PICCAN PARACETAMOL & DIPHENHYDRAMINE SYRUPSmPC

1. Name of themedicinal product

PiccanParacetamol&Diphenhydramine Syrup

2. Qualitativeandquantitativecomposition

Paracetamol120mg+Diphenhydramine12.5mg

Sr. No	Ingredients	Spec	Qty Per 5ml	Function
1.	Diphenhydramine	BP	6.25mg	API
2.	Paracetamol BP	BP	60mg	API
3.	Propylene glycol	BP	300mg	Solvent
4.	Methyl Hydroxybenzoate	BP	3.75mg	Preservative
5.	Propyl Hydroxybenzoate	BP	0.95mg	Preservative
6.	Glycerol	BP	450mg	Solvent
7.	PEG 4000	BP	175mg	Surfactant /Solvent
8.	Liquid Sorbitol	BP	750mg	Sweetner /Solvent
9.	Liquid Maltitol	BP	125mg	Sweetner
10.	Annato extract	BP	0.004mg	Colourant
11.	Givadan caramel flavor (Liquid)	BP	7.5mg	Flavour
12.	Purified Water	BP	5ML	Diluent

3. Pharmaceuticalform

OralSuspension

A clear, pale brownish syrupy liquid.

4. Clinicalparticulars

4.1 Therapeuticindications

Piccan® Paracetamol & diphenhydramine is used to relieve symptoms associated with teething such asheadache, sore throat, sore gums, aches and pains. Piccan® Paracetamol & diphenhydramine containsParacetamol which is an "analgesic' or 'pain relieving" medicine. It is used to relieve pain and reducehigh temperatures as in colds and influenza. Piccan® Paracetamol & diphenhydramine also containsDiphenhydramine Hydrochloride which is a sedating antihistamine, which helps reduce sickness andallergic reactions. Prolonged use without medical supervision can be dangerous. If symptoms persist formore than 3 days consult your doctor. Routine use not recommended. The product should beadministeredwith cautiontochildrenwithknown liver orkidney problems.

4.2 Posologyandmethodofadministration

Age	**HowMuch**	**HowOften(in24hours)**
3–12months	2.5ml – 5ml	3or 4 times
1year–5years	5ml – 10ml	3or 4 times
6yearsplus	10ml – 20ml	3times

Maximum

of3dosesper24hours.Donotexceed
the stateddose.
Carefullyadministerthecorrectvolumetothe
childusingthemeasuringdeviceprovidedinordertominimisetheriskofoverdose.
Parentsshouldconsultapharmacistorotherhealthcareprofessionalbeforeuseinchildrenunderбyearsof age.
Forshort-termuseonly.Notrecommendedforroutine use(Seesections4.4/4.1).
PiccanParacetamol&Diphenhydramineshouldbeadministeredwithcautiontopatients
withknownliverorrenalimpairment.(seesection4.4).

4.3 Contraindications

1. Largedosesofantihistaminesmayprecipitatefitsinepileptics.
2. Patientswithrarehereditaryproblemsoffructose intoleranceshouldnottakethismedicine.
3. This medicine should not be used in children with hypersensitivity to the active substance(s) or to anyof theexcipients.
4. This medicine should not be used in children who are taking monoamine oxidase inhibitors (MAOIs)orwithin14 days ofstoppingtreatment(Seesection4.5).
5. Thismedicine shouldnotbe usedinporphyricpatients.

4.4 Specialwarningsandprecautionsforuse

1. Donotexceedthestateddose.
2. Forshort-termuseonly(Seesection4.2).
3. Notrecommendedforroutineuse(seeSection4.1/4.2)
4. Parents or carers should seek medical attention if the child's condition fails to improve or deterioratesatanystage duringtreatment
5. Maycause drowsiness.Childrenreceivingthismedicationshouldbekeptundersupervision.
6. ContainsParacetamol.Donottake anyotherParacetamolcontainingproducts.
7. Immediatemedicaladvice shouldbesoughtintheeventofoverdosage becauseofthe riskofirreversibleliver damage.
8. Notmore than3dosesshouldbegiveninany24hours. (See section4.2)
9. Parents or carers should ensure that no other antihistamine/diphenhydramine containing productsareusedconcomitantly.
10. Parents should consult a pharmacist or other healthcare professional before use in children under 6yearsof age.
11. Keepoutofsightandreachof children.
12. Piccan Paracetamol & Diphenhydramine should be administered with caution to patients withknownliverorrenal impairment(seesection4.2).

