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| **Submissions to the Medicines Classification Committee for the Reclassification of**  **LIQUID PARACETAMOL**  **250mg/5mL**  **100ml Bottle** |
| **Present Classification:** Pharmacy-Only Medicine  **Classification Sought:** General Sale Medicine |

**Date prepared:** 22 July 2013

**Sponsor:** New Zealand Retailers Association (on behalf of Grocery Retailers)

**Applicant:** Pharmaceutical Solutions Ltd

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| Executive Summary |

Paracetamol is a painkiller that is a popular over-the-counter (OTC) drug throughout the world because it has a well-established safety profile with few side effects and it does not irritate the stomach when used properly. It is a common item in a household’s first aid kit as an analgesic (pain reliever) and an antipyretic (fever-lowering drug).

Paracetamol, known as acetaminophen in the United States, gained FDA approval in 1951. It has been available internationally for more than 60 years, firstly as prescription medicine then as a non-prescription medicine. The safety profile of paracetamol over this period has been well documented and well defined.

Certain packs of paracetamol are currently readily available for adults in the grocery channel; however there are no preparations of Paracetamol suitable for use in children available in the grocery channel.

Liquid paracetamol for use in children has been available in New Zealand since its registration in 1991. The current classification for liquid paracetamol is a ‘Pharmacy Only’ medicine in New Zealand, therefore it is only available from pharmacies and parents may face frustrations during urgent weekend requirements where most pharmacies may not be open, especially outside the major centres.

In overseas countries such as UK, Canada and USA, liquid paracetamol is available as ‘General Sale’.

The purpose of this application is to seek reclassification of paracetamol in undivided liquid form for oral use containing not more than 5 grams of paracetamol and not more than 100 ml of product, to ‘General Sale’ medicine.

This reclassification application chose the “Pamol” brand of paracetamol as the reference product as the “Pamol” brand is the most familiar brand to consumers and is the market brand leader in children’s analgesia for liquid paracetamol. The proposed reclassification will incorporate indications and warnings consistent with that currently approved for “Pamol” in the market as a ‘Pharmacy Only’ medicine.

The product is intended for short-term (48 hours) oral administration in children from 1 year and up, for the reduction of fever and temporary relief of mild-to-moderate pain associated with headache, earache, immunisation, toothache and symptoms of cold and flu. Please note there is a caution on the pack, not to give to children under 2 years of age except on medical advice.

As liquid Pamol is supplied in child proof bottles, it will also help minimise accidental overdosing by children if they unintentionally have access to the medicine.

The intention of this reclassification is to provide the consumer (parents/caregivers) with the choice of the self selection option and the convenience of purchasing liquid paracetamol for their children for the short term relief of pain and fever in an accessible environment which is not limited in hours of availability and/or location, as it is at Pharmacy level.

It is also an option for parents/caregivers who have pre-teen children who have difficulty swallowing capsules or tablets.

Supermarkets generally open much longer hours than pharmacies6. Aside from those in malls, few pharmacies open on Sundays. Grocery stores are more prevalent in rural areas where there may be no other options for quick access to these medicines. The latest information sourced by the NZ Retailers Association still confirms that supermarkets opening hours are two times longer on average compared to pharmacies. This classification change enables ease of access to parents/caregivers for those after hour requirements.

Its safety and efficacy in relieving fever and minor-moderate pain in children and even pregnant women have been reviewed extensively in the medical and scientific literature and the safety profile of paracetamol is well established. The proposed classification for liquid paracetamol is not expected to increase the potential risk of adverse events nor the potential for abuse or misuse. By simply being responsible with its use, consumers are able to maximize the benefits while avoiding harmful adverse events.

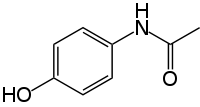
One of the potential safety risks of paracetamol is liver damage caused by excessive use or significant overdose. The packaging for “Pamol” emphasises the specific dosage requirements by age, frequency of administration, and the relevant safety warnings. It also provides consumers with access to further information and education (e.g. website and toll free information-line) thereby ensuring the avoidance of the potential risks for over-dosing.

