

EFFERFLU-C

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

EFFERFLU-C Effervescent tablets

COMPOSITION:

Each tablet contains:

Paracetamol	500 mg
Sodium ascorbate equivalent to Vitamin C	250 mg
Chlorphenamine maleate	2 mg

PHARMACOLOGICAL CLASSIFICATION:

A.5.8. Preparations for the common cold including nasal decongestants

PHARMACOLOGICAL ACTION:

EFFERFLU-C effervescent tablets have analgesic, antipyretic and antihistaminic properties.

Pharmacokinetics

Chlorphenamine maleate

Chlorphenamine maleate is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentration occurring about 2,5 to 6 hours after administration by mouth.

Chlorphenamine appears to undergo considerable first-pass metabolism. Unchanged chlorphenamine and metabolites are excreted primarily in the urine; excretion is dependent on urinary pH and flow rate. About 70% of chlorphenamine in the circulation is bound to plasma proteins.

Paracetamol

Following oral administration, paracetamol is well absorbed, with peak plasma concentrations

obtained after 0,5 to 1 hour. The plasma half-life is about 2 hours.

Plasma protein binding is variable.

Paracetamol is metabolised in the liver primarily by conjugation with glucuronic acid (about 60%), sulphuric acid (about 35%) and cysteine (about 3%). Paracetamol is renally excreted primarily as conjugated metabolites.

Sodium ascorbate

Sodium ascorbate is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissue. Plasma concentrations of ascorbic acid rise as the dose ingested are increased until a plateau is reached with doses of about 90 to 150 mg daily. Excess of the body's needs is rapidly eliminated unchanged in the urine. Ascorbic acid crosses the placenta and is distributed into breast milk.

INDICATIONS:

Efferflu-C is indicated for symptomatic relief of runny nose, sneezing, sore throat, headache and generalized aching due to colds and flu.

CONTRA-INDICATIONS:

EFFERFLU-C is contra-indicated in:

- Patients with hypersensitivity to any of the ingredients.
- Severe liver function impairment.
- Epilepsy
- Children under the age of 12 years.

WARNINGS:

EFFERFLU-C may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other 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.

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

Consult a medical practitioner if pain or fever persists or gets worse at the recommended dosage, if new symptoms occur or if redness and swelling is present, as these could be signs of a more serious condition.

Do not use EFFERFLU-C continuously for more than 10 days without consulting your doctor.

In the event of ovedosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Store in a safe place out of reach of children.

Patients suffering from hepatitis or alcoholism, or recovering from any form of liver disease, should not take excessive quantities of EFFERFLU-C.

Use with caution in renal disease.

INTERACTIONS:

Paracetamol:

Hepatotoxic medicines – Increased risk of hepatotoxicity.

Enzyme inducing medicines – Increased risk of hepatotoxicity. Possible decrease in therapeutic effects of EFFERFLU-C.

Metoclopramide – Absorption of EFFERFLU-C may be accelerated.

Cholestyramine – Absorption of EFFERFLU-C is reduced if given within one hour of cholestyramine.

Prolonged concurrent use of EFFERFLU-C with salicylates increases the risk of adverse renal effects.

Chlorphenamine maleate

Chlorphenamine maleate may enhance the sedative effect of central nervous system depressants, including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics,

Concurrent use of MAO inhibitors may prolong and intensify the anticholinergic and CNS depressant effect of chlorphenamine maleate. Concurrent use is not recommended. Care should be observed when tricyclic antidepressants, guanethidine, reserpine, methyldopa or atropine are taken concomitantly.

Chlorphenamine maleate given with ototoxic medication may mask the symptoms of ototoxicity such as tinnitus, dizziness or vertigo.

Vitamin C

Vitamin C should not be given for the first month after starting treatment with desferrioxamine due to increased iron toxicity.

Large doses of Vitamin C may increase serum ethinylestradiol concentrations in women taking oral contraceptives.

Concomitant use of Vitamin C and fluphenazine may result in decreased serum concentrations of fluphenazine.

