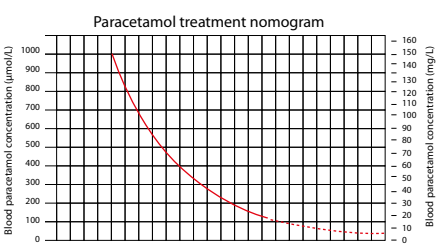
SCHEDULING STATUS: S0
PROPRIETARY NAME (AND DOSAGE FORM):
CALPOL PAEDIATRIC SUSPENSION
COMPOSITION: Each 5 ml contains: Paracetamol 120 mg; Methyl Hydroxybenzoate, 0,1% m/v; Propyl Hydroxybenzoate 0,02% m/v
Contains sugar (Sorbitol 0,75 ml & Glucose 2,0 ml) per 5 ml
Alcohol Free
Excipients
Malic acid, azorubine (E122), xanthan gum, maltilol liquid, strawberry flavour, sorbitol, nipasept sodium [sodium methyl parahydroxybenzoate, sodium ethyl parahydroxybenzoate and sodium propyl parahydroxybenzoate], anhydrous citric acid and purified water.
CATEGORY AND CLASS: A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.
PHARMACOLOGICAL ACTION: Paracetamol has analgesic and antipyretic actions.
INDICATIONS: CALPOL is indicated for symptomatic relief of mild to moderate pain such as headache, sore throat, toothache, teething pains and fever associated with colds and flu.
CONTRA-INDICATIONS: In patients with a history of hypersensitivity to paracetamol or excipients. Severe hepatic impairment (Child Pugh C).
WARNINGS AND SPECIAL PRECAUTIONS: CALPOL contains paracetamol which may be fatal in overdose. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. In the event of overdosage or suspected overdose and the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.
Paracetamol overdose may cause liver failure requiring liver transplant or lead to death. Underlying liver disease increases the risk of paracetamol-related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication. Hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, low body mass index, chronic heavy users of alcohol or have sepsis. Patients with depleted glutathione states using paracetamol may increase the risk of metabolic acidosis. If symptoms persist, seek medical. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Each 24 mg/ml (120 mg/5 ml) suspension contains sorbitol (E420) at 666.5 mg (2.0 ml) glucose (0.75 ml) per 5 ml and suspension. Sodium methyl-, sodium ethyl- and sodium propyl- parahydroxybenzoates (E219, E215, E217) may cause allergic reactions (possibly delayed).
INTERACTIONS: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; no effect with occasional doses.
DOSAGE AND DIRECTIONS FOR USE: DO NOT EXCEED THE RECOMMENDED DOSE. Shake the bottle before use. Infants under 3 months: NOT RECOMMENDED. May be given 3-4 times daily with an interval of 4 hours between each dose. No more than 4 doses in any 24-hour period. Consult your doctor if no relief is obtained with the recommended dosage.

Age	Average weight (kg)	Dose
3 – 6 months	6 -8	3,75 ml
6 – 24 months	8 – 12	5 ml
2 – 4 years	12 – 16	7,5 ml
4 – 6 years	16 - 20	10 ml

Body system	Undesirable effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune system disorders	Anaphylaxis, cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, Steven-Johnson syndrome and Toxic Epidermal Necrolysis	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

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 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 2 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 prothrombin time. Liver damage may lead to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.
Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia:
Evidence is limited, it is recommended that any adult person who has ingested 5-10 g or more of paracetamol (or/and possibly abdominal pain. Mild symptoms during the first 2 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 prothrombin time. Liver damage may lead to encephalopathy, coma and death.Acute renal failure with acute tubular necrosis may develop 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: child who has had more than 140 mg/kg within the preceding 4 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 stuperous 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 8 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 1 000 ml dextrose injection over the next sixteen hours.
The volume of intravenous fluid should be modified for children.
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 4 hours for 17 doses.
A plasma paracetamol level should be determined 4 hours after ingestion in all cases of suspected overdosage. Levels done before 4 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. Nomogram extracted from Essential Medicines Guideline, South African Department of Health, 2015. Those whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over 16 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 96 hours.



