SUMMARY OFPRODUCTCHARACTERISTICS

1. Nameofthe medicinalProduct
EMZOLYTE PLUS(OralRehydrationSalts BP20.5 gm plus Zinc sulphate 20mg)

2. Qualitativeandquantitativecomposition

Sr. No	Ingredients Chemical	Specification	Qty.Required /Sachet(gm)	Function
1	AnhydrousGlucose	BP	13.500	Active
2	SodiumChloride	BP	2.600	Active
3	SodiumCitrate	BP	2.900	Active
4	PotassiumChloride	BP	1.500	Active
5	Flavor Orange	HIS	0.100	Flavoringagent
6	Zinc sulphate	BP	20	

3. Pharmaceuticalform
OralRehydration
Description: Whitetooffwhite colored crystallinepowder.

4. Clinical particulars
4.1 Therapeuticindications
Emzoylte plus is indicatedfor thetreatmentofacutediarrheaand thetreatmentandpreventionof dehydrationbyreplacingfluidsandelectrolyteslostthroughdiarrhoea.

4.2 PosologyandmethodofadministrationAdul ts,the elderlyandchildrenover12 years:
Thecontents of oneor twosachetstobetakenaftereachloose motion.

Children 1to 12years:
Thecontents of onesachetto betakenaftereachloosemotion.

Infantsunder 1year:
Notto begivenunlessinstructedby a doctor, inwhichcase one to oneand a half theusual24hourfeed volume shouldbegiven.
Duringthefirst24hoursofillnessReplaviteshouldreplacenormalfeedsinbottlefedbabies,graduallyresu mingnormalfeedsasthebabygetsbetter.Inbreastfedbabies,firstlytherecommendedamountofRelatives houldbegivenandthenbreast feduntilsatisfactory.

Reconstitution
Thecontentsofeachsachetshouldbedissolvedin200ml(7fluidounces)offreshdrinkingwater(adultsandch ildren).
Freshlyboiledandcooledwatershouldbeusedforinfantsandwhenfreshwaterisnotavailable.Thesolutio nshouldbemadeupimmediatelybeforeuseandusedwithinonehour.Ifrefrigeratedthesolutioncanbekep tforupto24hours.Adoctorshouldbeconsultedifsymptomspersistforlongerthan24 – 48hours.

Methodofadministration
For oral use

4.3 Contraindications
Contraindicatedinpatientswithphenylketonuriaorthosewithhypersensitivitytoanyoftheingredients.

Oraltreatmentisinappropriateinsuchconditionsassevereddehydration,whichrequiresparenteralfluidtherapyorintestinalobstruction.

4.4 Specialwarningsandprecautionsforuse
Severeandpersistentdiarrhoeashouldbetreatedundermedicalsupervision.Ifsymptomspersistformorethan24— 48hours,medicaladviceshouldbesought.
Inabilitytodrinkor retainfluidsrequiresmedicalsupervision.

Children
• Rehydrationtreatmentshouldonly begiventochildrenunder 1 yearofage onmedicaladvice.
• Ifayoungchild(particularlyoneunder6monthsofage)hasdiarrhoeaand/orvomitingadviceshouldbesoughtfromapharmacist,doctororotherhealthcareprofessional.Ifthediarrhoeaand/or vomiting is severethechildshouldbeseenby a doctor as soonaspossible.

RenalImpairment
• Medicalsupervisionisnecessaryinpatientswithrenaldisease,includinganuriaandprolonged oliguria.

HepaticImpairment: Lowpotassiumor Sodiumdiets: Diabetes
• Treatmentshouldbe supervisedby a physician.
Thisproductcontainsdextrose.Patientswithrare-glucose-galactosemalabsorptionshouldnottakethismedicine.

4.5 InteractionwithothermedicinalproductsandotherformsofinteractionSodi

umBicarbonate
Increasesexcretionof lithium,resultingina reducedplasma-lithiumconcentration.

PotassiumChloride
ACE inhibitors(hyperkalemia);cyclosporine(increased risk ofhyperkalemia).
Potassiumsparingdiureticswherehyperkalemiamayresult.Noknowninteractionstootheractives.

4.6 Fertility,pregnancyand lactation
May beused duringpregnancyandlactationas thereare noknown adverseeffects.

4.7 Effectsonability todriveandusemachines
No studies ontheeffectson theabilityto driveand use machineshavebeenperformed.

4.8 Undesirableeffects
None stated.

4.9 Overdose
If significantoverdosageoccurs,serumandelectrolytes shouldbeevaluated.
Correctivemeasuresshouldbecarriedoutandlevelsmonitoreduntilareturntonormallevelsisachieved.

5. Pharmacologicalproperties

5.1 Pharmacodynamicproperties
Thereconstitutedsolutioncontainsamixtureofsodiumandpotassiumsaltsalongwithglucose,whichfacilitatestheabsorptionofsodiumandpotassiumfromtheintestine.Waterisdrawnfromthebowelbytheosmoticeffect.Aswellas"dryingup"thestools,thedehydrationandlossofelectrolytescaused bythediarrheaiscorrectedbythewater andelectrolytesabsorbed.

Pharmacotherapeuticgroup: ElectrolyteswithCarbohydrates
ATC Code:A07CA

5.2 Pharmacokineticproperties
Glucose
Afteroraladministrationglucoseiscompletelyabsorbedbyasodiumdependentuptakemechanismexhibitingsaturationkinetics.Bloodlevelsreturntonormalwithintwohours ofingestion.

PotassiumChloride
Nospecificcontrolmechanismslimitabsorptionofpotassium,whichisusuallycomplete.Potassiumisexcretedlargelybythekidneys,though10%isexcretedbythecolonicmucosa.Potassiumexcretionisreducedin patientswithrenalimpairmentandintheelderly,soextremecautionshouldbeused intreatingsuchpatientswithpotassiumsalts.

SodiumBicarbonate
Kineticsaredeterminedbythephysiologicalstateofthepatient atthetime.

SodiumChloride
Readilyabsorbedfromthegastrointestinaltract.Gutabsorption,particularlyinthejejunumisenhancedby theadditionofglucose.Underconditionsofsodiumbalance,theexcretionofsodiumintheurinewillmatch intake.

5.3 Pre-clinicalsafetydata
NotApplicable

6. Pharmaceuticalparticulars

6.1 Listofexcipients
Flavor OrangePowder

6.2 Incompatibilities
Notapplicable.

6.3 Shelflife
36 Months

6.4 Specialprecautions forstorage
Storebelow30°C.Protectfrom light&moisture.

6.5 Nature andcontentsofcontainer
20.5 gm powderpacked inaluminumfoilsachet.Such25 sachets'arepackedin cartonalongwithaninsert.

6.6 Specialprecautions fordisposal<and otherhandling>
NotApplicable

7. MARKETING AUTHORIZATIONHOLDERANDMANUFACTURINGSITEADDRESSES:

MarketingAuthorizationHolder
EMZOR PHARMACEUTCAL INDUSTRIES LIMITED
FLOWERGATE MIXED DEVELOPMENT SCHEME, KM 1 SAGAMU/BENIN EXPRESSWAY,SAGAMU,OGUNSTATE., NIGERIA

Manufacturing SiteAddresses
EMZOR PHARMACEUTCAL INDUSTRIES LIMITED
FLOWERGATE MIXED DEVELOPMENT SCHEME, KM 1 SAGAMU/BENIN EXPRESSWAY,SAGAMU,OGUNSTATE., NIGERIA

8. Marketingauthorization number
A4-8910

9. Dateoffirst<registration>/renewalofthe <registration>
NA

10. Dateofrevision oftext:
NA