PREGNANCY AND LACTATION:

The safety and efficacy in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE RECOMMENDED DOSE

Adults and children over 12 years: One tablet every 8 hours if necessary. Dissolve one tablet in a glass of water and drink the contents immediately once the whole tablet has dissolved.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:**Side effects:****Paracetamol***Blood disorders:*

Less frequent: Agranulocytosis, thrombocytopenia, leucopenia, pancytopenia, neutropenia and anaemia.

Hepato-biliary disorders:

Less frequent: Hepatitis.

Skin and subcutaneous tissue disorders:

Less frequent: Allergic dermatitis.

Renal and urinary disorders:

Less frequent: Renal colic, renal failure and sterile pyuria.

General disorders:

The following have been reported but the frequency is unknown:

Pancreatitis, dermatitis, skin rashes and other allergic reactions. The rash is usually erythematous or urticarial but sometimes more serious and accompanied by fever and mucosal lesions.

Chlorphenamine maleate:

Immune system disorder:

Less frequent: Anaphylaxis including tightness of the chest.

Nervous system disorders:

Frequent: Drowsiness.

Less frequent: Convulsions or seizures, dizziness, increased sweating, abnormal coordination, tremor, lassitude, euphoria, nervousness, insomnia, headache.

Eye disorders:

Less frequent: Blurred vision, diplopia.

Ear and labyrinth disorders:

Less frequent: Tinnitus.

Cardiac disorders:

Less frequent: Hypotension, palpitations.

Gastrointestinal disorders:

Frequent: Dryness of mouth, nose or throat, gastrointestinal upset, loss of appetite, constipation, diarrhoea, nausea, vomiting.

Hepato-biliary disorders:

Less frequent: Cholestasis, hepatitis or other hepatic function abnormalities.

Skin and subcutaneous tissue disorders:

Less frequent: Exfoliative dermatitis.

Renal and urinary disorders:

Less frequent: Difficult or painful urination, dysuria.

General disorders:

Less frequent: Oedema, fatigue.

Vitamin C:

Blood and lymphatic system disorders:

The following has been reported but the frequency is unknown:

Ascorbic acid in large doses may also result in haemolysis in patients with glucose-6-phosphate dehydrogenase deficiency.

Gastrointestinal disorders:

The following has been reported but the frequency is unknown:

Large doses are reported to cause diarrhoea and other gastrointestinal disturbances.

Renal and urinary disorders:

The following has been reported but the frequency is unknown:

Large doses may result in hyperoxaluria and the formation of renal calcium oxalate calculi.

Vitamin C should be given with care to patients with hyperoxaluria and to patients with G6PD deficiency.

Tolerance may be induced with prolonged use of large doses.

Special Precautions:

See "Warnings".

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Prompt treatment is essential. In the event of an overdose, consult a doctor immediately, or take the person directly to a hospital. 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 overdose 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 affect the potential seriousness of the overdose.

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 of paracetamol overdose:

Although evidence is limited it is recommended that any adult person who has ingested 5 – 10 grams or more of paracetamol (or child who has had more than 140 mg/kg) within the preceding four hours, should have 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 stuporose or comatose endotracheal intubations should precede gastric lavage in order to avoid aspiration.

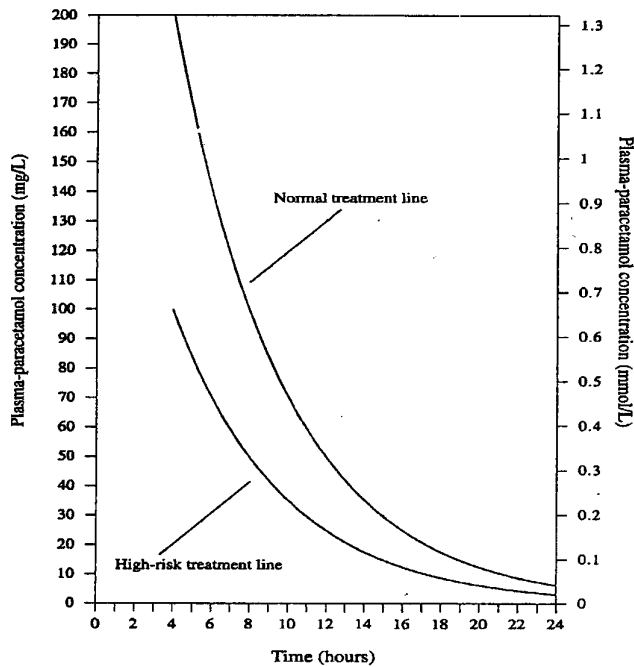
N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdose, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given **intravenously** over 15 minutes, followed by 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 the 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, 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.