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| Part A |

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| A.1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine |

**Name:** Paracetamol

**Chemical structure:**

**[](http://en.wikipedia.org/wiki/File:Paracetamol-skeletal.svg)**

**Molecular Formula:** [C](http://en.wikipedia.org/wiki/Carbon)8[H](http://en.wikipedia.org/wiki/Hydrogen)9[N](http://en.wikipedia.org/wiki/Nitrogen)[O](http://en.wikipedia.org/wiki/Oxygen)2

**Molecular Weight:** 151.17 g/mol

**CAS number:** 103-90-2

**USAN:** Acetaminophen (United States Adopted Name)

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| A.2. Proprietary name(s) |

This reclassification application chose Pamol as the reference product.

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| --- | --- |
| Sponsor | Product1 |
| Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics | Pamol Oral suspension, 250mg/5mL, Colour Free (Pharmacy only) |
| Pamol (Strawberry flavour) Oral suspension, 250mg/5mL, colour free (Pharmacy only) |

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| A.3. Name of company/organisation/individual requesting reclassification |

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| A.4. Dose form(s) and strength(s) for which a change is sought |

Our proposal is to reclassify paracetamol supplied in undivided liquid form for oral use from ‘Pharmacy Only’ medicine to ‘General Sale’ medicine, when containing not more than 5 grams of paracetamol and not more than 100 ml of product.

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| A.5. Pack size and other qualifications |

This reclassification request is to permit 100ml liquid paracetamol (50mg/1mL) to become a ‘General Sale’ medicine, when labelled for use in children from 1 year and up. It should be noted that it is advised not to give to children under 2 years of age except on medical advice.

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| A.6. Indications for which change is sought |

This proposal does not increase the range of indications or dosage recommendations for the use of paracetamol beyond those for existing liquid paracetamol.

No change is sought in relation to indications. The current approved indications for paracetamol products in New Zealand are:

* Relieves the pain and fever associated with headache, earache, immunisation, symptoms of cold and flu and toothache.

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| A.7. Present classification of medicine |

Paracetamol in liquid form is currently classified as a ‘Pharmacy Only’ medicine in New Zealand and the conditions are provided below:

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| Classification2 | Conditions (if any) |
| Prescription | except when specified elsewhere in this schedule |
| Pharmacy Only | **in liquid form**; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams; in slow-release forms containing 665 milligrams or less and more than 500 milligrams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack |
| General Sale | in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; in powder form in sachets containing 1 gram or less and not more than 10 grams |

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| A.8. Classification sought |

This application requests reclassification to ‘General Sale’ medicine status.

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| Classification | Conditions (if any) |
| General Sale | in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; in powder form in sachets containing 1 gram or less and not more than 10 grams; **in undivided liquid form for oral use** containing **not more than 5 grams of paracetamol and not more than 100 ml of product.** |

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| A.9. Classification status in other countries (especially Australia, UK, USA, Canada) |

Liquid paracetamol is available as General Sale in UK, Canada and USA. The conditions for General Sale in the UK are provided below. The status in Australia is similar to NZ, where is it only available in the pharmacies.

| Country | Conditions (if any) |
| --- | --- |
| UK3 | **Liquids** Adults & children 12 years and over  Max strength : 5%  Max pack : 160ml of the liquid product  Persons aged 6 years and over  Max strength: 5%  Max pack: individual unit doses of not more than 5ml, to a maximum of 12 unit doses *OR* multidose containers of not more than 80ml  Children under 12 years  Max strength : 2.4% Max pack : individual unit doses of not more than 5ml, to a maximum of 20 unit doses (100ml) *OR* multidose containers of not more than 100ml Max dose : 480mg, Max daily dose: 1920mg |
| Canada4 | Unscheduled (General Sale)  Acetaminophen in immediate release tablets, capsules, suppositories or liquid |

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| A.10. Extent of usage in New Zealand and elsewhere (e.g. sales volumes) and dates of original consent to distribute |

The Pamol brand of paracetamol in liquid form for children has been available registered in New Zealand from as early as 1994.

