
GLACIN
A brand of Paracetamol
500mg Tablets BP
For Pain Relief
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500mg Tablets BP
For Pain Relief
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
DO NOT EXCEED THE STATED DOSE
Paracetamol 500mg. tablets BP for fast relief from Headache, Toothache, Muscular Aches, pains, Cold symptoms and feverish conditions
Dosage: Unless otherwise directed by a Doctor
Adults: Two tablets 3 or 4 times daily but no more than 8 tablets in any 24hours
Children: 6-12 years, half to one tablet 3 or 4 times daily but not more than 4 tablets in any 24hours
GLACIN
A brand of Paracetamol
500mg Tablets BP
For Pain Relief
CLARION MEDICALS LTD
23A Afolabi Lesi Street, Ilupeju, Lagos Nigeria
96 Tablets
Storage: Store below 30°C
Formulated by: CLARION MEDICALS LIMITED
Manufactured By
MAY & BAKER (NIG) PLZ
No 1, May & Baker Avenue
Off Idiroko Road, Ota
Ogun State Nigeria
For
CLARION MEDICALS LTD
23 Afolabi Lesi Street
Ilupeju, Lagos
Nigeria
NAFDAC Reg No 04-8941
Batch No : AC22033
Mfg: Date : 06/2022
Exp: Date : 05/2027

Summary of ProductCharacteristics

1 NAMEOFTHEMEDICINALPRODUCT

Paracetamol 500mg tablets

2 QUALITATIVEANDQUANTITATIVECOMPOSITION

Each tablet contains 500mg paracetamol.
Excipient(s) with known effect: each tablet contains 25kg maize starch. For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Round,flat tablets,with a facet and a scoreline on the one side,with a 13mm diameter and 4mm thickness.Colour–white to almost white.

The tablet can be divided into equal doses.

4 CLINICALPARTICULARS

Therapeuticindications

Paracetamol is recommended for the short-termtreatmentofthemildtomoderatepainsuchasheadache,toothache, musculoskeletal disorders and menstrual pain and for fever associated with cold and flu.

Paracetamolisindicatedinadultsandadolescentsaged12orolder.

Posologyandmethodofadministration

Posology
The lowest effective dose should be used for the shortest time possible. The maximum daily dose must not be exceeded(3000 mg).

Dose depends on age and body weight, generally10to15mg/kgbody weightasasingledose,uptoamaximumof60mg/kg body weight as the total daily dose.

For dosing according to the body weight and age see the table.

Age	Bodyweight	Singledose	Maximumdailydose	Dosinginterval
12–15years	40-55 kg	500 mg	2-3g(maximumof4-6tabletsper24hours)	at least 4–6hours
>15years	40-55 kg	500 mg	2-3g(maximumof4-6tabletsper24hours)	at least 4–6hours
	>55kg	500–1,000mg	3g(maximumof6tabletsper24hours)	

Paracetamol is not recommended for children under12years of age.

If the pain persists for more than 5days or the fever lasts for more than 3days,or gets worse or other symptoms appear, a doctor should be consulted.

The elderly
Experience has indicated that normal adultdosage of paracetamol is usually appropriate.However,infrail,immobileelderly subjects or in elderly patients with renal or hepatic impairment, a reduction in the amount or frequency of dosing may be appropriate (see section 4.4).

Renal impairment
Paracetamol should be used with caution in patients with renal impairment as are duced dose and/or prolonged dosing interval may be necessary (see section 4.4).

Inpatients with renal insufficiency, the dose should be reduced:

Glomerularfiltrationrate	Dose
10–50ml/min	500mgevery6 hours
<10ml/min	500mgevery8 hours

Hepaticimpairment
Paracetamolshouldbeusedwithcautioninpatientswithhepaticimpairment(includingGilbert'ssyndrome)asareduceddose or prolonged dosing interval may be necessary (see section 4.4).

Methodofadministration:swallowthetabletwithwaterand,ifnecessary,thetabletcanbedividedintohalves.

Contraindications

Paracetamol should not be taken in case of:

- hypersensitivitytotheactivesubstanceortoanyoftheexcipientslistedinsection6.1.

Special warnings and precautions for use

Patients should be advised to consult their doctor when the pain lasts for more than 5days or the temperature remains high for more than 3 days or if these symptoms are accompanied by cough, headache, rash, nausea and vomiting.