A linear plot of plasma-paracetamol concentration against hours after ingestion:



1. The time coordinates refer to time after ingestion.
2. Plasma-paracetamol concentrations drawn before 4 hours may not represent peak concentrations.
3. The graph should be used only in relation to a single acute ingestion.
4. Patients whose plasma-paracetamol concentrations are above the normal treatment line should be treated.
5. Patients on enzyme-inducing drugs or with malnutrition or a history of alcohol abuse should be treated if their plasma-paracetamol concentrations are above the high-risk treatment line.
6. The value of such charts is uncertain if the patient is first seen 15 hours or more after ingestion, or has taken modified release preparations of paracetamol.

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.

Overdosage with EFFERFLU-C may result in anticholinergic effects (unsteadiness, severe drowsiness, severe dryness of throat, nose and mouth, redness of face and shortness of breath). Convulsions, tachycardia and cardiac arrhythmias may occur.

Overdosage may be fatal, especially in infants and children in whom the main symptoms are central nervous system stimulation and antimuscarinic effects. Deepening coma, cardiorespiratory collapse and death may occur within 18 hours. In adults, the usual symptoms are of central nervous system depression with drowsiness, coma and convulsions.

Hypotension may also occur. Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects even at the therapeutic doses.

Treatment is symptomatic and supportive.

IDENTIFICATION:

EFFERFLU-C is a white or almost white, round, flat tablet. It produces a slightly opalescent, colourless solution with a citrus flavour once dissolved in a glass of water.

PRESENTATION:

EFFERFLU-C is available in white polypropylene tubes closed with a low-density polyethylene cap. Each tube contains 12 tablets.

STORAGE INSTRUCTIONS:

Store below 25°C in a dry place. Keep the tube tightly closed.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

A39/5.8/0451

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION:

Pharma Dynamics (Pty) Ltd

F02 Grapevine House

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7945

DATE OF PUBLICATION OF THE PACKAGE INSERT:

26 May 2006

EFFERFLU-C

SKEDULERINGSSTATUS:

S2

EIENDOMSNAAM EN DOSEERVORM:

EFFERFLU-C Bruistablette

SAMESTELLING:

Elke tablet bevat:

Parasetamol	500 mg
Natriumaskorbaat ekwivalent aan vitamien C	250 mg
Chloorfenamienmaleaat	2 mg

FARMAKOLOGIESE KLASSIFISERING:

A. 5.8 Preparate vir die gewone verkoue insluitend nasale ontstummiddels

FARMAKOLOGIESE WERKING:

EFFERFLU-C bruistablette het pynstillende, koorswerende en antihistamien-eienskappe.

Farmakokinetika:

Chloorfenamienmaleaat

Chloorfenamienmaleaat word relatief stadig uit die spysverteringskanaal geabsorbeer, en piek plasmakonsentrasies word 2,5 tot 6 uur na toediening per mond bereik. Dit wil voorkom dat chloorfenamien aansienlike presistemiese metabolisme ondergaan. Onveranderde chloorfenamien en metaboliëte word primêr in die urine uitgeskei; uitskeiding is afhanklik van urinêre pH en vloeitempo. Ongeveer 70% van chlorofenamien in die sirkulasie is aan plasmaproteïene gebonde.

Parasetamol

Na orale toediening word parasetamol goed geabsorbeer en piek plasmakonsentrasies word na 0,5 tot 1 uur bereik. Die plasma halfleeftyd is ongeveer 2 uur.

Plasmaproteïenbinding is wisselvallig.

