Vicks Medinite

SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM

Vicks Medinite (Syrup)

COMPOSITION

Each 30 ml contains	
Paracetamol	600,0 mg
Ephedrine sulphate	8,0 mg
Doxylamine succinate	7,5 mg
Dextromethorphan hydrobromide	15,0 mg
Inactive ingredients	
Alcohol absolute	10,0 % v/v
Sodium benzoate	
Added as preservative	0,1 % m/v
Contains Sugar	

PHARMACOLOGICAL CLASSIFICATION

A.10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION

Paracetamol has analgesic and antipyretic properties. Doxylamine succinate has antihistamine properties with a prolonged effect. Dextromethorphan hydrobromide has antitussive properties. Ephedrine sulphate has sympathomimetic properties causing vasoconstriction. It also has smooth muscle relaxant effects.

INDICATIONS

Vicks Medinite nighttime colds medicine may be taken at bedtime for relief of major symptoms, associated with colds and influenza, such as nasal congestion, sniffing, headache, minor aches and pains and coughing.

CONTRA-INDICATIONS

Safety during pregnancy has not been established. Do not administer concurrently with monoamine oxidase inhibitors or in patients with known hypersensitivity to any of the active ingredients.

WARNINGS

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. If symptoms persist after five days, consult a doctor. Do not use continuously for more than 10 days without consulting a doctor.

This product contains paracetamol 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.

Dosages in excess of those recommended may cause severe liver damage.

PREGNANCY AND LACTATION

Pregnancy
The safety of this preparation in pregnancy has not been established

Breastfeeding
The safety of this preparation in lactation has not been established

DOSAGE AND DIRECTIONS FOR USE

Take Vicks Medinite at bedtime. Use dose cup provided and wash after use.
Adults 12 years and over:
30 ml in the dose cup provided (6 medicine measuresful) at bedtime.
Do not give this medicine to children under 12 years of age, unless directed by a doctor.
DO NOT EXCEED RECOMMENDED DOSE.
Method of administration
Oral

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side Effects

Paracetamol
Sensitivity reactions resulting in reversible skin rash or blood disorders may occur. Patients suffering from kidney or liver disease should take paracetamol under medical supervision.

Dextromethorphan hydrobromide
May cause drowsiness, dizziness, excitation, mental confusion and gastro-intestinal disturbances. Should be administered with caution to patients with liver disease and to asthmatic patients. High doses cause respiratory depression.

Doxylamine succinate
Doxylamine succinate may cause sedation varying from slight drowsiness to deep sleep and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination.

Other side effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea, or constipation and epigastric pain.

Doxylmanine succinate may also produce headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, drying of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands. Symptoms of stimulation may include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Large doses may precipitate fits in epileptics. Allergy and dermatological reactions may occur. Blood disorders including agranulocytosis and haemolytic anaemia, have been reported. Doxylamine succinate may enhance the sedative effect of the central nervous system depressants, including alcohol, barbiturates, hypnotic analgesics, sedatives and tranquillizers.

Effects of anticholinergic drugs such as atropine and tricyclic antidepressants, may be enhanced by the concomitant administration of doxylamine succinate. Doxylamine succinate may affect the metabolism of drugs in the liver.

Doxylamine should be used with care in conditions such as glaucoma and prostatic hypertrophy.

Ephedrine sulphate
Ephedrine sulphate may give rise to side effects such as giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tremors, anxiety, restlessness and insomnia.

Ephedrine sulphate should be avoided in patients with most types of cardiovascular disease, hypertension, hyperthyroidism, hyperexcitability, pheochromocytoma and close-angle glaucoma. In patients with prostatic enlargement, it may increase difficulty with micturition. It should be used with caution in patients receiving chloroform, cyclopropane, halothane or other halogenated anaesthetics.

The effects of ephedrine are diminished by guanethidine, reserpine and probably methyldopa and may be diminished or enhanced by tricyclic anti-depressants. Ephedrine may also diminish the effects of guanethidine and may increase the possibility of arrhythmias in digitalised patients.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Paracetamol
Prompt treatment is essential. In the event of 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.

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 diseases, AIDS, malnutrition, and with use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the 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 be apparent 12 or 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. In patients who are stuperose or comatose, endotracheal intubation should precede gastric lavage in order to avoid aspiration.

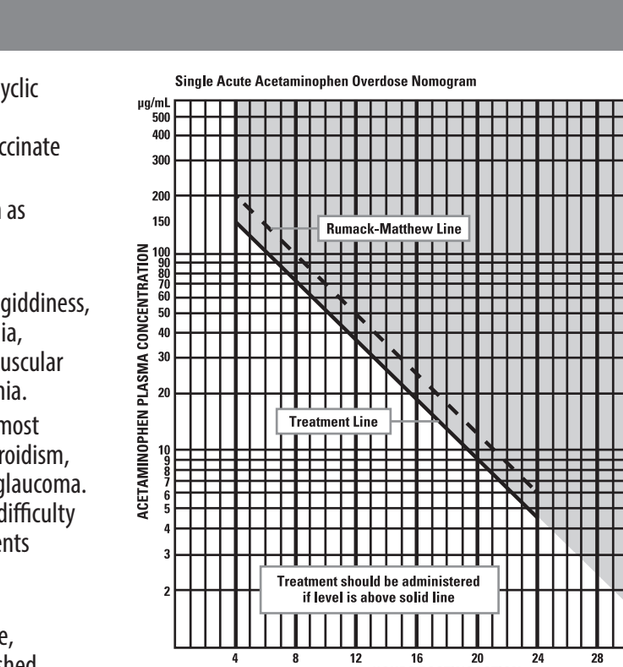
N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection is 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 1 000 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 overdose. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.