The paracetamolcontentinotherconcomitantlytakencombinedmedicinalproductsshouldbecheckedinordertoavoidthe risk of inadvertent overdosing.
Paracetamol should be administered with caution under the following circumstances(seesection4.2):

- glucose-6-phosphatedehydrogenasedeficiency
- haemolyticanaemia
- glutathionedeficiency
- dehydration
- elderly
- Gilbert'ssyndrome

Casesofparacetamolinducedhepatotoxicity,includingfatalcases,havebeenreportedinpatientstakingparacetamolatdoses within the therapeutic range. These cases were reported in patients with one or more risk factors for hepatotoxicity including low body weight (<50 kg), renal and hepatic impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs, and in acute and chronic malnutrition (low reserves of hepatic glutathione).Paracetamol should be administered with caution to patients with these risk factors.Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency (see section 4.9).Doses of paracetamol should be reviewed at clinically appropriate intervals and patients should be monitored for emergence of new risk factors for hepatotoxicity which may warrant dosage adjustment.

Clinicalsignsofliverdamagegenerallyonlystartafterafewdaysandclimaxafter4-6daysasarule.Anantidoteshouldbe administered as soon as possible. See also section 4.9.

Cautionshouldbeexercisedinpatientswithasthmawhoaresensitivetoacetylsalicylicacid,asmildreactionsofbronchospasm have been reported with paracetamol (cross-reaction).

The risks of overdose are greater in those with non-cirrhotic alcoholic liver disease due to alcohol intake. Caution should be exercisedinpatientswithchronicalcoholism.Insuchcases,thedoseshouldnotexceed2gdaily.Alcoholshouldnotbeused during treatment with paracetamol.

Cautioninpatientswithglutathionedepletedstatessuchassepsis;theuseofparacetamolmayincreasetheriskofmetabolic acidosis. Patientswithimpairedkidneyfunction(withlevelsofthecreatinineclearancebelow10ml/min)areadvisedtotake paracetamol in intervals of no less than 8 hours between two doses.

Thismedicinecontainslessthan1mmolsodium(23mg)pertabletthatistosayessentially'sodiumfree'.

Thismedicinecontainsonlyverylowlevelsofgluten(fromwheatstarch)andisveryunlikelytocauseproblemsifyouhave coeliac disease. Onetabletcontainsnomorethan3microgramsofgluten.Ifthepatienthaswheatallergy(differentformcoeliacdisease) he/she should not take this medicine.

Interactionwithothermedicinalproductsandotherformsofinteraction

Theconcomitantuseofparacetamolmightpotentiatetheeffectofcoumarinanticoagulants.

Cholestyraminereducestheabsorptionofparacetamol.Metoclopramideanddomperidonemayincreasetherateof absorption of paracetamol. However, concurrent use does not need to be avoided.

Theconcomitantuseofparacetamolwithphenothiazinesmayleadtohypothermia.

Enzymeinducers,suchasphenytoin,carbamazepine,phenobarbital,isoniazid,StJohn'swortmayincreasetheriskof hepatotoxicity.

Probenecidreducestheclearanceofparacetamolbyalmost50%.Thus,theparacetamoldosemaybehalvedduring concomitant treatment.

Paracetamolmayaffecttheplasmaconcentrationsofchloramphenicol.Monitoringofchloramphenicolplasmalevelsis recommended if combining paracetamol with chloramphenicol injection treatment.

OralcontraceptivesandRifampicinreducetheeffectsofparacetamol.

Paracetamolshouldnotbetakentogetherwithalcoholbecauseinductionofthemicrosomalethanol-oxidisingsystem(MEOS) may result in an increase of its hepatotoxicity. Patients consuming more than 50 ml hard alcohol per day should consult a doctor before taking paracetamol.

Fertility,pregnancyandlactation

Pregnancy:
Alargeamountofdataonpregnantwomenindicatesneithermalformities,norfeto/neonataltoxicity.Epidemiologicalstudies onneurodevelopmentinchildrenexposedtoparacetamolinuteroshowinconclusiveresults.Ifclinicallyneeded,paracetamol canbeusedduringpregnancyhoweveritshouldbeusedatthelowesteffectivedosefortheshortestpossibletimeandatthe lowest possible frequency.