Parasetamol word in die lewer gemetaboliseer hoofsaaklik deur konjugasie met glukuronsuur (ongeveer 60%), swawelsuur (ongeveer 35%) en sisteïen (ongeveer 3%). Parasetamol word primêr as gekonjugeerde metaboliete deur die niere uitgeskei.

Natriumaskorbaat

Natriumaskorbaat word maklik uit die spysverteringskanaal geabsorbeer en wyd in liggaamsweefsels versprei. Plasmakonsentrasies van askorbiensuur styg soos die dosis wat ingeneem word, toeneem totdat 'n plato met dosisse van ongeveer 90 tot 150 mg daaglik bereik word. Oormatige hoeveelhede wat die liggaam se behoeftes oorskry, word vinnig onveranderd in die urine uitgeskei. Askorbiensuur beweeg oor die plasenta en word in borsmelk versprei

INDIKASIES:

Efferflu-C word vir die simptomatiese verligting van loopneus, nies, seer keel, hoofpyn en algemene seer lyf as gevolg van verkoues en griep aangedui.

KONTRA-INDIKASIES:

EFFERFLU-C is teenaangedui in:

- Pasiënte met hipersensitiwiteit teenoor enigeen van die bestanddele.
- Ernstige inkorting van lewerfunksie.
- Epilepsie.
- Kinders jonger as 12 jaar.

WAARSKUWINGS:

EFFERFLU-C mag lei tot slaperigheid en belemmerde konsentrasie wat deur die gelyktydige inname van alkohol en ander sensusisteemdepressante vererger mag word. Pasiënte moet,

veral aan die begin van terapie, aangeraai word om nie voertuie te bestuur of masjiene te hanteer of potensieel gevaarlike take aan te pak nie, waar verlies aan konsentrasie tot ongelukke mag lei.

Dosering van EFFERFLU-C wat die aanbevelings oorskry, mag ernstige lewerskade veroorsaak. Raadpleeg 'n mediese praktisyn indien pyn of koors voortduur of vererger op die aanbevole dosering, as nuwe simptome voorkom, of as rooiheid en swelling teenwoordig is, omdat dit tekens van 'n ernstiger toestand mag wees.

Moenie EFFERFLU-C aanhoudend vir langer as 10 dae gebruik sonder om jou dokter te raadpleeg nie.

In 'n geval van oordosering of vermoede oordosis en nieteenstaande die feit dat die persoon asimptomaties mag wees, moet die naaste dokter, hospitaal of Gifsentrum onmiddellik gekontak word.

Bewaar in 'n veilige plek buite bereik van kinders.

Pasiënte wat aan hepatitis of alkoholisme ly, of wat van enige soort lewersiekte herstel, behoort nie oormatige hoeveelhede EFFERFLU-C te neem nie.

Gebruik versigtig in niersiekte.

INTERAKSIES:

Parasetamol

Hepatotoksiese medisyne - Verhoogde risiko van hepatotoksiteit.

Ensiem-induserende medisyne - Verhoogde risiko van hepatotoksiteit. Moontlike vermindering in die terapeutiese uitwerkings van EFFERFLU-C.

Metoklopramid - Absorpsie van EFFERFLU-C mag versnel word.

Cholestiramien - Absorpsie van EFFERFLU-C word verminder as dit binne een uur na inname van cholestiramien toegedien word.

Verlengde gelyktydige gebruik van EFFERFLU-C saam met salisilate verhoog die risiko van nadelige renale insidente.

Chloorfenamienmaleaat

Chloorfenamienmaleaat mag die kalmerende effek van sentrale senusisteemdepressante, insluitend alkohol, barbiturate, hipnotika, opioïede analgetika, angswerende kalmeermiddels, en antipsigotiese middels, versterk.

Gelyktydige gebruik van MAO-inhibeerders mag die anticholinergiese en SSS-depressante uitwerking van chloorfenamienmaleaat verleng en versterk. Gelyktydige gebruik word nie aanbeveel nie. Sorg moet uitgeoefen word as trisikliese antidepressante, guanetidien, reserpien, metioldopa of atropien gelyktydig geneem word.

As chloorfenamienmaleaat saam met ototoksiese medikasie toegedien word, mag dit die simptome van ototoksiteit soos tinnitus, duiseligheid of vertigo, versluier.