4.5 Interactionwithother medicinal productsandotherformsofinteractions

Theanticoagulanteffectofwarfarinandothercoumarinsmaybeenhancedbyprolongedregularuseofparacetamol with increasedriskofbleeding;occasionaldoseshavenosignificanteffect.

Therateof absorptionofparacetamolmaybeincreasedbymetoclopramideordomperidoneandabsorptionreducedby cholestyramine.

Chronicalcoholintakecanincreasethehepatotoxicityofparacetamol overdose.Acutealcoholintakemaydiminishan individual'sabilitytometaboliselargedosesof paracetamol,theplasmahalf-lifeof whichcanbeprolonged.

Theuseof drugsthatinducehepaticmicrosomalenzymes,suchasanticonvulsantsandoralcontraceptives,mayincreasethe extentofmetabolismof paracetamol,resultinginreducedplasmaconcentrations of thedrugandafastereliminationrate.

Diphenhydraminehydrochloridemayenhancethesedativeeffectsof CNSdepressantsincludingbarbiturates,hypnotics,opioid analgesics,anxiolyticsedatives,antipsychoticsandalcohol.Itmayalsohaveanadditiveantimuscarinicactionwithotherd rugs such as atropine and some antidepressants. Diphenhydramine hydrochloride should not be used in patientstakingmonoamine oxidaseinhibitors(MAOIs)orwithin14daysofstoppingtreatmentasthereisariskofserotoninsyndrome.

4.6 Fertility,pregnancyandlactation

Pregnancy

Thisproductshouldnotbeusedduringpregnancyunlessthepotential benefitoftreatmenttothemotheroutweighs any Possiblerisktothedevelopingfoetus.

Based on animal studies diphenhydramine is not expected to increase the risk of congenital anomalies (seesection5.3).

However, there are no adequate and well-controlled studies in pregnant women. Use of sedatingantihistaminesduringthe thirdtrimestermayresultinadversereactionsinprematureinfantsandneonates.Diphenhydramineshouldnotbe takenduringthethirdtrimester.

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity.Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusiveresults. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowesteffectivedosefortheshortestpossibletimeandat thelowestpossiblefrequency

Lactation

This product should not be used during breastfeeding unless the potential benefit of treatment to the motheroutweighs anypossiblerisk tothe nursinginfant.

Paracetamolisexcretedinbreastmilkbutnotinaclinicallysignificantamount.Todate,n oundesirableeffects onbreast-fedinfantshavebeenreported.

Diphenhydramine has been detected in breast milk, but levels have not been reported and the effects areunknown.However,becauseof thepotentialriskof antihistaminestonursinginfants,diphenhydramineisnotrecommended for use in nursing mothers. New-born or premature infants show increased sensitivity toantihistamines.

Fertility

Thereisnoinformationontheeffectof PiccanParacetamol&DiphenhydramineOralSolutiononfertility

4.7 Effectsonabilitytodriveandusemachines

Maycausedrowsiness.If affecteddonotdriveoroperatemachinery.

4.8 Undesirableeffects

Adverseeffectsof paracetamolarerarebuthypersensitivityincludingskinrashmayoccur.Therehavebeenreports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarilycausalityrelated toparacetamol**.**

Veryrarecases ofseriousskinreactions havebeenreported.

Cases of acute pancreatitis have been reported. Paracetamol has been widely used and reports of adversereactions arerare,andaregenerallyassociated withoverdosage.

Allergicreactionsoccuroccasionally.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol forabout a year and liver damage has been reported after daily ingestion of excessive amounts for shorterperiods. A review of a group of patients with chronic active hepatitis failed to reveal differences in theabnormalities of liver function in those who were long-term users of paracetamol nor was the control of thediseaseimprovedafterparacetamolwithdrawal.

Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; theseare not accompanied with liver failure and usually resolve with continued therapy or discontinuation ofparacetamol.

Nephrotoxiceffectsareuncommonandhavenotbeenreportedinassociationwiththerapeuticdoses,exceptafterprolo ngedadministration.

Diphenhydramine Side

EffectsCommonside-effects:

CNSeffects:Drowsiness(usuallydiminisheswithinafewdays),paradoxicalstimulation,headache,psychomotor impairment.

Antimuscarinic effects: Urinary retention, dry mouth, blurred vision, gastrointestinal disturbances,thickenedrespiratorytractsecretions.

Rare side-effects: Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleepdisturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disordersandliver dysfunction.

Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation ofthe medicinal product is important. It allows continued monitoring of the benefit/risk balance of themedicinal product. Healthcare professionals are asked to report any suspected adverse reactions viaNAFDACPHARMACOVIGILANCE

4.9 Overdose

Liverdamageispossibleinadults whohavetaken10gormoreofparacetamol.Ingestionof5gormoreofparacetamolmayleadtoliverdamage ifthepatienthas riskfactors (seebelow).

Riskfactors

Ifthe patient

a) Isonlongtermtreatment wihcarbamazepine,phenobarbital,phenytoin,primidone,rifampicin,StJohn'sWortorotherdrugsthat induceliverenzymes.

Or

b) Regularlyconsumesethanolinexcessof recommendedamounts

Or

c) Islikelytobeglutathionedepletede.g.eatingdisorders,cysticfibrosis,HIVinfection,starvation,cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia andabdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucosemetabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress toencephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acutetubularnecrosis,stronglysuggestedbyloinpain,haematuriaandproteinuriamaydevelopevenintheabsenceofs evereliverdamage.Cardiacarrhythmiasandpancreatitis havebeenreported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significantearly symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptomsmaybelimitedtonauseaor vomitingandmaynotreflectthesevirityofoverdoseortheriskoforgandamage.Managementshouldbeinaccordance withestablishedtreatmentguidelines,seeBNFoverdosesection.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasmaparacetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations areunreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol,however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of theantidote declines sharply after this time. If required, the patient should be given intravenous N-acetylcysteine inline with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitablealternative for remote areas, outside hospital. Management of patients who present with serious hepaticdysfunctionbeyond 24hfrom ingestionshouldbe discussedwiththeNPIS oraliverunit.

Mild cases of overdose with antihistamines are mainly characterised by prominent anticholinergic effectsincluding dry mouth, headache, nausea, tachycardia and urinary retention. Larger overdoses will haveadditional antihistamine effects which may depress or stimulate the CNS. In small children, the stimulatoryeffects predominate and clinical features include hallucinations, ataxia and convulsions. The child may be hot,flushed and have dilated pupils. Cardiorespiratory depression and coma can subsequently develop followed byrapid death. Overdosing diphenhydramine in adults usually results in drowsiness followed by convulsions andcoma. Fever and flushing are uncommon. Overdosed patients are best treated by gastric lavage andsupportive measures. Administration of activated charcoal may be useful. Convulsions can be controlled withdiazepam.Peripheral anticholinergiceffectscanbecontrolledwithsubcutaneous neostigmine.

5. Pharmacologicalproperties

5.1 Pharmacodynamicproperties

Paracetamol is an antipyretic and analgesic. Diphenhydramine HCl is an antihistamine withanticholinergic,anti-emetic, anti-allergic andsedativeeffects.

5.2 Pharmacokineticproperties

Paracetamol and Diphenhydramine HCl are both readily absorbed from the gastro-intestinal tract. Bothare widely distributed throughout the body. Both are metabolized in the liver and excreted in the urine.As Piccan Paracetamol & Diphenhydramine is a solution, absorption of the actives is rapid following oralingestion.

5.3 Preclinicalsafetydata

Conventionalstudies usingthecurrentlyacceptedstandardsfortheevaluationof toxicitytoreproductionanddevelopmentarenotavailable.

6. Pharmaceuticalparticulars

6.1 Listof excipients

PropyleneGlycol

MethylHydroxybenzoate

Propyl

HydroxybenzoateGlycero

l

Peg(4000)

Liquid

SorbitolLiquid

MaltitolAnnattoE

xtracts

GivandanCaramelFlavour(Liquid)

6.2 Incompatibilities

Nonestated

6.3 Shelflife

36months

6.4 Specialprecautionsforstorage

Storebelow30°C.Protectfromlight.Storeintheoriginalpackage.

6.5 Natureandcontentsofcontainer

Bottles:Clo	Amber(TypeIII) Petbottle
sure:Packs	HDPE,childresistant,tamperevident10
izes:	0ml
Dosingdevice:	2.5/5/10mlmeasuringdevice.

6.6 Specialprecautionsfordisposalandother handling

Anyunusedmedicinalproductorwastematerialshouldbedisposedof inaccordancewithlocal requirements.

7. MarketingAuthorization Holder

Name and Address of Manufacturer

MAY & BAKER NIGERIA PLC

1, May & Baker Avenue

Off Idiroko Road Ota

Ogun State

Name and Address of Applicant

Kensington International Marketing Company Nig. Ltd.,

9/11 Olatunde Onasanya Street

Ajuwon, Ifakoljaiye,

Lagos State.

8. Marketing Authorization Number(s)N/A

9. Dateofrevisionofthe text

8th February2024