1.NAMEOFTHEMEDICINALPRODUCT

GASMAGCHEWABLETABLET

2.QUALITATIVEANDQUANTITATIVECOMPOSITION

Eachtabletcontains:

DriedAluminiumHydroxideGel120mg

MagnesiumTrisilicate250mg

Simeticone25mg

Excipientswithknowneffect:

Forafulllistofexcipients,seesection6.1

3. PHARMACEUTICALFORM

Chewabletablets.

Lightyellow,round,flattabletswithbevelededges,with"Gs'engravedononeside;withdiameter16mmandthickness4mm.

4.CLINICALPARTICULARS

4.1Therapeuticindications

GASMAGTABLETisindicatedinthesymptomaticreliefof:Dyspepsia,Heartburn,Flatulence,Hyperacidity,Indigestion.

4.2 PosologyandMethodofadministration

Posology

AdultsandChildrenover12years

1–2tabletstobesuckedorchewedaftermeal,atbedtimeorwhendiscomfortisfelt.Frequencyofdosagemaybeincreaseddependingontheseverityofsymptoms.

Children6to12years:

Onetablettobesuckedorchewedaftermeals,atbedtimeorwheneverdiscomfortisfelt.

Childrenunder6years:Notrecommended.

Elderly:SameasadultdoseunlessotherwiserecommendedbyPhysician.

Methodofadministration

Tobechewedbeforeswallowing.

4.3Contraindications

GASMAGiscontraindicatedinpatientswhoarehypersensitivetoanyoftheactivesubstancesorexcipients,areseverelydebilitatedorsufferingfromKidneyfailure.

GASMAGisalsocontraindicatedinpatientswithHypophosphatemia,Rarehereditaryproblemsoffructoseintolerance,glucose-galactosemalabsorptionorsucrase-isomaltaseinsufficiency.

4.4Specialwarningsandprecautionsforuse

Aluminiumhydroxidemaycauseconstipationandmagnesiumsaltsoverdosemaycausereducedmotilityofthebowel.LargedosesofGasmagmaytriggeroraggravateintestinalobstructionandileusinpatientswhoareathigherrisksuchasthosewithrenalimpairment,ortheelderly.

Aluminiumhydroxideisnotwellabsorbedfromthegastrointestinaltract,andsystemiceffectsaretherefore rareinpatientswithnormalrenalfunction.However,excessivedosesorlong-termuse,orevennormaldosesinpatientswithlow-phosphorousdiets,mayleadtophosphatedepletion(duetoaluminium-phosphatebinding)accompaniedbyincreasedboneresorptionandhypercalciuriawiththeriskofosteomalacia.Medicaladviceisrecommendedincaseoflong-termuseorinpatientsatriskofphosphatedepletion.

Inpatientswithrenalimpairment,plasmalevelsofbothaluminiumandmagnesiumincrease.Inthesepatients,along-termexposuretohighdosesofaluminiumandmagnesiumsaltsmayleadtoencephalopathy,dementia,microcyticanemiaorworsendialysis-inducedosteomalacia.

Aluminiumhydroxidemaybeunsafeinpatientswithporphyriaundergoinghemodialysis.Theprolonged useofantacidsinpatientswithrenalfailureshouldbeavoided.

Thereislittleevidencethataluminiumcontainingantacidsareariskfactorfor Alzheimer'sdisease.

Hypermagnesaemiamayoccur,usuallyinpatientswithbowelobstructionorrenalimpairment.

GASMAGTABLETScontainSucralose;careshouldbetakeninpatientswithrarehereditaryproblemsoffructoseintolerance,glucose-galactosemalabsorptionorsucrose-isomaltaseinsufficiency.

CareshouldbetakeninthetreatmentofDiabeticpatients.

Concurrentuseofantacidmayantagonizetheeffectofpentagastrinandhistamineinthe evaluationofgastricacidsecretoryfunction,hence,administrationofantacidisnotrecommendedonthe morningofthetestday.

KEEPALLMEDICINESOUTOFTHEREACHOFCHILDREN

4.5Interactionwithothermedicinalproductsandotherformsofinteraction

GASMAGshouldnotbetakensimultaneouslywithothermedicinesastheymayinterferewiththeirabsorption iftakenwithin1hour.