Vitamien C

As gevolg van verhoogde ystertoksiteit, moet vitamien C nie in die eerste maand na begin van behandeling met desferrioksamien, toegedien word nie.

Groot dosisse vitamien C mag serumtiniel estradiolkonsentrasies verhoog by vrouens wat orale voorbehoedmiddels neem.

Gelyktydige gebruik van Vitamien C en flufenasien mag verlaagde serumkonsentrasies van flufenasien veroorsaak.

SWANGERSKAP EN LAKTASIE:

Die veiligheid en doeltreffendheid tydens swangerskap en laktasie is nie vasgestel nie.

DOSERING EN GEBRUIKSAANWYSINGS:

MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE

Volwassenes en kinders ouer as 12 jaar: Een tablet elke 8 uur indien nodig. Los een tablet op in 'n glas water en drink die inhoud onmiddellik nadat die hele tablet opgelos is.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Neuwe-effekte:

Parasetamol

Bloedversteurings:

Minder frekvent: Agranulose, trombositopenie, leukopenie, pansitopenie, neutropenie en anemie.

Hepatobiliêre versteurings:

Minder frekvent: Hepatitis

Vel- en onderhuidse weefselversteurings:

Minder frekvent: Allergiese dermatitis

Renale en urinêre versteurings:

Minder frekvent: Renale koliek, nierversaking en steriele piurie.

Algemene versteurings:

Die volgende is aangemeld, maar die frekwensie is onbekend:

Pankreatitis, dermatitis, veluitslae en ander allergiese reaksies. Die veluitslag is gewoonlik eritemateus of urtikarieel, maar soms is dit meer ernstig en word dit begelei deur koors en slymvliesletsels.

Chloorfenamienmaleaat:*Immuunsisteemversteurings:*

Minder frekvent: Anafilakse insluitend benoude bors.

Senusisteemversteurings:

Frekvent: Slaperigheid

Minder frekvent: Konvulsies of stuipe, duiseligheid, verhoogde sweet, abnormale koördinasie, tremor, lusteloosheid, euforie, senuagtigheid, slaaploosheid, hoofpyn.

Oogversteurings:

Minder frekvent: Versteurde visie, diplopie.

Oor- en doolhofversteurings:

Minder frekvent: Tinnitus

Kardiale versteurings:

Minder frekvent: Hipotensie, hartkloppings

Gastroïntestinale versteurings:

Frekvent: Droë mond, neus of keel, gastroïntestinale ontsteldheid, verlies aan apyt, hardlywigheid, diarree, naarheid, braking.

Hepatobiliêre versteurings:

Minder frekvent: Cholestase, hepatitis of ander lewerfunksie-abnormaliteite.

Vel- en onderhuidse weefselversteurings:

Minder frekvent: Eksfoliatiewe dermatitis.

Renale en urinêre versteurings:

Minder frekvent: Moeilike of pynlike urinering, disurie.

Algemene versteurings:

Minder frekwent: Edeem, moegheid.

Vitamien C:

Bloed- en limfatiese sisteemversteurings:

Die volgende is aangemeld, maar die frekwensie is onbekend:

Askorbiesuur in groot dosisse mag ook hemolise veroorsaak by pasiënte met 'n gebrek aan glukose-6-fosfaat-dehidrogenase.

Gastroïntestinale versteurings:

Die volgende is aangemeld, maar die frekwensie is onbekend:

Daar word berig dat groot dosisse diarree en ander gastroïntestinale versteurings veroorsaak.

Renale en urinêre versteurings:

Die volgende is aangemeld, maar die frekwensie is onbekend:

Groot dosisse mag hiperoksalurie en die vorming van renale kalsiumoksalaatstene veroorsaak.

Vitamien C moet met omsigtigheid toegedien word aan pasiënte met hiperoksalurie en aan pasiënte met 'n G6PD-gebrek.

Toleransie mag met verlengde gebruik van groot dosisse geïnduseer word.

Spesiale Voorsorgmaatreëls:

Sien "Waarskuwings".