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, should continue treatment if concentrations are above the "high risk treatment line". Prothrombin index correlates best with survival.

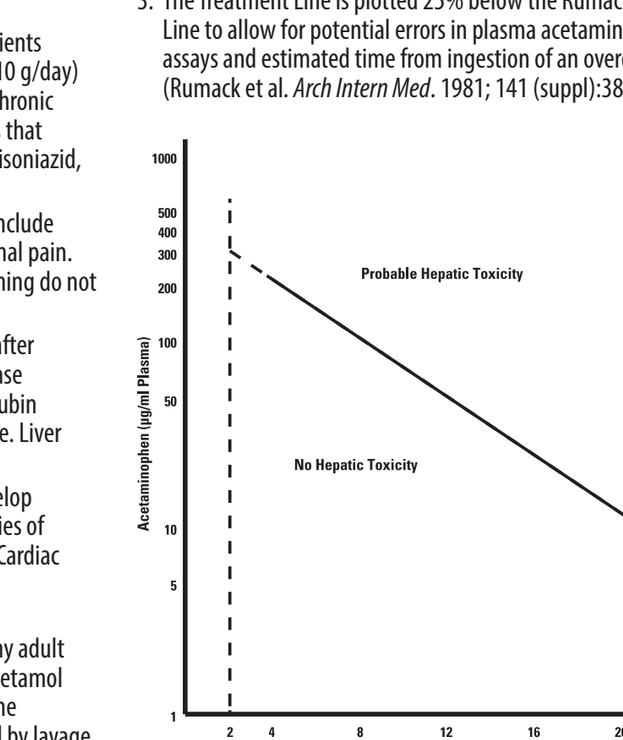
Monitor all patients with significant ingestions for at least ninety six hours.



Nomogram: acetaminophen plasma concentration vs time after acetaminophen ingestion (adapted with permission from Rumack and Matthew. *Pediatrics*. 1975;55:871 – 876). The nomogram has been developed to estimate the probability of whether a plasma acetaminophen concentration in relation to the interval postingestion will result in hepatotoxicity and, therefore, whether acetylcysteine therapy should be administered.

CAUTIONS FOR USE OF THIS CHART:

1. Time coordinates refer to time postingestion.
2. Graph relates only to plasma concentrations following a single, acute overdose ingestion.
3. The Treatment Line is plotted 25% below the Rumack-Matthew Line to allow for potential errors in plasma acetaminophen assays and estimated time from ingestion of an overdose (Rumack et al. *Arch Intern Med*. 1981; 141 (suppl):380 – 385)



Semilogarithmic plot of plasma acetaminophen levels vs.time
Rumack BH. Matthew H. Acetaminophen Poisoning and Toxicity. Pediatrics 1975 (55)871 – 876

Dextromethorphan Hydrobromide
Respiratory depression

Doxylamine Succinate
Symptoms of overdosage may include convulsions and excitation

Ephedrine Sulphate
Symptoms of overdosage may include paranoid psychosis, delusions and hallucinations.

Post-marketing Experience

Special Precautions
This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

IDENTIFICATION

Vicks Medinite is a clear, slightly viscous green liquid with an anise aroma and taste.

PRESENTATION

Bottles containing 90 ml or 180 ml with special dose cup.

STORAGE INSTRUCTIONS

Store at or below 25°C. Keep out of reach of children.

REGISTRATION NUMBER

H/10.1/140
Namibia Reg.No: 90/10.1/001383

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Procter & Gamble South African Trading (Pty) Ltd,
15 Alice Lane Towers, Alice lane, Sandton, Johannesburg, 2196

DATE OF PUBLICATION OF THE PACKAGE INSERT

31st May 2015

Vicks Medinite

SCHEDULING STATUS: S2

Read this entire leaflet carefully because it contains important information for you.
This medicine is available without a doctor's prescription, for you to treat mild illness.
Nevertheless you still need to use Vicks Medinite Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Vicks Medinite Syrup with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days

PROPRIETARY NAME AND DOSAGE FORM

Vicks Medinite (Syrup)

COMPOSITION OF THE MEDICINE, THAT IS, WHAT VICKS MEDINITE SYRUP CONTAINS

Each 30 ml contains	
Paracetamol	600,0 mg
Ephedrine sulphate	8,0 mg
Doxylamine succinate	7,5 mg
Dextromethorphan hydrobromide	15,0 mg
Inactive ingredients	
Alcohol absolute	10,0 % v/v
Sodium benzoate	
Added as preservative	0,1 % m/v
Contains sugar	

INDICATIONS

Approved indication and use, that is, what Vicks Medinite Syrup is used for
Vicks Medinite must be taken at bedtime for relief of major symptoms, associated with colds and influenza, such as nasal congestion, sniffing, headache, minor aches and pains and coughing.

INSTRUCTION BEFORE TAKING

Vicks Medinite should not be used if you

- are allergic to dextromethorphan, paracetamol, ephedrine sulphate, doxylamine succinate or other ingredients (see excipients above in the composition of the medicine).
- are taking medicines called monoamine oxidase inhibitors (MAOIs – are a type of antidepressant) or have taken them in the last few days.

Do not give Vicks Medinite Syrup to children under twelve years of age.

Take special care with Vicks Medinite Syrup
Talk to your doctor or pharmacist before taking this medicine if you

- have asthma
- have ever had liver problems
- are diabetic or have difficulty digesting some sugars.