Breastfeeding:
Paracetamolisexcretedinverylowconcentrationsinthemother'smilkandisnotknowntocauseadverseeffectstobreast-fed children.

Effectsonabilitytodriveandusemachines

Therearenodataforadverseinfluenceontheactiveattention,coordinationofmovementsandreflexeswhenparacetamolis taken.

Undesirableeffects

The adverse drug reactions are categorized by systems and organs with the following frequency by using the following convention:verycommon(≥1/10),common(≥1/100to<1/10),uncommon(≥1/1,000to<1/100)rare(≥1/10,000to<1/1,000), very rare (<1 / 10,000), with unknown frequency (cannot be estimated from the available data).

Intherapeuticdoses,theadversedrugreactionsarealownumberandrare.
In rare cases haemolytic anaemia, neutropenia, leukopenia and very rarely – pancytopenia and thrombocytopenia with haemorrhagicdiathesisareobserved.Paracetamolmaycauseallergicreactions–itchingandrash,andmorerarely–difficulty in breathing, constriction in the throat, swelling of the lips, tongue, face.

SystemOrganClass	Frequency	Adversereactions
Bloodandlymphaticsystemdisorders	Rare	Platelet disorders, stem cell disorders, agranulocytosis, thrombocytopenia,neutropenia,leukopenia,haemolytic anaemia, pancytopenia
Immunesystemdisorders	Rare	Allergies(excludingangioedema)
	Very rare	Anaphylacticshock,hypersensitivityreaction(requiring discontinuation of treatment)
Metabolismandnutritiondisorders	Very rare	Hypoglycaemia
Psychiatricdisorders	Rare	Depression,confusion,hallucination
Nervoussystemdisorders	Rare	Tremor,headache
Eyedisorders	Rare	Abnormalvision
Respiratory,thoracicandmediastinaldisorders	Very rare	Bronchospasm
Gastrointestinaldisorders	Rare	Haemorrhage,abdominalpain,diarrhoea,nausea,vomiting
Hepatobiliarydisorders	Rare	Elevatedlivertransaminase,abnormalhepaticfunction,hepatic failure, hepatic necrosis, jaundice
	Very rare	liverdamage
Skinandsubcutaneoustissuedisorders	Rare	Rash,urticaria,angioedema,Allergicdermatitis
	Very rare	Seriousskinreactionshavebeenreported
	Notknown	Stevens-Johnsonsyndrome,toxicepidermalnecrolysis
Renalandurinarysystem	Very rare	Sterilepyuria(cloudyurine),renalsideeffects

Liverdamagewithparacetamolhasoccurredinconjunctionwithalcoholabuse.Theriskofkidneydamagecannotbeentirely ruled out with long-term use.

Interstitial nephritis has been reported incidentally after prolonged use of high doses. Some cases of erythema multiforme, oedemaofthelarynx,anaemia,liveralterationandhepatitis,renalalteration(severerenalimpairment,haematuria,anuresis) and vertigo have been reported.

Veryrarecasesofseriousskinreactionshavebeenreported.

Reportingofsuspectedadversereactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoringofthebenefit/riskbalanceofthemedicinalproduct.Healthcareprofessionalsareaskedtoreportanysuspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

Overdose

Acuteoverdosingofparacetamolmayresultindosage-dependenthepatotoxicityandacuterenalimpairment.Inaddition, taking paracetamol for a long time, as well as the concomitant use with enzyme inductors, such as anticonvulsants and isoniazid, also poses risk of hepatotoxicity or chronic nephropathy.

Inundernourishedpatientsandinvegetarians,theglutathionelevelsaredecreasedandthisincreaseofriskofhepatotoxicity.

In clinical terms, paracetamol-induced hepatotoxicity is expressed in: cyanosis, anaemia, vomiting, fever, rash, methemoglobinemiaandstimulationofthecentralnervoussystemprogressingtodelirium,convulsions,coma,vascular collapse and death.

Chronicnephropathyischaracterisedbyinterstitialnephritesandpapillarynecrosis.
Chronicalcoholics(whoconsumemorethan100mlhardalcoholeveryday)areexposedtomuchhigherriskofstomach bleeding and pancreatitis.