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Vinnige behandeling is essensieel. In geval van 'n oordosering, behoort 'n dokter onmiddellik geraadpleeg te word, of die persoon moet direk na 'n hospitaal geneem word. 'n Vertraging in die aanvang van behandeling kan beteken dat die teenmiddel te laat toegedien word om effektief te wees. Tekens van lewerskade is dikwels vertraag tot die tyd van effektiewe behandeling verby is.

Vatbaarheid vir parasetamoltoksisiteit is verhoog in pasiënte wat herhaalde hoë dosisse (meer as 5-10g/dag) parasetamol vir verskeie dae geneem het, in chroniese alkoholisme, chroniese lewersiekte, VIGS, wanvoeding, en met die gebruik van geneesmiddels wat mikrosomale oksidasie in die lewer induseer, soos barbiturate, isoniasied, rifampisien, fenitoïen en karbamasepien.

Simptome van parasetamoloordosering tydens die eerste 24 uur sluit bleekheid, naarheid, braking, anoreksie en moontlik ook abdominale pyn, in. Ligte simptome tydens die eerste twee dae van akute vergiftiging beïnvloed nie die potensiële erns van die oordosering nie.

Lewerskade mag 12 tot 48 uur na inname te voorskyn kom of selfs later, aanvanklik deur verhoging van die serumtransaminase- en laktiese dehidrogenase-aktiwiteit, verhoogde serumbilirubienkonsentrasie en verlenging van die protrombientyd. Lewerskade mag tot ensefalopatie, koma en sterftes lei.

Akute nierversaking met akute tubulêre nekrose mag selfs in die afwesigheid van ernstige lewerskade ontwikkel. Abnormaliteite in glukosemetabolisme en metaboliese asidose mag voorkom. Hartaritmieë is aangemeld.

Behandeling van parasetamoloordosering:

Alhoewel bewyse beperk is, word dit aanbeveel dat by enige volwasse persoon wat binne die voorafgaande vier uur 5-10 gram parasetamol of meer ingeneem het (of by 'n kind wat meer as

140 mg/kg ingeneem het) die maag deur maagspoeling geledig word (emese mag toepaslik wees by kinders) en 'n enkele dosis van 50 g geaktiveerde houtskool deur die maagspoelbuis toegedien moet word. Inname van kleiner hoeveelhede parasetamol mag behandeling noodsaak by pasiënte wat vatbaar vir parasetamolvergiftiging is (sien hierbo). By pasiënte wat hul bewussyn verloor het of in 'n koma is, moet endotracheale intubasie die maagspoeling voorafgaan om aspirasie te voorkom.

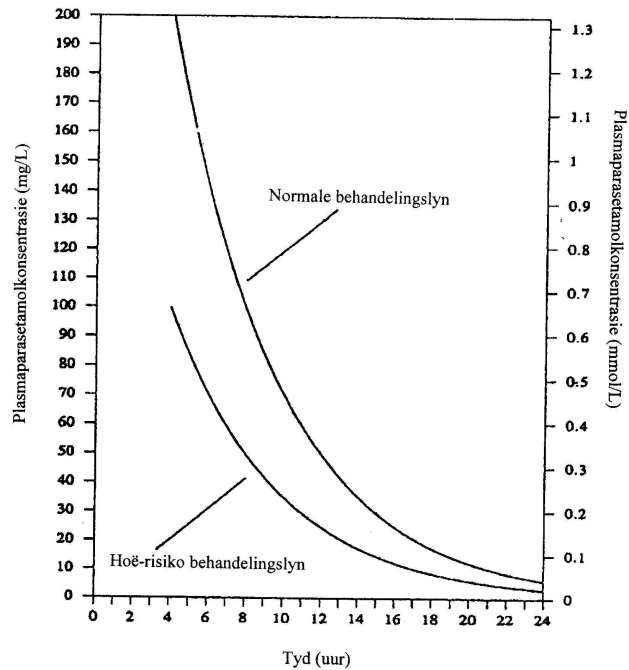
N-asetielsisteïen moet in alle gevalle waar oordosering vermoed word, so gou as moontlik toegedien word, liefs binne agt uur na oordosering, alhoewel behandeling tot 36 uur na inname nog steeds van voordeel mag wees, veral as meer as 150 mg/kg parasetamol geneem is. 'n Aanvanklike dosis van 150 mg/kg van N-asetielsisteïen in 200 ml dekstrose-inspuiting moet **intraveneus** oor 15 minute toegedien word, gevolg deur 'n infusie van 50 mg/kg in 500 ml dekstrose-inspuiting oor die volgende vier uur, en dan 100 mg/kg in 1000 ml dekstrose-inspuiting oor die volgende sestien uur.