Taking other medicines
Do not take Vicks Medinite Syrup if you are taking medicines for depression or Parkinson's disease, called monoamine oxidase inhibitors (MAOIs), or have done so in the last 14 days.

Pregnancy and Breastfeeding
If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, or pharmacist or other health care professional for advice.

WARNINGS

Driving and using machines
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.

It should be noted that this medicine contains a small amount of alcohol.

Important information about some of the ingredients of Vicks Medinite Syrup
This medicine contains

- 10% volume of **alcohol**. This may be harmful to those suffering from alcoholism.
  This is to be taken into consideration by pregnant or breast feeding women, children and high risk groups such as patients with liver disease or epilepsy.
- **Sugar** (sucrose) – each 15 ml adult dose contains 8,25 g of sucrose

If symptoms persist after ten days, consult a doctor. Do not use continuously for more than 10 days without consulting a doctor

This product contains paracetamol 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.

Dosages in excess of those recommended may cause severe liver damage.

INTERACTIONS

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of Vicks Medinite Syrup with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

INSTRUCTIONS ON HOW TO TAKE VICKS MEDINITE SYRUP

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

Always take Vicks Medinite Syrup exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of Vicks Medinite Syrup is too strong or too weak, talk to your doctor or pharmacist.

Dosage
Take Vicks Medinite at bedtime. Use dose cup provided and wash after use.
Adults 12 years and over:
30 ml in the dose cup provided (6 medicine measuresful) at bedtime.

Do not give this medicine to children under 12 years of age, unless directed by a doctor.

Do not exceed the recommended dose
If you take more syrup than you should or give more syrup than recommended or in the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Vicks Medinite Syrup
If you accidentally miss a dose, **do not** take a double dose; just take the next dose as normal.

If you have any further questions on the use of this product, ask your pharmacist.

Do not share medicines prescribed for you with others. In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Method of administration
Oral

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Like all medicines, Vicks Medinite Syrup can cause side effects, although not everyone gets them. Rarely, the syrup may cause dizziness or stomach upset.

Not all side effects reported for this medicine are included in the leaflet. Should your health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Side effects

Paracetamol
Sensitivity reactions resulting in reversible skin rash or blood disorders may occur. Patients suffering from kidney or liver disease should take paracetamol under medical supervision.

Dextromethorphan hydrobromide
May cause drowsiness, dizziness, excitation, mental confusion and gastro-intestinal disturbances. Should be administered with caution to patients with liver disease and to asthmatic patients. High doses cause respiratory depression.

Doxylamine succinate
Doxylamine Succinate may cause sedation varying from slight drowsiness to deep sleep and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination.

Other side effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea, or constipation and epigastric pain.

Doxylmanine succinate may also produce headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, drying of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands. Symptoms of stimulation may include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Large doses may precipitate fits in epileptics. Allergy and dermatological reactions may occur. Blood disorders including agranulocytosis and haemolytic anaemia, have been reported. Doxylamine succinate may enhance the sedative effect of the central nervous system depressants, including alcohol, barbiturates, hypnotic analgesics, sedatives and tranquillizers.

Effects of anticholinergic drugs such as atropine and tricyclic antidepressants, may be enhanced by the concomitant administration of doxylamine succinate. Doxylamine Succinate may affect the metabolism of drugs in the liver.

Doxylamine succinate should be used with care in conditions such as glaucoma and prostatic hypertrophy.

Ephedrine Sulphate
Ephedrine sulphate may give rise to side effects such as giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tremors, anxiety, restlessness and insomnia.

Ephedrine sulphate should be avoided in patients with most types of cardiovascular disease, hypertension, hyperthyroidism, hyperexcitability, pheochromocytoma and close-angle glaucoma. In patients with prostatic enlargement, it may increase difficulty with micturition. It should be used with caution in patients receiving chloroform, cyclopropane, halothane or other halogenated anaesthetics.

The effects of ephedrine are diminished by guanethidine, reserpine and probably methyldopa and may be diminished or enhanced by tricyclic anti-depressants. Ephedrine may also diminish the effects of guanethidine and may increase the possibility of arrhythmias in digitalised patients.

Special Precautions
This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

IDENTIFICATION

Vicks Medinite is a clear, slightly viscous green liquid with an anise aroma and taste.

PRESENTATION

Bottles containing 90 ml or 180 ml with special dose cup.

STORAGE INSTRUCTIONS

Store at or below 25°C. Keep out of reach of children.

Do not take Vicks Medinite after the expiry date which is printed on the bottle or carton.

The expiry date refers to the last day of the month stated.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist on how to dispose of medicines if no longer required. These measures will help protect the environment.

REGISTRATION NUMBER

H/10.1/140
Namibia Reg.No: 90/10.1/001383 NS1

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Procter & Gamble South African Trading (Pty) Ltd,
15 Alice Lane Towers, Alice Lane, Sandton, Johannessburg, 2196

DATE OF PUBLICATION OF THE PACKAGE INSERT

31st May 2015

Vicks Medinite

SKEDULERINGSTATUS: S2

EIENDOMSNAAM EN DOSEERVORM

Vicks Medinite (Stroop)

SAMESTELLING

Elke 30 ml bevat	
Parasetamol	600,0 mg
Efedriensulfaat	8,0 mg
Doksielamiensuksinaat	7,5 mg
Dekstrometorfaanhidrobromied	15,0 mg
Onaktiewe bestanddele	
Absolute alkohol	10,0 % v/v
Natriumbensoaat	
As bewaarmiddel	0,1 % m/v
Bevat suiker	

FARMAKOLOGIESE KLASSIFIKASIE

A.10.1 Hoesmiddels en ekspektorante

FARMAKOLOGIESE WERKING

Parasetamol het analgetiese en antipiretiese eienskappe. Doksielamiensuksinaat het antihistamieneienskappe met 'n langwerkende effek. Dekstrometorfaanhidrobromied het hoesonderdrukkende eienskappe. Efedriensulfaat het simpatomimetiese eienskappe wat vasokonstriksie veroorsaak. Dit het ook 'n effek as verslapper van gladde spier.