Paracetamol-inducedhepato-andnephrotoxicityareattributabletotheformationofoxidativemetabolite, N-acetyl-para-benzoquinoneimine(NAPQI),intheliverandtoalowerextent–inthekidneys.NAPQIconnectsthrougha covalentbondtothesulfhydrylgroupsofthetissuemacromolecules,whichresultsincellularnecrosis.Thetaking of N-acetylcysteineormethionineupto10-12hoursafteracuteoverdosingmaydecreasethehepatotoxicitybyconnectionto NAPQI. But these agents do not prevent renal toxicity. The maximum daily dose of paracetamol is 4 g.

Long-termadministrationofhighdosesofparacetamol(2-3timesmaximumdailydose)mayresultinimpairmentoftheliver functions (the skin and the eyes become yellow, nausea, stomach pain or discomfort, easily getting tired).

Treatmentincaseofoverdose: Immediatetransfertohospital.Bloodsamplingtodetermineinitialparacetamolplasma concentration. The stomach must be emptied by causing emesis or active carbon Gastric lavage TheantidoteN-acetylcysteine,shouldbeadministeredassoonaspossibleinaccordancewithNationaltreatmentguidelines. The cardiac function and the serum electrolytes should be monitored and corrected if need arises. In case of appearance of convulsions or central nervous system agitation, should be administered diazepam.

5 PHARMACOLOGICALPROPERTIES

Pharmacodynamicproperties

Pharmacotherapeuticgroup:Otheranalgesicsandantipyretics,ATCcode:N02BE01
Paracetamol is an analgesic that acts peripherally, probably blocking the generation of impulses in bradykinin-sensitive chemoreceptorsthatcausethepain.Althoughitisaprostaglandinsynthaseinhibitor,thesynthaseoftheCNSappearstobe more sensitive to this than the peripheral one. This may explain why the paracetamol does not have an anti-inflammatory activity. The analgesic effect starts within 30 minutes, with maximum effect within 1 to 2 hours and lasts up to 4 to 5 hours. The antipyreticeffectstartswithin30to60minutes.Themaximumantipyreticeffectisbetween2to3hoursandtheeffectlastsup to 8 hours.

Pharmacokineticproperties

Absorption
Afteroraluse,paracetamolisrapidlyandalmostcompletelyabsorbedbythegastrointestinaltract. Paracetamol plasma peak concentration is reached in 30 to 60 minutes

Distribution
Paracetamolisrapidlydistributedthroughoutmostbodyfluids,presentingaminimumbindingtoplasmaproteinsat therapeutic concentrations.

Metabolism
HepaticMetabolism:Paracetamolismetabolizedintheliverandexcretedintheurinemainlyasglucuronideandsulfate conjugates; less than 5% is excreted as unchanged form.
Asmallfraction(lessthan4%)istransformedthroughcytochromeP450intoametabolitethatisconjugatedwithglutathione. In massive intoxications, the amount of this metabolite is high. Theconjugationcapacityisnotmodifiedintheelderly.

Elimination
Theplasmaeliminationhalf-lifeisapproximately2hours.

Preclinicalsafetydata

Extensive studies revealed no evidence of a relevant genotoxic risk for paracetamol within the therapeutic, i.e. non-toxic, dose range.

Long-termstudiesonratsandmicedonotindicateanyrelevanttumorigeniceffectsatnon-hepatotoxicdosesofparacetamol.

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and developmentare not available.

Besidesthat,thereisnopre-clinicaldataofrelevancetotheprescriberwhichisadditionaltothatalreadyincludedinother sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

List of excipients

Maize starch
Methyl Paraben
Avicel 101
Magnesium stearate
Talcum powder

Incompatibilities

Notapplicable

Shelflife

5 years

Specialprecautionsforstorage

Store below 30°C.

Nature and contents of container

PVC/aluminiumblisters,12,tablets

Special precautions for disposal

Waste material should be disposed of safely. Patients/carers should be encouraged to return any unused product to the Pharmacy, where it should be disposed of following national and local requirements.

7 MARKETINGAUTHORISATIONHOLDER

CLARION MEDICALS LIMITED
23 FOLABI LESI STREET ILUPEJU , LAGOS

8. DRUG PRODUCT MANUFACTURER

May& Baker NIGER Plc.
No. 1 May & Baker Avenue off idiroko Road, Ota, Ogun State Nigeria

9. NAFDAC REGISTRATION NUMBER(S) 04-8941