There are currently two 250mg/5ml liquid Pamol products suitable for use in children age 1 year and up registered and marketed in NZ and are listed below:

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsor | Product1 | Pack sizes | Approval date |
| Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics | Pamol Oral suspension, 250mg/5mL, Colour Free (Pharmacy only) | 100ml, 200ml, 500ml | 3/02/1994 |
| Pamol (Strawberry flavour) Oral suspension, 250mg/5mL, colour free (Pharmacy only) | 100ml, 200ml | 9/06/2005 |

Unit Sales in New Zealand (2012) supplied by the current sponsor Aspen:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Pamol All Ages Orange C/F 100mL | Pamol All Ages Orange C/F 200mL | Pamol All Ages Strawb C/F 100mL | Pamol All Ages Strawb C/F 200mL |  |
| **2012/Jan** | 888 | 660 | 2,472 | 1,542 | **6,666** |
| **2012/Feb** | 672 | 1,260 | 2,052 | 1,518 | **6,654** |
| **2012/Mar** | 2,940 | 3,756 | 6,120 | 10,800 | **28,560** |
| **2012/Apr** | 756 | 930 | 2,016 | 1,440 | **5,967** |
| **2012/May** | 336 | 312 | 840 | 714 | **2,778** |
| **2012/Jun** | 984 | 1,806 | 3,828 | 4,200 | **12,606** |
| **2012/Jul** | 1,332 | 1,797 | 3,672 | 4,488 | **12,753** |
| **2012/Aug** | 888 | 1,584 | 2,208 | 5,298 | **10,878** |
| **2012/Sep** | 924 | 2,400 | 3,732 | 5,184 | **13,992** |
| **2012/Oct** | 1,140 | 1,008 | 2,304 | 2,172 | **7,968** |
| **2012/Nov** | 216 | 144 | 648 | 420 | **1,596** |
| **2012/Dec** | 1,007 | 2,004 | 3,324 | 3,912 | **12,707** |
|  | **12,083** | **17,661** | **33,216** | **41,688** | **123,125** |

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| A.11. Labelling or draft labelling for the proposed new presentation(s) |

The proposed liquid products will be labelled with the same directions for use, indications and warning statements as the Pamol for Children oral suspension currently marketed in New Zealand, only the ‘Pharmacy medicine’ statement to be removed.

There is no requirement for different dosing instructions or indications for ‘General Sale’ medicine. It is important to ensure consistency of information across the Pamol range so that parents accustomed to using the product are not confused with conflicting information on packs bought in differing outlets.

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| A.12. Proposed warning statements if applicable |

The proposed liquid product will be labelled with the same warning statement as the oral suspension currently marketed in New Zealand. Pamol as an example:

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| HOW TO USE PAMOL:   * DO not use if the cap seal is broken or missing. * **Shake the bottle before use.** * Carefully measure the correct dosage as shown in the dosage chart. * Administer in water or fruit juice if necessary. * After use, tighten the cap to engage the child resistant closure.   CAUTION:   * **Dose should be given every 4 to 6 hours as required with not more than 4 doses in 24 hours.** * **Do not give to children under 2 years of age except on medical advice.** * **Prolonged use can be harmful. Do not use for more than 48 hours without seeking medical advice.**     Store below 25oC but do not refrigerate. Protect from light |

The above label warnings meet the labelling requirements stated in the Medsafe label statement database for paracetamol liquid5.

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| A.13. Other products containing the same active ingredient(s) and which would be affected by the proposed change |

There are currently 6 other liquid preparations containing Paracetamol 250mg/5ml or less packed in 100ml bottle suitable for use in children registered in NZ and are listed below:

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsor | Product1 | Pack sizes | Approval date |
| Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics | Pamol Oral suspension, 250mg/5mL, Colour Free (Pharmacy only) | 100ml, 200ml, 500ml | 3/02/1994 |
| Pamol (Strawberry flavour) Oral suspension, 250mg/5mL, colour free (Pharmacy only) | 100ml, 200ml | 9/06/2005 |
| GlaxoSmithKline (NZ) Ltd | Panadol Children 3 months - 12 years Oral suspension, 120mg/5mL, Strawberry (Pharmacy only) | 100ml, 200ml | 20/07/1993 |
| PSM Healthcare Ltd trading as API Consumer Brands | Paracare For Children 6+ years & Adults Oral suspension, 250mg/5mL, Double Strength (Pharmacy only) | 100ml, 200ml | 17/10/1991 |
| Multichem NZ Limited | Paracetamol 250mg/5 mL Oral suspension, 250mg/5mL, Ethics (Pharmacy only) | 100ml, 200ml, 500ml | 15/07/2010 |
| AFT Pharmaceuticals Ltd | Six Plus Parapaed Oral suspension, 250mg/5mL (Pharmacy only) | 100ml, 200ml, 500ml, 1l | 29/05/2003 |

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| Part B |

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| B.1. A statement of the benefits to both the consumer and to the public expected from the proposed change |

Paracetamol was first marketed in the United States in 1953 and has been available internationally for about 60 years, firstly as prescription medicine then as a non-prescription medicine. Currently liquid paracetamol is only available for self-selection by patients from a pharmacy. The Pamol product range has been available at this level of classification for several years.