Nomogram Source: Daly FF, Fountain JS, Murray L, Graudins A, Buckley NA; Panel of Australian and New Zealand clinical toxicologists. Guidelines for the management of paracetamol poisoning in Australia and New Zealand -explanation and elaboration. A consensus statement from clinical toxicologists consulting to the Australasian poisons information centres. Med J Aust. 2008 Mar 3:188(5):296-301

IDENTIFICATION: Pink coloured uniform suspension with a strawberry odour.
PRESENTATION: Amber glass bottles of 50 ml and 100 ml with a white, child resistant, tamper evident closure with a white outer cap, natural inner cap and a natural tamper evident band. Amber PET bottles of 50 ml and 100 ml.
STORAGE INSTRUCTIONS: Protect from light. Minimal air exposure. Store in a well closed container at or below 25 °C.
Keep out of reach of children.
REGISTRATION NUMBER: A B/2.7/767
DATE OF PUBLICATION OF THIS PACKAGE INSERT:
Date on the registration certificate of the medicine: 14 April 1989
Date of the most recently revised package insert as approved by council: 1 August 2016
Additional countries registration details:

Country	Scheduling status (or Category of distribution)	Registration no.
Botswana	S4	B9317485
Namibia	NS0	11/2.7/0043
Zambia	GS	025/018
Zimbabwe	HR	83/2.1/1671

ATC Code: N02BE01 - Anilides
NAME AND BUSINESS ADDRESS OF MANUFACTURER:
GlaxoSmithKline Consumer Healthcare South Africa (Pty) Ltd. 39 Hawkins Avenue, Epping Industria 1, Cape Town, 7460
Trademarks are owned by or licensed to the GSK group of companies.

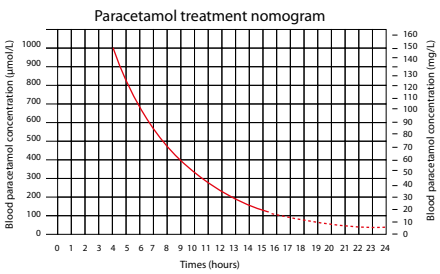
SKEDULERINGSTATUS: S0
EIENAARSKAPNAAM (EN DOSERINGSVORM):
CALPOL PEDIATRIESE SUSPENSIE
SAMESTELLING: Elke 5 ml bevat: Parasetamol 120 mg; Metielhidroksibensoaat 0,1% m/v; Propielhidroksibensoaat 0,02% m/v;
Bevat suiker (Sorbitol 0,75 ml & Glukose 2,0 ml) per 5 ml
Alkoholvry
Hulpstowwe
Appelsuur, azorubien (E122), xantangom, maltilolvloeistof, aarbeismaak, sorbitol, nipaseptnatrium [natriummetielparahidroksibensoaat, natriumetielparahidroksibensoaat en natriumpropielparahidroksibensoaat], watervrye sitroensuur en gesuiwerde water.
KATEGORIE EN KLAS: A 2.7 Koorswerende of koorswerende en anti-inflammatoriese pynstiller.
FARMAKOLOGIESE AKSIE: Parasetamol het pynstillende aksies.
INDIKASIES: CALPOL word aangedui vir simptomatiese verligting van ligte tot matige pyn soos hoofpyn, keelseer, tandpyn, tandkrypyn en koors wat verband hou met verkoue en griep.
KONTRA-INDIKASIES: CALPOL is teenaangedui by pasiënte met 'n vorige geskiedenis van hipersensitiwiteit vir parasetamol of hulpstowwe.
Ernstige lewersiekte ("Child Pugh C").
WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS: CALPOL bevat parasetamol wat dodelik met oordosis kan wees. Moenie met ander produkte wat parasetamol bevat, gebruik nie. Gelyktydige gebruik met ander produkte wat parasetamol bevat, kan 'n oordosis veroorsaak. In die geval van 'n oordosis of vermoedelike oordosis en ondanks die feit dat die persoon asimptomaties kan wees, moet die naaste dokter, hospitaal of gifsentrum onmiddellik gekontak word.
Oordosis parasetamol kan lewerversaking veroorsaak, wat leweroorplanting kan vereis of tot die dood kan lei.
Onderliggende lewersiekte verhoog die risiko van parasetamolverwante lewerskade. Pasiënte wat gediagnoseer is met lewer- of nierversaking, moet mediese advies inwin voordat hulle hierdie medikasie neem. Gevalle van lewerdisfunksie/-versaking is aangemeld by pasiënte met uitgeputte glutatioonvlakke, soos diegene wat ernstig ondervoed is, anoreksies is, 'n lae liggaamsmassa-indeks het, chroniese alkoholiste is of sepsis het. By pasiënte met glutatioon-uitgeputte toestande kan die gebruik van parasetamol die risiko van metaboliese asidose verhoog. As simptome voortduur, moet mediese advies gekry word.
Pasiënte met seldsame oorerflike probleme met fruktose-intoleransie moet hierdie medisyne nie gebruik nie.
Elke suspensie van 24 mg/ml (120 mg/5 ml) bevat sorbitol (E420) teen 666,5 mg (2,0 ml) glukose (0,75 ml) per 5 ml en suspensie.
Natriummetielparahidroksibensoaat, natriumetielparahidroksibensoaat en natriumpropielparahidroksibensoaat (E219, E215, E217) kan allergiese reaksies veroorsaak (moontlik vertraag).
INTERAKSIES: Die antistollingseffek van warfarien en ander kumariene kan verhoog word deur langdurige daaglikse gebruik van parasetamol met 'n verhoogde risiko van bloeding; af en toe dosisse het geen beduidende effek nie.
DOSIS EN GEBRUIKSAANWYSINGS: MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE. Skud die bottel voor gebruik. Babas jonger as drie maande: NIE AANBEVOLE NIE. Mag drie tot vier keer per dag toegedien word, maar met 'n interval van 4 uur tussen elke dosis. Nie meer as vier dosisse in 'n tydperk van 24 uur nie. Raadpleeg u dokter as u geen verligting kry met die aanbevole dosis nie.