INDIKASIES

Vicks Medinite verkouemedisyne vir die nag kan teen slaaptyd gedrink word vir die verligting van die ergste simptome van verkoue en griep, soos neusverstopping, nies, hoofpyn, ligte pyne en skete en hoes.

KONTRA-INDIKASIES

Die veiligheid tydens swangerskap is nie bepaal nie. Moenie saam met monoamienoksidaseremmers of vir pasiënte met 'n bekende hipersensitiwiteit vir enige van die aktiewe bestanddele gegee word nie.

WAARSKUWINGS

Hierdie medisyne kan tot lomerigheid en swak konsentrasie lei wat vererger word deur die gelyktydige inname van alkohol of ander onderdrukkers van die sentrale senustelsel. Pasiënte moet gewaarsku word om nie motor te bestuur of masjinerie te hanteer of moontlike gevaarlike take uit te voer waar 'n gebrek aan konsentrasie tot ongelukke kan lei nie. Raadpleeg 'n dokter indien simptome na vyf dae voortduur. Moenie vir meer as 10 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.

Hierdie produk bevat parasetamol wat teen 'n oordosis noodlottig kan wees. In geval van oordosering of vermoedelike oordosering en onafgesien daarvan dat die persoon sonder simptome kan wees, moet die naaste dokter, hospitaal of vergiftigingsentrum onmiddellik geskakel word.

Dosisse hoër as die aanbevole kan ernstige lewerskade veroorsaak.

INTERAKSIES

SWANGERSKAP EN BORSVOEDING

Swangerskap
Die veiligheid van hierdie produk tydens swangerskap en borsvoeding is nie bepaal nie.

Borsvoeding
Die veiligheid van hierdie produk tydens borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS

Drink Vicks Medinite teen slaaptyd. Gebruik die verskafde doseerkoppie en was dit na gebruik.
Volwassenes van 12 jaar en ouer:
30 ml in die verskafde doseerkoppie (6 medisynemate) teen slaaptyd.
Moenie hierdie medisyne aan kinders jonger as 12 jaar gee nie, tensy 'n dokter so sê.
MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.
Metode van toediening
Oraal

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Newe-effekte

Parasetamol
Sensitiwiteitsreaksies wat tot omkeerbare veluitslag of bloedversteurings lei, kan voorkom. Pasiënte wat aan nier- of lewersiektes ly, moet parasetamol onder mediese toesig gebruik.

Dekstrometorfaanhidrobromied
Mag lomerigheid, duiseligheid, opgewektheid, geestelike verwardheid en gastro-intestinale versteurings veroorsaak. Moet versigtig gegee word aan pasiënte met lewersiekte of met asma. Hoë dosisse veroorsaak asemhalingsonderdrukking.

Doksielamiensuksinaat
Doksielamiensuksinaat kan sedasie veroorsaak wat kan wissel van ligte lomerigheid tot h diep slaap met onvermoë om te konsentreer, lusteloosheid, duiseligheid, hipotensie, spierswakheid en gebrek aan koördinasie.

Ander newe-effekte is onder meer gastro-intestinale versteurings soos naarheid, braking, diarree of hardlywigheid en maagpyn.

Doksielamiensuksinaat kan ook hoofpyn, versteurde visie, tinnitus, ekstase of depressie, prikkelbaarheid, nagmerries, anoreksie, moeilike urinering, droë mond, benoude bors en tinteling, swaarheid en swakheid van die hande veroorsaak. Simptome van stimulasie kan onder meer slaaploosheid, senuagtigheid, tagikardie, tremore, spiertrekkings en konvulsies wees.

Groot dosisse kan toevalle in epileptici aanbring. Allergie en dermatologiese reaksies kan voorkom. Bloedversteurings, waaronder agranulositose en hemolitiese anemie, is aangemeld.

Doksielamiensuksinaat kan die sederende effekte van sentralesenustelselonderdrukkers waaronder alkohol, barbiturate, hipnotiese analgetika, sedeermiddels en kalmeermiddels versterk.

Effekte van anticholinergiese middels, soos atropien en trisikliese antidepressante, kan deur die gelyktydige toediening van doksielamiensuksinaat versterk word. Doksielamiensuksinaat kan die metabolisme van geneesmiddels in die lewer beïnvloed.

Doksielamien moet versigtig gebruik word tydens toestande soos gloukoom en prostaathipertrofie.

Efedriensulfaat
Efedriensulfaat kan effekte soos duiseligheid, hoofpyn, naarheid, braking, sweet, dors, tagikardie, pyn in die bors, hartkloppings, moeilike urinering, spierswakheid en bewerasie, angs, rusteloosheid en slapeloosheid veroorsaak.