Paracetamol is classed as an analgesic/antipyretic which is commonly used to relieve pain and fever. Paracetamol in tablet and capsule form are readily available for adults in the grocery channel; however there is no liquid paracetamol available for children.

Pharmacy operating hours are generally short compared to operating hours of supermarkets. This can limit the access of patients to required medication. The reclassification of liquid paracetamol (250mg/5mL) bottle to a General Sale Medicine will allow parents/caregivers easier and more convenient access to an effective and safe short term therapy. A study in New Zealand by the NZ Retailers Association concluded that supermarkets were open for 101.5 hours per week on average and pharmacies were open 55.1 hours per week on average in the same areas examined6. Latest survey by the NZ Retailers Association still confirms that supermarkets opening hours are two times longer on average compared to pharmacies. This reclassification enables access to parents with after hour requirements. The dosage chart on the pack with age guidelines provides a very clear instruction and is easy for parents to understand and follow.

Contact details are available on the pack if consumers wish to seek medical advice and any further information. There are sufficient warnings to alert parents and caregivers when not to use paracetamol for their children and also when to seek medical attention. It is clearly stated on the pack that the medication is not to be used for more than 48 hours without seeking medical advice and dose should be given every 4 to 6 hours as required with not more than 4 doses in 24 hours.

This change also means that consumers in New Zealand will have the same access to liquid paracetamol as consumers in the United States, United Kingdom and Canada.

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| B.2. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated |

The indications for use and dose form proposed in this reclassification application for liquid paracetamol are essentially identical to those for Pamol for Children currently available as ‘Pharmacy Medicine’.

Pamol oral suspension, containing 250mg/5mL of paracetamol is indicated for relief of pain and fever associated with headache, earache, immunisation, symptoms of cold and flu and toothache. A pharmacist or physician does not normally identify the need for symptomatic relief in the proposed indications; all of these pain symptoms are well characterised, usually of limited duration, and easily identified by a consumer who currently self-select and self-medicate with non-prescription analgesics.

The labelling directs consumers to seek medical advice and consult doctor for children under 2 years of age and for all other children not to use for more than 48 hours without seeking medical advice. We believe that consumers recognize that prolonged pain is a sign of something more serious and therefore able to adequately evaluate this and seek appropriate medical treatment.

The proposed pack sizes of 100ml provide for a maximum of 10 days treatment for 1 - 5 years old children however the labelling clearly states that the product is for short term use only for up to 48 hours and with a maximum of 4 doses in 24 hours.

The easily recognisable and short-term nature of the indications for use ensures that neither medical diagnosis nor on-going medical management are required.

All required warnings and cautionary statements for paracetamol are included on the package. Additional statements on the correct dosage and dosing frequency for children are highlighted on the package to increase the parents/caregivers awareness on the importance of correct paracetamol dosing. A dosing guide is also clearly available on the package to help parents/caregivers to determine the appropriate dose for their child.

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| B.3. Relevant comparative data for like compounds |

Paracetamol versus Aspirin

Paracetamol has a very similar structure to aspirin. Aspirin is one of a class of drugs called non-steroidal anti-inflammatory drugs (NSAIDS) that has antipyretic (fever reducing)*,* anti-inflammatory and analgesic (pain relieving)effects. When taken, aspirin is metabolized, and absorbed into the bloodstream, through the lining of the stomach. Aspirin is often thought to be somewhat “stronger” than paracetamol, but the antipyretic activity and the analgesic effect are the same for most indications.12, 13, 14

However, aspirin is not recommended for use in children, and shouldn’t be used in some patients with bleeding disorders because of its adverse events; it can cause upset stomach, indigestion and heartburn.

Even coated or buffered aspirin can irritate the lining of the stomach. Its use by children who have fevers, especially those associated with flu or chicken pox has been associated with the development of Reye's syndrome, a dangerous, sometimes fatal condition10.

Paracetamol, on the other hand, is a medicine that works much like aspirin which has been proven more effective than aspirin in headache8, sore throats and fever9. It also lowers fevers and helps with mild pain, like aspirin, but it does not treat the inflammation that can occur with muscle sprains or arthritis. However, paracetamol is relatively less irritating to the stomach and safer for children and people with bleeding disorders.