Aluminium-containingantacidssuchasGASMAGmaypreventtheproperabsorptionofdrugssuchastetracyclines,vitamins,ciprofloxacin,ketoconazole,hydroxychloroquine,chloroquine,chlorpromazine,rifampicin,cefdinir,cefpodoxime,levothyroxine,rosuvastatin,H2antagonists,atenolol,cyclines,diflunisal,digoxin,bisphosphonates,ethambutol,fluoroquinolones,sodiumfluoride,glucocorticoids,indomethacin,isoniazid,lincosamides,metoprolol,phenothiazineneuroleptics,penicillamine,propranololandironsalts.

LevothyroxinemayalsobindtoSimeticonewhichmaydelayorreducetheabsorptionoflevothyroxine.

Polystyrenesulphonate

Cautionisadvisedwhenusedconcomitantlywithpolystyrenesulphonateduetothepotentialrisksofreducedeffectivenessoftheresininbindingpotassium,ofmetabolicalkalosisinpatientswithrenalfailure(reportedwithaluminiumhydroxideandmagnesiumhydroxide)andofintestinalobstruction(reportedwithaluminiumhydroxide).

Quinidine:
Concomitantuseofaluminiumproductswithquinidinesmayincreasetheserumlevelsofquinidineandleadtoquinidineoverdosage.

Tetracycline:
Duetothealuminiumcontent,GASMAGshouldnotbeconcomitantlyadministeredwithtetracycline-containingantibioticsoranytetracyclinesalts.

Citrates:
Aluminiumhydroxideandcitratesmayresultinincreasedaluminiumlevels,especiallyinpatientswithrenalimpairment.

Urinealkalinisationsecondarytoadministrationofmagnesiumhydroxidemaymodifyexcretionofsomedrugs;thus,increasedexcretionofsalicylateshasbeenseen.

Urinaryexcretionofamphetaminesandquinidinemaybeinhibitedwhenusedconcurrentlywithantacidsindosesthatcausetheurinetobecomealkaline.Dosageadjustmentmaybeneededwhentherapywithantacidsisinitiated,discontinuedorifdosageischanged.

Prioradministrationofaluminiumcontainingantacidsmaydecreasestomachandbladder uptakeofsodiumpertchnetateTc99m.

4.6PregnancyandLactation

ThesafetyofGASMAGSUSPENSIONinpregnancyhasnotbeenevaluated.Therearenoadequatehuman datafromtheuseofaluminiumhydroxideandmagnesiumhydroxideinpregnantwomen.Noconclusions canbedrawnregardingwhetherornotGASMAGTABLETissafeforuseduringpregnancy. GASMAGTabletsshouldbeusedduringpregnancyonlyifthepotentialbenefitstothemotheroutweighthe potentialrisks,includingthosetothefetus.

Lactation
Becauseofthelimitedmaternalabsorption,whenusedasrecommended,minimalamounts,ifany,ofalu miniumhydroxideandmagnesiumsaltcombinationsareexpectedtobeexcretedintobreastmilk.

Simeticoneisnotabsorbedfromthegastrointestinaltract.

Noeffectsonthebreastfednewborn/infantareexpectedsincethesystemicexposureofthebreast-feedingwomantoaluminiumhydroxide,magnesiumhydroxideandsimethiconeisnegligible.

4.7Effectsonabilitytodriveandusemachines

GASMAGhasnoinfluenceontheabilitytodriveandusemachinesreported.

4.8Undesirableeffects

*Immunesystemdisorders*suchashypersensitivityreactions,suchaspruritus,urticaria,angioedemaand anaphylacticreactions.Thefrequencyofoccurrenceisunknown.

*Gastrointestinal*sideeffectsareuncommon.
Uncommon:diarrhoeaorconstipation
Frequencynotknown:abdominalpain
Metabolismandnutritiondisorders
Veryrare:Hypermagnesaemia,includingobservationsafterprolongedadministrationof magnesiumhydroxidetopatientswithrenalimpairment.
Frequencynotknown:Hyperaluminemia

Hypophosphatemia,inprolongeduseorathighdosesorevennormaldosesofthe productinpatientswithlow-phosphorusdietswhichmayresultinincreasedbone resorption,hypercalciuria,andosteomalacia.

Largedosesofaluminiumhydroxidecancauseintestinalobstruction.

Renalcalculiwithmagnesiumtrisilicate
Theformationofrenalcalculicontainingsilicaisunusual,buthasbeenreportedina smallnumberofpatients.Inmostofthesereportedcases,stoneformationwasattributed totheprolonged,andsometimesexcessive,intakeofantacidsthatcontainedmagnesium trisilicate.

4.9Overdose

Significantsymptomsareunlikelyfollowingoverdosage.Nocaseofoverdosehasbeenreported.

