PICCAN®
TEETHING REMEDY

COMBINED PATIENT AND MEDICAL PROFESSION INFORMATION LEAFLET

Please read this information leaflet carefully before you start to use this product. For further information on how to use this product please ask your doctor or pharmacist.

PRESENTATION

5ml of Piccan® Teething Remedy contains the following ingredients:
Paracetamol 120mg
Diphenhydramine Hydrochloride 12.5mg
Also contains Macrogol, Glycerol, Propylene Glycol, Sorbitol, Maltitol, Nipasept, Caramel Flavour, Annatto Extract, Purified Water.

Piccan® Teething Remedy is a caramel flavoured oral solution, packed in 100ml amber glass bottles with tamper evident cap. If seal is broken on the bottle, return immediately and request a replacement.

INDICATIONS

Piccan® Teething Remedy is used to treat mild to moderate pain like teething pain, headache, sore throat, aches and pains. Piccan® Teething Remedy contains Paracetamol which is an 'analgesic' or 'pain relieving' medicine. It is used to relieve pain and reduce high temperatures as in colds and influenza. Piccan® Teething Remedy also contains Diphenhydramine Hydrochloride which is a sedating antihistamine, which helps reduce sickness and allergic reactions.
Prolonged use without medical supervision can be dangerous. If symptoms persist for more than 3 days consult your doctor. Routine use not recommended. The product should be administered with caution to children with known liver or kidney problems.

CONTRAINDICATIONS

Do not use if your child is allergic to Paracetamol or Diphenhydramine or any of the ingredients.

DOSAGE AND ADMINISTRATION

The following doses of Piccan® Teething Remedy are to be taken orally.

3 months - 1 year:	2.5ml - 5ml 3 to 4 times daily
1 - 5 years:	5ml - 10ml 3 to 4 times daily
6 years and over:	10 - 20ml 3 times daily
Under 3 months:	Not to be used unless on doctor's advice

WARNING/PRECAUTIONS

1. **Contains PARACETAMOL.** Do not give with any other paracetamol containing products.
2. Do not exceed the recommended dose.
3. Do not repeat the dose more frequently than every four hours.
4. Do not take more that 4 doses in a 24 hour period.
5. Do not give to children who are sensitive to any of the ingredients listed at the beginning of this leaflet.
6. Talk to your doctor or pharmacist before using this product if your child has kidney or liver problems.
7. Talk to your doctor before using this product if the child is taking other medicines including those for epilepsy or fits.
8. Talk to your doctor if your child is taking any medicines to thin the blood, control nausea and vomiting, or to reduce blood lipids.
9. Prolonged use of this product, except under medical supervision, can be harmful.
10. The medicine contains 1.06g of Sorbitol in each 5ml spoonful. Therefore each dose supplies up to 4.3g of Sorbitol. Unsuitable for children with hereditary fructose intolerance. Can cause stomach upset and diarrhoea.
11. The effects of alcohol and other sedatives may be increased whilst taking this medicine.
12. Some drugs may affect the absorption of Paracetamol these include colestyramine (to treat blood cholesterol), and metoclopramide and domperidone (to treat nausea/feeling sick and vomiting/being sick); the effect of warfarin and other drugs which thin the blood may be increased by Paracetamol.
    Diphenhydramine causes a reduction in the absorption rate of certain benzodiazepines such as temazepam.
    Diphenhydramine Hydrochloride will have an additive antimuscarinic action with other antimuscarinic drugs such as atropine and some antidepressants.

PREGNANCY AND LACTATION

The product is licensed for use in infants and children. Safety in pregnancy or lactating mothers has not been established.

EFFECTS ON ABILITY TO DRIVE/OPERATE MACHINERY

Piccan® Teething Remedy may cause drowsiness. If affected, children are advised not to ride bicycles.

POSSIBLE ADVERSE DRUG REACTIONS

These are infrequent and usually mild including skin rashes and other hypersensitivity reactions. Haematological reactions have been reported including thrombocytopenia, leucopenia, pancytopenia, neutropenia, and agranulocytosis however these were not necessarily causally related to paracetamol. Additional to the above, diphenhydramine can cause CNS depression, sleep, drowsiness & incoordination (common). Headache, dry mouth, production of phlegm, blurred vision, constipation, heartburn, cardiac arrhythmia, photosensitivity. Other side effects that have been reported include convulsions, sweating, myalgia, paraethesias, extrapyramidal effects, tremor, sleep disturbances, depression, tinnitus, hypotension and hairloss.

OVERDOSE

Immediate medical advice should be sought in the event of an overdose even if the child seems well because of the risk of delayed serious liver damage. Overdose is likely in adults who have taken as little as 10-16g of paracetamol (4-6 bottles) or equivalent. Prompt treatment is essential, and involves gastric lavage, followed by oral or intra-venous administration of acetylcysteine or alternatively oral methionine. If activated charcoal has been given to absorb paracetamol, this should be eliminated from the stomach prior to using oral acetylcysteine or oral methionine in order to prevent absorption of the antidote.

PHARMACOLOGICAL PROPERTIES

Paracetamol can be given by mouth to treat mild to moderate pain and for fever. It is often the antipyretic or analgesic of choice, particularly in patients whom salicylates or other NSAIDs are contraindicated, e.g. Asthma. Diphenhydramine is an antihistamine that acts to reduce inflammation and irritation associated with teething pains, it also has anti-emetic properties, which reduce sickness, and a pronounced and relatively short acting sedative effect.

PHARMACOLOGICAL PROPERTIES

Peak plasma concentration of paracetamol occurs 10-16 minutes after oral administration. Paracetamol is distributed into most bodily tissues, and elimination half-life varies from 1 to 3 hours.

Paracetamol is metabolised mainly in the liver, and excreted in the urine as glucuronide and sulphate conjugates. Peak plasma concentration of diphenhydramine occurs 1-4 hours after oral administration. It is well absorbed through the gastrointestinal tract although high first-pass metabolism may affect systemic availability. Metabolism is extensive, with metabolites excreted in the urine. Both actives are known to cross the placenta and are excreted in breast milk.

PHARMACEUTICAL PARTICULARS

Storage: Protect from light. Do not refrigerate. Keep below 25°C

THIS IS A MEDICAMENT

- A medicament is a product which affects your health.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor or pharmacist.

Keep medicament out of reach of children

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Kensington International Marketing Company Ltd.

KIMCO

Manufactured under licence for Kensington International Marketing Co. Ltd., Wimborne, Dorset, UK by Ricesteele Manufacturing Ltd., Belgard Road, Dublin, Ireland.

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