Additionally, there are currently no liquid preparations of aspirin available in the market to allow for accurate dosing or palatable dosage form for children.

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| B.4. Local data or special considerations relating to New Zealand |

Over the past 60 years, paracetamol has gradually moved from prescription medicine to lower levels of classification, including ‘Pharmacy Only’ and ‘General Sales’ status. This reclassification is not to increase the maximum daily dose or packaging size but to launch liquid paracetamol for children from ‘Pharmacy Only’ to ‘General Sales’ category.

Therefore, it is not expected there would be any special considerations relating to New Zealand for this reclassification when warning statements and instruction for use is clear and easy to be followed.

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| B.5. Interactions with other medicines |

**When two or more medicines are taken at the same time, the effects of one of the medicines can be changed by the other.**

Paracetamol undergoes metabolism in the liver, therefore, drugs that enhance the action of liver enzymes that break down paracetamol can lower the therapeutic effects of paracetamol. This can in turn reduce the therapeutic effects of paracetamol Drugs known to enhance the action of liver enzymes include carbamazepine and rifampicin. This potential toxic effect of this drug in the liver is heightened when combined with alcohol.

Paracetamol may also interact with many drugs including other type of pain killers that relieves pain and drugs for indigestion such as **domperidone**and **metoclopramide.**

The intestinal absorption of paracetamol is reduced by cholestyramine. This can lower the effects of paracetamol29. To avoid this, paracetamol must be given 3 to 4 hours after cholestyramine or an hour prior to cholestyramine administration.

As the probability of a child being prescribed with the above mentioned medicines thought to interfere with paracetamol absorption is very low, it is unlikely for drug interaction to occur in this patient group; the main target group for this reclassification application.

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| B.6. Contraindications |

Paracetamol is contraindicated in individuals with known hypersensitivity to paracetamol or other pain relievers, renal and hepatic impairment. The product is also contraindicated in individuals who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angiodema or urticaria) in response to aspirin or other NSAIDs.

Most drugs are not safe to be taken during pregnancy. But women in all stages of pregnancy can take paracetamol safely. In fact, it is the treatment of choice for short-term fever and minor aches and pains during pregnancy.

The current label indicates the following contraindications/cautions:

CAUTION:

* Dose should be given every 4 to 6 hours as required with not more than 4 doses in 24 hours.
* Do not give to children under 2 years of age except on medical advice.
* Prolonged use can be harmful. Do not use for more than 48 hours without seeking medical advice.

These statements will remain on the label.

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| B.7. Possible resistance |

It is not expected that short term use (maximum of 48 hours) of paracetamol with correct dosing will cause any resistance to develop.

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| B.8. Adverse events - nature, frequency etc |

When used in the recommended therapeutic doses appropriately, paracetamol is usually well tolerated and the adverse effects of paracetamol are rare30. However, large doses, chronic use, and alcohol abuse can lead to serious adverse effect such as liver damage. Chronic alcohol intake may further increase the risk of bleeding in the stomach. Hypersensitivity reactions including skin and other allergic reactions may occur occasionally and haematological reactions have also been reported15.

The toxicity of paracetamol is closely linked to its metabolism. Paracetamol intoxication typically includes 4 phases11. Clinical features listed by the Committee on Drugs (2001)11;

* 1st phase: anorexia, nausea, vomiting, malaise, and diaphoresis.
* 2nd phase: those first-phase signs resolve and are replaced by right upper quadrant pain or tenderness, liver enlargement, and oliguria in some patients. Bilirubin and hepatic enzyme levels become elevated, and the prothrombin time becomes prolonged.
* 3rd phase: usually 3 to 5 days into the course, anorexia, nausea, vomiting, and malaise reappear, along with signs of hepatic failure, including jaundice, hypoglycemia, coagulopathy, and encephalopathy. Renal failure and cardiomyopathy may also develop.
* 4th phase: associated with recovery or progression to death from complete liver failure.

Below is the number of NZ cases for the both adults and children reported to the Joint Adverse Event Notification System (JAEN) for the period from 01 January 2000 to 01 March 2013. JEANS contains information from reports of adverse events that the Therapeutic Goods Administration (TGA) and Centre for Adverse Reactions Monitoring (CARM) have received in relation to medicines used in Australia and New Zealand7. Please note these reported adverse events do not state the age of the patient.