Efedriensulfaat moet vermy word vir pasiënte met die meeste vorme van kardiovaskulêre siekte, hipertensie, hipertireose, oormatige opgewektheid, feochromositoom en nouhoek-gloukoom. In pasiënte met vergroting van die prostaat, kan dit probleme met urinering vererger. Dit moet versigtig gebruik word deur pasiënte wat chloroform, siklopropaan, halotaan of ander gehalogeneerde narkosemiddels ontvang.

Die effekte van efedrien word deur guanetidien, reserpien en waarskynlik metieldopa verswak en kan deur trisikliese anti-depressante verswak of versterk word. Efedrien kan ook die effekte van guanetidien verlaag en kan die moontlikheid van aritmie in gedigitaliseerde pasiënte verhoog.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Parasetamol
Spoedige behandeling is noodsaaklik. Raadpleeg 'n dokter onmiddellik in geval van oordosering of neem die pasiënt direk na 'n hospitaal. 'n Vertraging in die aanvang van behandeling kan beteken dat die teenmiddel te laat gegee word om effektief te wees.

Getuienis van lewerskade verskyn dikwels eers nadat die tyd vir effektiewe behandeling reeds verstryk het.

Vatbaarheid vir toksisiteit vanweë parasetamol is hoër in pasiënte wat herhaalde hoë dosisse (meer as 5 - 10 g/dag) vir verskeie dae gebruik het, met chroniese alkoholisme, chroniese lewersiekte, VIGS, wanvoeding en met die gebruik van middels wat oksidase deur lewermikrosome induseer, soos barbiturate, isoniasied, rifampisien, fenitoïen en karbaamasepien.

Simptome in die 24 uur na oordosering met parasetamol is onder meer bleekheid, naarheid, braking, anoreksie en moontlik buikpyn. Ligte simptome in die eerste twee dae na akute vergiftiging toon nie die moontlike ernstigheid van oordosering nie.

Lewerskade kan 12 tot 48 uur of later na inname sigbaar raak en aanvanklik deur h toename in die konsentrasie van transaminase in die serum en aktiwiteit van melksuurdehidrogenase, hoër vlakke bilirubin in die serum en verlenging van protrombientyd. Lewerskade kan tot enkefalopatie, koma en die dood lei.

Akute nierversaking met akute tubulêre nekrose kan ontwikkel, selfs al is daar nie ernstige lewerskade nie. Abnormaliteite in glukosemetabolisme en metaboliese asidose kan voorkom. Hartaritmie is aangemeld.

Behandeling van oordosering met parasetamol
Hoewel getuienis beperk is, word aanbeveel dat enige volwassene wat 5 - 10 g of meer parasetamol in die voorafgaande vier uur ingeneem het (of h kind wat meer 140 mg/kg ingekry het), maaglediging deur maagspoeling moet ondergaan (vir kinders kan emese voldoende wees) en h enkele dosis van 50 g geaktiveerde houtskool moet deur die maagbuis toegedien word. Behandeling van pasiënte wat vatbaar vir vergiftiging deur parasetamol is, kan na inname van kleiner hoeveelhede parasetamol as hierdie nodig wees.

Vir pasiënte wat in stupor of koma is, moet endotrageale intubasie voor maagspoeling gedoen word om aspirasie te voorkom.

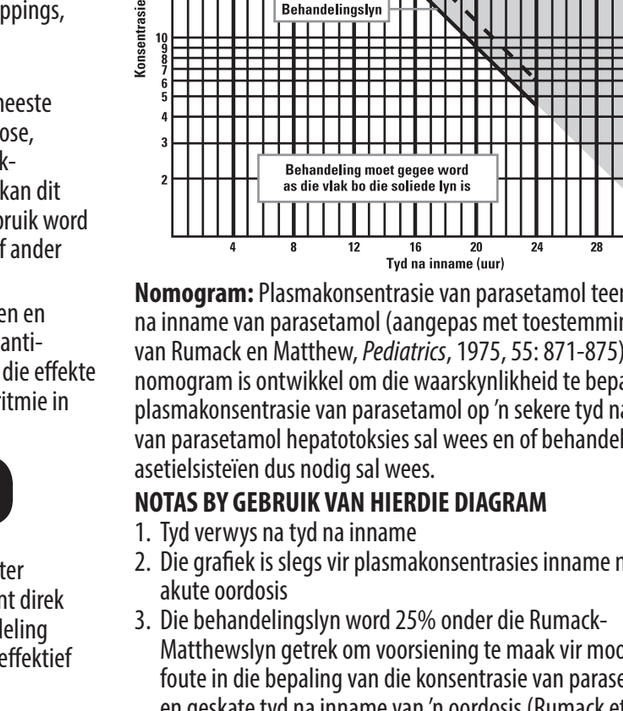
N-asetielsisteïen moet so gou as moontlik en verkieslik binne agt uur na oordosering aan alle gevalle van vermoedelike oordosering gegee word, hoewel behandeling tot 36 uur na inname steeds voordelig sal wees, veral as meer as 150 mg/kg parasetamol gedrink is. 'n Aanvanklike dosis van 150 mg/kg N-asetielsisteïen in 200 ml dekstrose-inspuiting intraveneus oor 15 minute gegee gevolg deur h intraveneuse infusie van 50 mg/kg in 500 ml dekstrose-inspuiting oor die volgende 4 uur en dan 100 mg/kg in 1000 ml dekstrose-inspuiting oor die volgende sestien uur. Die volume intraveneuse vloeistof moet vir kinders aangepas word.

Hoewel die orale formulering nie die behandeling van keuse is nie, kan 140 mg/kg opgelos in water aanvanklik gegee word, gevolg deur 70 mg/kg elke vier uur vir sewentien dosisse.