Ouderdom	Gemiddelde gewig (kg)	Dosis
3-6 maande	6 -8	3,75 ml
6-24 maande	8 – 12	5 ml
2-4 jaar	12 – 16	7,5 ml
4-6 jaar	16 – 20	10 ml

MOENIE VOORTDUREND VIR LANGER AS DRIE DAE GEBRUIK SONDER OM U DOKTER TE RAADPLEEG NIE.
NEWE-EFFEKTE:
Die volgende kovensie is gebruik vir die indeling van ongewenste effekte: baie algemeen (≥1/10), alegmeen (≥1/100, <1/10), ongewoon (≥1/1.000, <1/100), skaars (≥1/10.000, <1/1000), baie skaars (<1/100), skaars (≥1/10.000, <1/1000), baie skaars (<1/10.000), nie bekend nie (kan nie uit beskirbare data geraam word nie).

Liggaamstelsel	Ongewenste effek	Frekwensie
Bloed- en limfstelselafwykings	Trombositopenie	Baie skaars
Immuunstelsel-afwykings	Anafilakse, kutane hipersensitiwiteitsreaksies, insluitend veluitslag, angio-edeem, Steven-Johnson-sindroom en toksiese epidermale nekrolise	Baie skaars
Asemhalings-, torakale en mediastinale afwykings	Brongospasma by pasiënte wat sensitief is vir aspirien en ander NSAID's	Baie skaars
Hepatobiliêre afwykings	Hepatiese disfunksie	Baie skaars

Pasiënte met die seldsame oorerflike toestand van sorbitol en maltilol as gevolg van fruktose-intoleransie, moet nie **CALPOL Pediatriese-suspensie** gebruik nie.
BEKENDE SIMPTOME VAN OORDOSISEN GEGEWENS VAN DIE BEHANDELING: Oordosis parasetamol kan lewerversaking veroorsaak, wat leweroorplanting kan vereis of tot die dood kan lei. Akute pankreatitis is waargeneem, gewoonlik met lewerdisfunksie en lewertoksisiteit.
Vinnige behandeling is noodsaaklik. In die geval van 'n oordosis, raadpleeg onmiddellik 'n dokter of neem die persoon direk na 'n hospitaal. 'n Vertraging in die aanvang van die behandeling kan beteken dat die teenmiddel te laat gegee word om effektief te wees. Bewyse van lewerskade word dikwels vertraag totdat die tyd vir effektiewe behandeling verstryk het. Die vatbaarheid vir parasetamoltoksisiteit word verhoog by pasiënte wat herhaaldelik hoë dosisse (meer as 5-10 g/dag) parasetamol vir 'n paar dae geneem het, by chroniese alkoholisme, chroniese lewersiekte, vigs, wanvoeding en die gebruik van medisyne wat mikrosomale leweroksidasie veroorsaak soos barbiturate, isoniazid, rifampisien, fenitoïen en karbamazepien. Simptome van 'n oordosis parasetamol in die eerste 24 uur sluit bleekheid, naarheid, braking, anoreksie en moontlik buikpyn in. Ligte simptome gedurende die eerste twee dae van akute vergiftiging weerspieël nie die moontlike erns van die oordosis nie. Lewerskade kan 12 tot 48 uur of later na inname duidelik word, aanvanklik deur verhoogde serumtransaminase en melksuurdehidrogenase-aktiwiteit, verhoogde konsentrasie van bilirubien in die serum en verlenging van die protrombintyd. Lewerskade kan lei tot enkefalopatie, koma en die dood. Akute nierversaking met akute tubulêre nekrose kan ontwikkel selfs in die afwesigheid van ernstige lewerskade. Abnormaliteite van glukosemetabolisme en metaboliese asidose kan voorkom. Hartaritmieë is aangemeld.
Behandeling van parasetamol-oordosis:
Alhoewel bewyse beperk is, word dit aanbeveel dat elke volwassene wat 5-10 g of meer parasetamol ingeneem het (of 'n kind wat meer as 140 mg/kg gehad het) binne die voorafgaande vier uur die maag moet laat leegspoel (uitbarsting kan voldoende wees vir kinders) en 'n enkele dosis van 50 g geaktiveerde houtskool toegedien via die spoelbuis. Inname van hoeveelhede parasetamol wat kleiner is as dit, kan behandeling benodig by pasiënte wat vatbaar is vir parasetamolvergiftiging (sien hierbo). By pasiënte wat stuporeus of in 'n koma is, moet endotrageale intubasie die maagspoeling voorafgaan om aspirasie te vermy.
N-asetielsisteïen moet so gou as moontlik aan alle gevalle van vermoedelike oordosis toegedien word, verkieslik binne ag uur na oordosis, hoewel behandeling tot 36 uur na inname steeds voordelig kan wees, veral as meer as 150 mg/kg parasetamol geneem is. 'n Aanvanklike dosis van 150 mg/kg N-asetielsisteïen in 200 ml dekstrose-inspuiting word **binneaars** gegee gedurende 15 minute, gevolg deur 'n infusie van 50 mg/kg in 500 ml dekstrose-inspuiting oor die volgende vier uur en dan 100 mg/kg in 1 000 ml dekstrose-inspuiting oor die volgende sestien uur.
Die volume binneaarse vloeistof moet vir kinders aangepas word.
Alhoewel die mondelinge formulering nie die gekose behandeling 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-parasetamolvlak moet vier uur na inname bepaal word in alle gevalle van vermoedelike oordosis. Vlakke wat voor vier ure gedoen is, kan misleidend wees. Pasiënte wat die risiko loop om lewerskade op te doen en dus voortgesette behandeling met N-asetielsisteïen benodig, kan geïdentifiseer word volgens hul 4-uur-plasmaparasetamolvlak. Die plasma-parasetamolvlak kan teen tyd, sedert die inname in die nomogram, hieronder geteken word. Die nomogram moet slegs in verband met 'n enkele akute inname gebruik word.