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| Number of reports/cases (NZ)  Multiple adverse events have been reported for some patients | 350 |
| Number of cases with a single suspected medicine – paracetamol (NZ)  (The TGA or CARM think there is a possibility that the medicine caused the adverse event) | 307 |

Diagnosis and early signs of poisoning

The diagnosis of paracetamol poisoning is usually identified easily and most consumers self-medicate with non-prescription paracetamol. The early features of paracetamol poisoning include nausea and vomiting18. Hepatic tenderness may appear after about 12 hours and may persist for 18 – 72 hours19.

Renal Failure

Less frequently, in approximately 3% of all patients, paracetamol toxicity may cause renal failure, sometimes preceded by back pain and renal tenderness19, 20.

While renal failure occurs in patients usually with severe hepatic necrosis, this is not always the case. In 324 patients with paracetamol toxicity indicated by a high plasma paracetamol level, 33 (10.2%) developed renal failure, 18 (5.5%) were without hepatic failure and 3 (1%) were without any abnormality of liver function or prothrombin time21.

Although there is evidence that renal damage in paracetamol poisoning is due to metabolic activation of paracetamol by renal P450 mixed-function oxidases, the reason some patients develop renal failure in the absence of hepatic damage is unclear18. Renal failure is a common complication of fulminant hepatic failure (FHF) from any cause, but is reported to be no more frequent in patients when the liver damage is paracetamol induced22.

In a study of 662 patients with acute liver failure, 275 were cases of severe paracetamol-induced hepatotoxicity. 131 (48%) of these 275 cases were the result of an unintentional overdose and 19 (7%) of the 275 patients had not exceeded the maximum daily dose of 4g23.

Other Features

There are number of adverse events caused after overdose. However, for short term emergency use with appropriate dose, the risk is extremely low.

Acute abdominal pain, pancreatitis and paralytic ileus have been rarely reported in paracetamol poisoning, usually after an interval of 1-5 days18.

Hypoglycaemia may occur between 12 and 72 hr after overdose, due to impairment of hepatic gluconeogenesis24, 25.

Hypophosphataemia may occur as a complication of FHF, but is also common in the early stages of paracetamol poisoning26.

Adverse gastrointestinal or renal events from short term use of paracetamol appear to be quite rare in children28.

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| B.9. Potential for abuse or misuse |

Paracetamol has been readily available in many countries for several years as an OTC product.

The proposed reclassification of liquid form of paracetamol for children to a ‘General Sale’ medicine is not expected to increase the potential for abuse or misuse as this is for short-term emergency treatment only.

The pack size is limited to 100ml in the manufacturer’s original packaging will also ensure product is for short term emergency treatment only. It is clearly stated on the pack that the medication is not to be used for more than 48 hours without seeking medical advice and not to give to children under 2 years of age except on medical advice, therefore reinforces informed use by parents/caregivers.

The key to further minimizing potential risks to the consumer is to continue to find better ways to educate (detailed information can be provided on website – [www.pamol.co.nz](http://www.pamol.co.nz)), encourage consumers to read, comprehend and comply with current label warnings and directions for use.

Overdose

Deliberate or accidental overdose with paracetamol dose affect a significant medical problem because of the resultant hepatotoxicity. The risk associated with overdose of paracetamol is the most significant issue that must be addressed. However, this proposed reclassification of liquid paracetamol for children to a ‘General Sale’ medicine is not expected to change instructions or indications but to use for short-term emergency treatment only. Dosage chart is provided with warning statements. As noted above, patients are likely to seek medical advice as directed on the product label and there is no reason to believe that the availability of liquid paracetamol as a ‘General Sale’ product will increase the frequency of overdose with paracetamol. The change is simply a more accessible and convenient way for consumers to source a readily available product in a new environment.

The product is also packed in child-resistant packaging which can prevent accidental overdosing by a child whom may unintentionally have physical access to the medicine.

Suicide Attempts

Because paracetamol is a potent drug that is available without prescription, it is often used in suicide attempts, and in this respect it is potentially more dangerous than other OTC drugs such as aspirin. This is because paracetamol overdoses often cause liver failure. However, this liquid paracetamol for children will be prepared for dosing by parents/caregivers’, therefore, the potential for harm from inappropriate use is extremely low.

Prolonged Use

Parents are unlikely to use the drug for prolonged periods of time for their children without medical advice. The distinctive package labelling and size of the packaging should also assist in reducing this risk.

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