SUMMARYOFPRODUCTCHARACTERISTICS

1. NameofthemedicinalProduct
EMZOLYTE(OralRehydrationSaltsBP20.5gm)

2. Qualitativeandquantitativecomposition

Sr.No	Ingredients Chemical Name	Specification	Qty. Required /Sachet (gm)	Function
1	Dextrose	BP	13.500	Active
2	SodiumChloride	BP	2.600	Active
3	SodiumCitrate	BP	2.900	Active
4	PotassiumChloride	BP	1.500	Active
5	Flavour :Orange Powder		0.100	Flavoringagent

3. Pharmaceuticalform
OralRehydration
Description: Whitetooffwhitecolouredcrystallinepowder.

4. Clinicalparticulars
4.1 Therapeuticindications
Oralrehydrationsaltisindicatedforthetreatmentofacutediarrheaandthetreatmentandprevention of dehydrationby replacing fluids andelectrolyteslostthroughdiarrhoea.

4.2 PosologyandmethodofadministrationAdul ts,theelderlyandchildrenover12years:
Thecontentsofoneortwosachetstobetakenaftereachloosemotion.

Children1to12years:
Thecontentsofonesachettobetakenaftereachloosemotion.

Infantsunder1year:
Not to be given unless instructed by a doctor, in which case one to one and a halfthe usual 24 hourfeedvolumeshouldbegiven.
During the first 24 hours of illness Replavite should replace normal feeds in bottle fed babies,graduallyresumingnormalfeedsasthebabygetsbetter.Inbreastfedbabies,firstlytherecomme ndedamountof Relativeshouldbegiven andthenbreastfeduntil satisfactory.

Reconstitution
The contents of each sachet should be dissolved in 200 ml (7 fluid ounces) of fresh drinking water(adultsandchildren).
Freshlyboiledand cooled water shouldbe used for infants and whenfreshwater is not available.Thesolutionshouldbe madeupimmediatelybeforeuse and used within one hour.Ifrefrigeratedthe solutioncanbe kept forup to 24 hours. Adoctorshould be consulted ifsymptoms persistforlongerthan24–48hours.

Methodofadministration
Fororaluse

4.3 Contraindications
Contraindicatedinpatientswithphenylketonuriaorthosewithhypersensitivitytoanyoftheingredients.

Oraltreatmentisinappropriateinsuchconditionsasseveredehydration,whichrequiresparenteral fluidtherapy orintestinalobstruction.

4.4 Specialwarningsandprecautionsforuse
Severeandpersistentdiarrhoeashouldbetreatedundermedicalsupervision.Ifsymptomspersistfor morethan24—48hours,medicaladviceshouldbesought.
Inabilitytodrinkorretainfluidsrequiresmedicalsupervision.

Children
• Rehydrationtreatmentshouldonlybegiventochildrenunder1yearofageonmedicaladvice.
• If a young child (particularly one under 6 months of age) has diarrhoea and/or vomiting adviceshould be sought from a pharmacist, doctor or other health care professional. If the diarrhoeaand/orvomitingissevere thechildshouldbe seenbya doctor assoonaspossible.

RenalImpairment
• Medicalsupervisionisnecessaryinpatientswithrenaldisease,includinganuriaandprolonged oliguria.

HepaticImpairment: LowpotassiumorSodiumdiets:Diabetes
• Treatmentshouldbesupervisedbyaphysician.
Thisproductcontainsdextrose.Patientswithrare-glucose-galactosemalabsorptionshouldnottakethismedicine.

4.5 InteractionwithothermedicinalproductsandotherformsofinteractionSod

iumBicarbonate
Increasesexcretionoflithium,resultinginareducedplasma-lithiumconcentration.

PotassiumChloride
ACEinhibitors(hyperkalemia);cyclosporine(increasedriskofhyperkalemia).
Potassiumsparingdiureticswherehyperkalemiamayresult.Noknowninteractionstootheractives.

4.6 Fertility,pregnancyandlactation
Maybeusedduringpregnancyandlactationastherearenoknownadverseeffects.

4.7 Effectson abilityto driveandusemachines
Nostudiesontheeffectsontheabilitytodriveandusemachineshavebeenperformed.

4.8 Undesirableeffects
Nonestated.

4.9 Overdose
Ifsignificantoverdosageoccurs,serumandelectrolytesshouldbeevaluated.
Correctivemeasuresshouldbecarriedoutandlevelsmonitoreduntilareturntonormallevelsisachieved.

5. Pharmacologicalproperties

5.1 Pharmacodynamicproperties
Thereconstitutedsolutioncontainsa mixtureof sodium andpotassium saltsalongwithglucose,which facilitates the absorptionof sodiumandpotassiumfromthe intestine.Waterisdrawnfromthebowelbytheosmoticeffect.Aswellas"dryingup"thestools,thedehydration andlossofelectrolytescausedbythediarrheaiscorrectedbythewaterandelectrolytesabsorbed.

Pharmacotherapeuticgroup: ElectrolyteswithCarbohydrates
ATC Code:A07CA

5.2 Pharmacokinetic
propertiesDextrose
Afteroraladministrationdextrose/glucoseiscompletelyabsorbedbyasodiumdependentuptakemech anism exhibiting saturation kinetics.Bloodlevelsreturn to normal withintwo hours ofingestion.

PotassiumChloride
Nospecificcontrolmechanismslimitabsorptionofpotassium,whichisusuallycomplete.Potassium is excreted largely by the kidneys, though 10% is excreted by the colonic mucosa.Potassium excretion is reduced in patients with renal impairment and in the elderly, so extremecautionshouldbeusedintreatingsuchpatients withpotassiumsalts.

SodiumBicarbonate
Kineticsaredeterminedbythephysiologicalstateofthepatientatthetime.

SodiumChloride
Readily absorbed from the gastrointestinal tract. Gut absorption, particularly in the jejunum isenhanced by the addition of glucose. Under conditions of sodium balance, the excretion of sodiumintheurinewillmatchintake.

5.3 Pre-clinicalsafetydata
NotApplicable

6. Pharmaceuticalparticulars

6.1 Listofexcipient
FlavourOrangePowder

6.2 Incompatibilities
Notapplicable.

6.3 Shelflife
36Months

6.4 Specialprecautionsforstorage
Storebelow30°C.Protectfromlight&moisture.

6.5 Natureandcontentsofcontainer
20.5gmpowderpackedinaluminumfoilsachet.Such25sachets'arepackedin cartonalongwithaninsert.

6.6Specialprecautionsfordisposal<andotherhandling>
NotApplicable

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITEADDRESSES:

MarketingAuthorizationHolder
AlphaceuticalsLimited
Address: 97 High Street,
Rickmansworth,Hertfordshire, WD3 1EF,
United
KingdomTelephone:+441923836379
Telefax:+441923840160
Email:marketing@neomedic.co.uk

ManufacturingSiteAddresses

Company name :Emzor Pharmaceutical Industries Limited

Address :Flowergate Mixed Development Scheme, Km 1, Sagamu/Benin Expressway,Makun, Sagamu,Ogun-State.

8. Marketingauthorizationnumber
NA

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

10. Dateofrevisionoftext:
NA