In alle gevalle van vermoedelike oordosering moet die vlak van parasetamol in die plasma vier uur na inname bepaal word. Vlakke wat voor vier uur gemeet word, kan misleidend wees. Pasiënte met 'n risiko vir lewerskade en wat dus voortgesette behandeling met N-asetielsisteïen nodig het, kan volgens die plasmavlakke van parasetamol op 4 uur geïdentifiseer word. Die plasmavlak van parasetamol teen tyd sedert inname kan in die nomogram hier onder gestip word. Die nomogram moet slegs vir h enkele akute inname gebruik word.

Diegene wie se plasmavlakke van parasetamol bo die "behandelingslyn" is, moet steeds N-asetielsisteïen teen 100 mg/kg intraveneus vir sestien uur ontvang totdat herstel intree. Pasiënte met hoër vatbaarheid vir lewerskade moet steeds behandeling ondergaan as konsentrasies bo die "lyn vir behandeling van hoë risiko" is. Die protrombienindeks korreleer die beste met oorlewing.

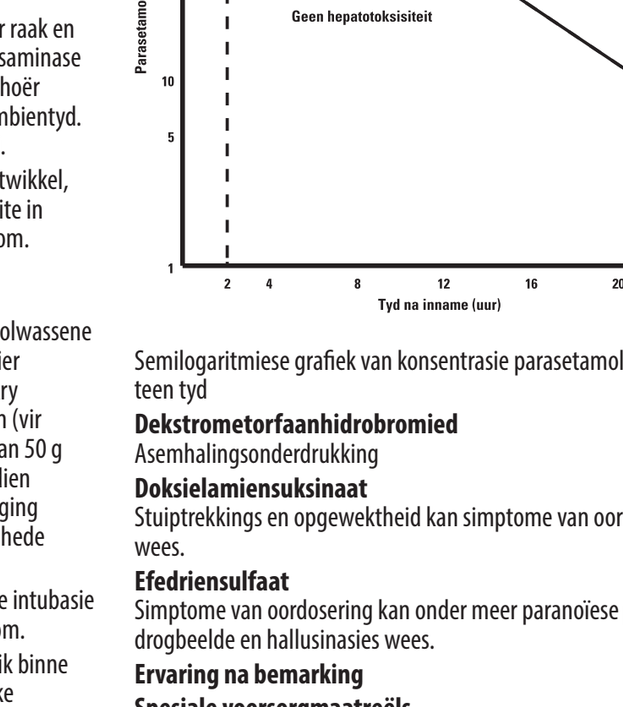
Moniteer alle pasiënte met beduidende innames vir ten minste ses en negentig uur.



Nomogram: Plasmakonsentrasie van parasetamol teen tyd na inname van parasetamol (aangepas met toestemming van Rumack en Matthew, *Pediatrics*, 1975, 55: 871-875). Die nomogram is ontwikkel om die waarskynlikheid te bepaal of 'n plasmakonsentrasie van parasetamol op 'n sekere tyd na inname van parasetamol hepatotoksies sal wees en of behandeling met asetielsisteïen dus nodig sal wees.

NOTAS BY GEBRUIK VAN HIERDIE DIAGRAM

1. Tyd verwys na tyd na inname
2. Die grafiek is slegs vir plasmakonsentrasies inname na 'n enkele akute oordosis
3. Die behandelingslyn word 25% onder die Rumack-Matthewslyn getrek om voorsiening te maak vir moontlike foute in die bepaling van die konsentrasie van parasetamol en geskate tyd na inname van 'n oordosis (Rumack et al. *Arch Intern Med*, 1981; 141 (suppl): 380-385



Semilogaritmiese grafiek van konsentrasie parasetamol in plasma teen tyd

Dekstrometorfaanhidrobromied
Asemhalingsonderdrukking

Doksielamiensuksinaat
Stuiptrekkings en opgewektheid kan simptome van oordosering wees.

Efedriensulfaat
Simptome van oordosering kan onder meer paranoïese psigose, drogbeelde en hallusinasies wees.

Ervaring na bemarking

Spesiale voorsorgmaatreëls
Hierdie medisyne kan tot lomerigheid en swak konsentrasie lei wat vererger word deur die gelyktydige inname van alkohol of ander onderdrukkers van die sentrale senustelsel. Pasiënte moet gewaarsku word om, veral aan die begin van behandeling, nie motor te bestuur of masjinerie te hanteer of moontlike gevaarlike take uit te voer waar 'n gebrek aan konsentrasie tot ongelukke kan lei nie.

IDENTIFIKASIE

Vicks Medinite is 'n helder, effens viskeuse groen vloeistof met die geur en smaak van anys.

AANBIEDING

Bottels met 90 ml of 180 ml met spesiale doseerkoppie.

BEWARINGSINSTRUKSIES

Bewaar by of benede 25 °C. Hou buite bereik van kinders.

REGISTRASIENOMMER

H/10.1/140
Namibia Reg.No: 90/10.1/001383 NS1

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Procter & Gamble South African Trading (Edms) Beperk,
15 Alice Lane Towers, Alice lane, Sandton, Johannesburg, 2196

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

31st May 2015

Vicks Medinite

SKEDULERINGSTATUS: S2

Lees hierdie hele voubiljet noukeurig deur omdat dit belangrike inligting vir u bevat.
Hierdie medisyne is sonder 'n dokter se voorskrif vir u beskikbaar om 'n matige siekte te behandel.
U moet Vicks Medinite Stroop nogtans versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- Moenie Vicks Medinite Stroop aan enigiemand anders gee nie.
- Vra u apteker as u nog inligting of raad nodig het.
- U moet 'n dokter raadpleeg as u simptome vererger of nie binne 10 dae verbeter nie.

