodeïen mag afhanklikheid tot gevolg hê.

As u kind meer TENSOPYN PAEDIATRIESE STROOP inneem as wat hy of sy behoort:

TENSOPYN PAEDIATRIESE STROOP bevat parasetamol en kodeïen wat dodelik kan wees. In die geval van oordosering of as 'n oordosering vermoed word, al het die persoon geen simptome nie, moet die naaste dokter, hospitaal of gifhulpsentrum onmiddellik geraadpleeg word.

Onmiddellike behandeling is noodsaaklik. Indien u of u kind 'n oordosering ingeneem het, raadpleeg u dokter dadelik, of neem die persoon onmiddellik na die naaste hospitaal. Enige vertraging van die aanvang van die behandeling kan beteken dat die teenmiddel te laat gegee word om effektief te wees. Lewerskade is moontlik indien behandeling nie dadelik gegee word nie. Gespesialiseerde behandeling is noodsaaklik so gou moontlik. Die nuutste inligting in verband met oordosering kan verkry word by die naaste gifhulpsentrum.
Groter dosisse as die wat aanbeveel word kan lewerskade veroorsaak.
Oordosering is baie gevaarlik by klein kindertjies.

BERGINGS- EN VERNIETIGINGSINLIGTING:
Bewaar by of benede 25 °C, op 'n koel plek en beskerm teen lig. Hou die bottel dig toe tot gereed vir gebruik. Berg die medisyne in die oorspronklike houer tot gereed vir gebruik.
HOU BUITE BEREIK VAN KINDERS.
Neem alle ongebruikte medisyne na 'n apteek vir vernietiging.
Moenie ongebruikte medisyne in riool (bv. toilette) of in asblikke weggooi nie.

AANBIEDING VAN TENSOPYN PAEDIATRIESE STROOP:
'n 100 ml amber glas bottel, met 'n wit plastiese prop met 'n ring wat dui op die verseëling, verpak in 'n karton.

IDENTIFIKASIE VAN TENSOPYN PAEDIATRIESE STROOP:
'n Helder, kleurlose stroop met 'n reuk en smaak van vars kersies.

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DATUM VAN PUBLIKASIE VAN DIE PASIËNT INLIGTINGSBLAD:
16 Februarie 2011 04/2014
BRITEPAK