Nomogram extracted from Essential Medicines Guideline, South African Department of Health, 2015.
Diegene wie se plasmaparasetamol-vlakke bo die "normale behandelingslyn" is, moet herhaaldelik oor sestien uur voortgaan met N-asetielsisteïenbehandeling met 100 mg/kg IV, tot herstel. Pasiënte met 'n verhoogde vatbaarheid vir lewerskade, soos hierbo geïdentifiseer, moet die behandeling voortsit as die konsentrasies bo die "hoërisikobepalingslyn" is. Protrombienindeks korreleer die beste met oorlewing. Monitor vir ten minste 96 uur alle pasiënte met beduidende inname.

Nomogram Source: Daly FF, Fountain JS, Murray L, Graudins A, Buckley NA; Panel of Australian and New Zealand clinical toxicologists. Guidelines for the management of paracetamol poisoning in Australia and New Zealand -explanation and elaboration. A consensus statement from clinical toxicologists consulting to the Australasian poisons information centres. Med J Aust. 2008 Mar 3:188(5):296-301

IDENTIFIKASIE: Pienkgekleurde eenvormige suspensie met 'n aarbeireuk.
VOORSTELLING: Amber glasbottels van 50 ml en 100 ml met 'n wit sluiting wat kinderbestand is met 'n wit peutervrye buitedoppie, 'n natuurlike binnedoppie en 'n natuurlike peutervrye band.
Amber PET-bottels van 50 ml en 100 ml.
BERGINGINSTRUKSIES: Beskerm van lig.
Blootstelling aan lug sal minimaal wees.
Berg in 'n houer wat dig kan toemaak teen of onder 25 °C.
Hou buite bereik van kinders.
REGISTRASIENOMMER: A B/2.7/767
DATUM VAN PUBLIKASIE VAN HIERDIE PROFESSIONELE INLIGTING:
Datum op die registrasiesertifikaat van die medisyne: 14 April 1989
Datum van die mees onlangste hersiene pakkiebyvoegsel soos goedgekeur deur raad: 1 Augustus 2016
Bykomende lande se registrasiebesonderhede:

Land	Skeduleringstatus (of kategorie van verspreiding)	Registrasienommer
Botswana	S4	B9317485
Namibië	NS0	11/2.7/0043
Zambië	GS	025/018
Zimbabwe	HR	83/2.1/1671

ATC-kode: N02BE01 - Anilides

NAAM EN BESIGHEIDSADRES VAN VERVAARDIGER:
GlaxoSmithKline-gebruikergesondheids Suid-Afrika (Pty) Ltd, Hawkinslaan 39, Epping Industrieë1, Kaapstad, 7460
Handelsmerke is in besit van of gelisensieer aan die GSK groep van maatskappye.