EIENDOMSNAAM EN DOSEERVORM

Vicks Medinite (Stroop)

SAMESTELLING VAN DIE MEDISYNE, DIT IS, WAT VICKS MEDINITE STROOP BEVAT

Elke 30 ml bevat	
Parasetamol	600,0 mg
Efedriensulfaat	8,0 mg
Doksielamiensuksinaat	7,5 mg
Dekstrometorfaanhidrobromied	15,0 mg
Onaktiewe bestanddele	
Absolute alkohol	10,0 % v/v
Natriumbensoaat	
As bewaarmiddel	0,1 % m/v
Bevat suiker	

INDIKASIES

Goedgekeurde indikasies en gebruike, dit is, waarvoor Vicks Medinite Stroop gebruik word
Vicks Medinite verkouemedisyne vir die nag kan teen slaaptyd gedrink word vir die verligting van die ergste simptome van verkoue en griep, soos neusverstopping, nies, hoofpyn, ligte pyne en skete en hoes.

AANWYSINGS VOORDAT DIT GEBRUIK WORD

Vicks Medinite moet nie gebruik word nie as u

- allergies is vir dekstrometorfaan, parasetamol, efedriensulfaat, doksielamiensuksinaat of ander bestanddele is (kyk hulpstowwe hier bo in die samestelling van die medisyne).
- medisyne genaamd monoamienoksidaseremmers (MAOR's - antidepressante) gebruik of in die afgelope paar dae gebruik het nie.

Moenie Vicks Medinite Stroop aan kinders onder twaalf jaar oud gee nie.

Wees besonder versigtig met Vicks Medinite Stroop
Sê vir u dokter of apteker voordat u hierdie medisyne gebruik as u

- asma het
- ooit lewerprobleme gehad het
- 'n diabeet is of probleme het om sommige suikers te verteer.

Gebruik van ander medisyne
Moenie Vicks Medinite Stroop drink as u medisyne genaamd monoamienoksidaseremmers (MAOR's) vir depressie of Parkinson se siekte gebruik of in die afgelope 14 dae gebruik het nie.

Swangerskap en borsvoeding
As u swanger is of u baba borsvoed terwyl u hierdie medisyne gebruik, moet u asseblief u dokter, apteker of ander gesondheidskundige om advies vra.

WAARSKUWINGS

Motorbestuur en gebruik van masjinerie
Hierdie medisyne kan tot lomerigheid en swak konsentrasie lei wat vererger word deur die gelyktydige inname van alkohol of ander onderdrukkers van die sentrale senustelsel. Pasiënte moet gewaarsku word om nie motor te bestuur of masjinerie te hanteer of moontlike gevaarlike take uit te voer waar 'n gebrek aan konsentrasie tot ongelukke kan lei nie.

Let op dat hierdie medisyne 'n klein hoeveelheid alkohol bevat.

Belangrike inligting oor sommige van die bestanddele in Vicks Medinite Stroop
Hierdie medisyne bevat

- 10% **alkohol** per volume. Dit kan skadelik wees vir diegene wat aan alkoholisme ly.
  Dit moet in gedagte gehou word deur swanger of borsvoedende vroue, kinders en groepe met 'n hoë risiko, soos pasiënte met lewersiekte of epilepsie.
- **Suiker** (sukrose) - elke 15 ml volwasse dosis bevat 8,25 g sukrose

Raadpleeg 'n dokter indien simptome na tien dae voortduur. Moenie vir meer as 10 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.

Hierdie produk bevat parasetamol wat teen 'n oordosis noodlottig kan wees. In geval van oordosering of vermoedelike oordosering en onafgesien daarvan dat die persoon sonder simptome kan wees, moet die naaste dokter, hospitaal of vergiftigingsentrum onmiddellik geskakel word.

Dosisse hoër as die aanbevole kan ernstige lewerskade veroorsaak.

INTERAKSIES

As u ander medisyne op h gereelde basis gebruik, waaronder aanvullende of tradisionele medisyne, kan die gebruik van Vicks Medinite Stroop saam met hierdie medisyne ongewensde interaksies veroorsaak. Raadpleeg u dokter, apteker of ander gesondheidskundige asseblief om raad.

AANWYSINGS HOE OM VICKS MEDINITE STROOP TE GEBRUIK

Moenie medisyne wat vir u voorgeskryf is aan enigiemand anders gee nie.

Gebruik Vicks Medinite Stroop altyd presies soos wat u dokter aan u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie. Praat met u dokter of apteker as u dink dat die effek van Vicks Medinite Stroop te sterk of te swak is.

Dosis
Drink Vicks Medinite teen slaaptyd. Gebruik die verskafde doseerkoppie en was dit na gebruik.

Volwassenes van 12 jaar en ouer:

30 ml in die verskafde doseerkoppie (6 medisynemate) teen slaaptyd.

Moenie hierdie medisyne aan kinders jonger as 12 jaar gee nie, tensy 'n dokter so sê.

Moenie die aanbevole dosis oorskry nie.
As u meer stroop gedrink het as wat u moes of meer as die aanbevole dosis stroop gegee het of in geval van oordosering, raadpleeg u dokter of apteker. As nie een beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.