Die volume van die intraveneuse vloeistof behoort vir kinders aangepas te word.

Alhoewel die orale formulering 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 Plasmaparasetamolvlak moet in alle gevalle waar oordosering vermoed word, vier uur na inname bepaal word. Vlakke wat voor vier uur bepaal word mag misleidend wees, tensy dit hoog is. Pasiënte wat aan die risiko van lewerskade blootgestel is en dus volgehoue behandeling met N-asetielsisteïen benodig, kan volgens hulle plasmaparasetamolvlak uitgekien word. Die plasmaparasetamolvlak kan teen tyd sedert inname grafies aangeteken word.

'n Liniêre grafiek van plasmaparasetamolkonsentrasie teenoor ure na inname



- 1 Die tydkoördinate verwys na tyd na inname.
- 2 Die plasmaparasetamolkonsentrasies wat voor 4 uur getrek is, mag nie piek konsentrasies weerspieël nie.
- 3 Die grafiek moet alleenlik in verband met 'n enkele akute inname gebruik word.
- 4 Pasiënte by wie die plasmaparasetamolkonsentrasies hoër is as die normale behandelingslyn, moet behandel word.
- 5 Pasiënte op ensiem-induserende geneesmiddels, of wat aan wanvoeding ly, of 'n geskiedenis van alkohelmisbruik het, behoort behandel te word as hulle plasmaparasetamolkonsentrasies hoër as die hoë-risiko behandelingslyn is.
- 6 Die waarde van sulke grafieke is onseker as die pasiënt eers 15 uur of langer na inname gesien word, of as 'n gemodifiseerde-vrystellingspreparaat van parasetamol geneem is.

Pasiënte by wie die plasmaparasetamolkonsentrasies hoër as die "normale behandelingslyn" is, behoort N-asetielsisteïen-behandeling 100 mg/kg IV vir sestien uur herhaaldelik tot herstel, te ontvang. Pasiënte met verhoogde vatbaarheid vir lewerskade soos hierbo geïdentifiseer, moet behandeling ontvang indien die konsentrasies hoër is as die "hoë-risiko behandelingslyn". Die protrombienindeks korreleer die beste met oorlewing.

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

Oordosering met EFFERFLU-C mag anticholinergiese uitwerkings veroorsaak (onbestendigheid, ernstige slaperigheid, ernstige droë keel, neus en mond, rooiheid van die gesig en kortasem). Konvulsies, tagikardie en hartaritmieë mag voorkom.

Oordosering mag noodlottig wees, veral by suigeling en kinders waar die hoof simptome sentrale senustestimulasie en antimuskarietiese effekte is. Toenemende koma, kardiopulmonêre kollaps en dood mag binne 18 uur voorkom. By volwassenes, is die gebruikelike simptome sentrale senustestimulasie met slaperigheid, koma en konvulsies.

Hipotensie mag ook voorkom. Bejaarde pasiënte is meer vatbaar vir die sentrale senustestimulasie en hipotensiewe effekte selfs teen die terapeutiese dosisse.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

EFFERFLU-C is 'n wit of naaswit, ronde, plat tablet. Dit produseer 'n effens opalessende, kleurlose oplossing met 'n sitrusgeur nadat dit in 'n glas water opgelos is.

AANBIEDING:

EFFERFLU-C is beskikbaar in wit polipropileen buise wat met 'n lae-densiteit poliëtileen dop gesluit is. Elke buis bevat 12 tablette.

BERGINGS- EN WYSINGS:

Bewaar onder 25°C in 'n droë plek. Hou die buis dig gesluit.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIE-NOMMER:

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