Symptomsofoverdosageincludenausea,vomiting,gastrointestinalirritation,abdominal painanddiarrhoea/constipation.Abdominaldistensionmayoccur.Largedosesofthis productmaytriggeroraggravateintestinalobstructionandileusinpatientsatrisk. Treatmentshouldbesymptomaticandsupportive.

Treatmentofaluminiumandmagnesiumoverdose:aluminiumandmagnesiumare eliminatedthroughurinaryroute;consideradministrationofIVcalciumgluconate, rehydrationandforceddiuresis.Incaseofrenaldeficiency,haemodialysisorperitoneal dialysisisnecessary.

5.PHARMACOLOGICALPROPERTIES

5.1Pharmacodynamicproperties

Antacidscontrolaciditybyneutralizingthegastricacid.ThisresultsinincreasedpHofstomachcontents,thusprovidingthereliefofthesymptomsofthehyperacidity.Acidconcentrationwithinthelumenofoesophagusisalsoreduced,resultinginanincreasedintraoesophagealpH.Antacidsalsoreducepepsinactivity.

Driedaluminiumhydroxideandmagnesiumtrisilicateareusedasantacids.Aluminiumhydroxidehasconstipatingeffectswhereasmagnesiumhydroxide andmagnesiumtrisilicatehaslaxativeeffects.Thesearegivenincombinationto counteracttheseeffectsandachieveabalance.

Simethiconeisusedfortherelieffortheflatulenceandabdominaldiscomfort.Itisa gastricdefoamingagentthatworksbyalteringtheelasticityofinterfacesofmucus-embeddedbubblesinthegastrointestinaltract.Thegasbubblesarethusbrokendownor coalescedandinthisformgasismoreeasilyeliminatedthrougheructationorpassing flatus.

5.2Pharmacokineticproperties

ThemodeofactionoftheGASMAGSUSPENSIONdoesnotdependonabsorptionintothesystemiccirculation.

Aluminiumhydroxide,givenorallyslowlyreactswiththehydrochloricacidinthe stomachtoformsolublealuminiumchloride,someofwhichisabsorbed.Thepresenceof foodorotherfactorsthatdecreasegastricemptyingprolongstheavailabilityof aluminiumhydroxidetoreactandmayincreasetheamountofaluminiumchlorideformed.

Absorbedaluminiumiseliminatedintheurineandpatientswithrenalfailureare thereforeatparticularriskofaccumulation.Thealuminiumcompoundsremaininginthe gastrointestinaltract,whichaccountformostofthedoseforminsolublepoorly,absorbed salts,whichareexcretedinthefaeces.

Magnesium,givenbymouth,reactsrelativelyrapidlywithhydrochloricacidinthe stomachtoformmagnesiumchlorideandwater.Approximately10%ofthemagnesium isslowlyabsorbedfromthegastrointestinaltractandexcretedintheurine;therestisexcretedviathefaeces.

Simethiconeisnotabsorbedfromthegastrointestinaltract.

5.3Preclinicalsafetydata

Aluminiumandmagnesiumsaltshavenotbeenreportedtohaveanymutagenicpotential orcarcinogenicity.Therearenopreclinicaldataofrelevancetotheprescriberwhichare additionaltothatalreadyincludedinothersectionsoftheprescribinginformation.

6.PHARMACEUTICALPARTICULARS

6.1Listofexcipients

CornStarchN.F.,MicrocrystallineCellulose,LactoseMonohydrate,CalciumCarbonate,PVPK-30,QuinolineYellow,Maltodextrine,Sucralose,SodiumBenzoate,PeppermintFlavour,Aerosil200.

6.3Shelflife

24Months

6.4Specialprecautionsforstorage

Storeinacoolanddryplace.
Storebelow30°C.
Protectfromdirectsunlight.
Keepallmedicinesawayfromchildren.

6.5Natureandcontentsofcontainer<andspecialequipmentforuse,administrationo rimplantation>

a)Carton:Printedcartonmanufacturedfromwhitefoldingboxboard.

b)StripsofSurfaceprintedhardtemperaluminumfoil.

Boxof5x4's.

6.6Specialprecautionsfordisposal<andotherhandlin g>

Nospecialrequirements.

7.<APPLICANT/MANUFACTURER>

NeimethInternationalPharmaceuticalPlc.

Plot16,AkanniDohertyLayout(Billingsway),
OregunIndustrialEstate,
Oregun,Lagos.

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