As u vergeet om Vicks Medinite Stroop te drink
Indien u per ongeluk 'n dosis oorslaan, **moenie** 'n dubbele dosis drink nie; drink die volgende dosis net soos normaalweg.

As u nog vrae oor die gebruik van hierdie produk het, vra asseblief vir u apteker.

Moenie medisyne wat vir u voorgeskryf is aan ander gee nie. Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kry hulp van die naaste hospitaal of vergiftigingsentrum.

Metode van toediening
Oraal

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Soos alle medisyne, kan Vicks Medinite Stroop newe-effekte veroorsaak, hoewel nie almal dit kry nie. In enkele gevalle kan die stroop duiseligheid of maagontsteldheid veroorsaak.

Nie alle newe-effekte wat vir hierdie medisyne aangemeld is, is in hierdie blad opgeneem nie. As u gesondheidstoestand vererger terwyl u hierdie medisyne gebruik, moet u u dokter, apteker of ander gesondheidskundige om advies raadpleeg.

Newe-effekte

Parasetamol
Sensitiwiteitsreaksies wat tot omkeerbare veluitslag of bloedversteurings lei, kan voorkom. Pasiënte wat aan nier- of lewersiektes ly, moet parasetamol onder mediese toesig gebruik.

Dekstrometorfaanhidrobromied
Mag lomerigheid, duiseligheid, opgewektheid, geestelike verwardheid en gastro-intestinale versteurings veroorsaak. Moet versigtig gegee word aan pasiënte met lewersiekte of met asma. Hoë dosisse veroorsaak asemhalingsonderdrukking.

Doksielamiensuksinaat
Doksielamiensuksinaat kan sedasie veroorsaak wat kan wissel van ligte lomerigheid tot h diep slaap met onvermoë om te konsentreer, lusteloosheid, duiseligheid, hipotensie, spierswakheid en gebrek aan koördinasie.

Ander newe-effekte is onder meer gastro-intestinale versteurings soos naarheid, braking, diarree of hardlywigheid en maagpyn.

Doksielamiensuksinaat kan ook hoofpyn, versteurde visie, tinnitus, ekstase of depressie, prikkelbaarheid, nagmerries, anoreksie, moeilike urinering, droë mond, benoude bors en tinteling, swaarheid en swakheid van die hande veroorsaak. Simptome van stimulasie kan onder meer slaaploosheid, senuagtigheid, tagikardie, tremore, spiertrekkings en konvulsies wees.

Groot dosisse kan toevalle in epileptici aanbring. Allergie en dermatologiese reaksies kan voorkom. Bloedversteurings, waaronder agranulositose en hemolitiese anemie, is aangemeld. Doksielamiensuksinaat kan die sederende effekte van sentralesenustelselonderdrukkers waaronder alkohol, barbiturate, hipnotiese analgetika, sedeermiddels en kalmeermiddels versterk.

Effekte van anticholinergiese middels, soos atropien en trisikliese antidepressante, kan deur die gelyktydige toediening van doksielamiensuksinaat versterk word. Doksielamiensuksinaat kan die metabolisme van geneesmiddels in die lewer beïnvloed.

Doksielamien moet versigtig gebruik word tydens toestande soos gloukoom en prostaathipertrofie.

Efedriensulfaat
Efedriensulfaat kan effekte soos duiseligheid, hoofpyn, naarheid, braking, sweet, dors, tagikardie, pyn in die bors, hartkloppings, moeilike urinering, spierswakheid en bewerasie, angs, rusteloosheid en slapeloosheid veroorsaak.

Efedriensulfaat moet vermy word vir pasiënte met die meeste vorme van kardiovaskulêre siekte, hipertensie, hipertireose, oormatige opgewektheid, feochromositoom en nouhoek-gloukoom. In pasiënte met vergroting van die prostaat, kan dit probleme met urinering vererger. Dit moet versigtig gebruik word deur pasiënte wat chloroform, siklopropaan, halotaan of ander gehalogeneerde narkosemiddels ontvang.

Die effekte van efedrien word deur guanetidien, reserpien en waarskynlik metieldopa verswak en kan deur trisikliese anti-depressante verswak of versterk word. Efedrien kan ook die effekte van guanetidien verlaag en kan die moontlikheid van aritmie in gedigitaliseerde pasiënte verhoog

Spesiale voorsorgmaatreëls
Hierdie medisyne kan tot lomerigheid en swak konsentrasie lei wat vererger word deur die gelyktydige inname van alkohol of ander onderdrukkers van die sentrale senustelsel. Pasiënte moet gewaarsku word om, veral aan die begin van behandeling, nie motor te bestuur of masjinerie te hanteer of moontlike gevaarlike take uit te voer waar 'n gebrek aan konsentrasie tot ongelukke kan lei nie.

IDENTIFIKASIE

Vicks Medinite is 'n helder, effens viskeuse groen vloeistof met die geur en smaak van anys.

AANBIEDING

Bottels met 90 ml of 180 ml met spesiale doseerkoppie.

BEWARINGSINSTRUKSIES

Bere by of benede 25°C. Hou buite bereik van kinders.

Moenie Vicks Medinite na die vervaldatum op die bottel of karton gebruik nie.

Die vervaldatum verwys na die laaste dag van die genoemde maand.

Medisyne moet nie in die dreineringstelsel of in huishoudelike afval gegooi word nie.

Vra vir u apteker hoe om van medisyne ontslae te raak wat nie meer gebruik word nie. Hierdie maatreëls sal help om die omgewing te bewaar.

REGISTRASIENOMMER

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Namibia Reg.Nr: 90/10.1/001383 NS1

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