SUMMARY OF PRODUCT CHARACTERISTICS

1.NAMEOFTHEFINISHED PRODUCT

Colodium Capsule2 mg

2.QUALITATIVEANDQUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PERCAPSULE(MG)
Loperamide Hydrochloride	2mg

For excipients, see 6.1

3.PHARMACEUTICALFORM

Capsule

Green opaqueand greyopaquecapsulewith "HD"printed on oneend and "CD2"on theotherend ofthe capsule.

4.CLINICALPARTICULARS

4.1Therapeuticindication

Forthereliefofacutenonspecificdiarrhoeaandofchronicdiarrhoeaassociatedwithinflammatory bowel disease, as well as to reduce the volume of discharge from ileotomies.

4.2PosologyandMethodofadministration

Usual adult dose : Oral,6to8mgperdayuptoamaximumof16mgperday. Usual

paediatric dose : Below 6 years – Not recommended.

6 to 8 years -Oral,4.0mgperdayindivideddoses 9to 12years-Oral, 6.0mgperdayin divided doses

4.3 Contraindication

Infants and patients with severe colitis or diarrhea associated with pseudomembranous colitis resulting from treatment with broad spectrum antibiotics.

4.4Specialwarningsandprecautionsforuse

- Loperamideisnotrecommendedforchildrenunder6 yearsofage. Itsusehasbeenassociatedwith fatal episodes of paralytic ileus in infacts and young children.
- Appropriatefluid and electrolytetherapyshould begivento protect against dehydration in all cases of diarrhea. Oral rehydration therapy – which is the use of appropriate fluids including oral rehydration salts remains the most effective treatment for dehydration due to diarrhea. The intake of as much of these fluids as possible is therefore imperative.
- Drug-induced inhibition of peristalsis my results in fluid retention in the intestine, which may aggravateandmaskdehydrationanddepletionofelectrolytes.Ifseveredehydrationorelectrolete

imbalance is present, loperamide should be withheld until appropriate corrective therapy has been initiated.

- Safetyforusein pregnancyandlactation hasnot beenestablished.
- Use of this medication should be carefully considered when the following medical problems exist: Conditionswhereconstipationshouldbeavoided,dehydration,diarrheacausedbyinfectious organisms, hepatic function impairment.
- Theuseofhigherthantherecommendeddosesforcontrolofthediarrheamaycauseabnormal heart rhythms and serious cardiac events leading to death. However, in adult patients receiving the recommendeddosageofloperamide,casesofsyncopeandventriculartachycardiahavebeen reported. Some of these patients were taking other drugs or had other risk factors that may have increasedtheirriskofcardiacadversereactions.Abuseandmisuseofloperamide,asanopiod substitute, have been described in individuals with opiod addiction (see Overdose).

4.5Interactionwithothermedicinalproductsandotherformsofinteraction

None known.

4.6Pregnancyandlactation

Safetyforusein pregnancyand lactationhasnotbeen established.

Effectsonabilitytodriveand use machines

Not Applicable

UndesirableEffects

- Abdominalpain and other gastrointestinaldisturbancesincludingtoxic megacolon.
- Dry mouth
- Dizziness,fatigue,CNS depression
- Nausea,vomitingandlossofappetite
- Skin rashes
- Constipation
- CardiacDisorders:QT/QTcintervalprolongation,Torsadesdepointes,otherventricular arrhythmias, cardiac arrest, syncope, and death (see Warnings and Precautions)

Overdose

Clinicalfeatures:Nausea,epigastricdiscomfort,constipation,dizziness,drowsiness,stuporandcoma.
In individuals who have intentionallyingested overdoses (reported in doses from 40 mg to 792 mg per day) of loperamide HCl, prolongation of the QT/QTc interval Torsade de Pointes, other ventricular arrhythmias and cardiac arrest, have been observed (see Warnings and Precautions). Fatal cases have also been reported.

Treatment:Emesisorgastriclavageisunnecessaryunlessaverysubstantialoverdosehasbeeningested. Naloxone 0.4 to 1.2 mg IV may antagonize the clinical features described above

5.PHARMACOLOGICALPROPERTIES

5.1Pharmacodynamicproperties

Loperamide is a synthetic derivative of pethidine that inhibits gut motility and may alsoreducegastrointestinalsecretions. Loperamidebindstotheopiatereceptorinthe gutwall.Consequently,itinhibitsthe release ofacetylcholine andprostaglandins, therebyreducingpropulsiveperistalsis,andincreasingintestinaltransittime. Loperamide increases viscosity, increases bulk density, reduces daily fecal volume, and diminishes loss of fluids and electrolytes. Loperamide increases the tone of the anal sphincter, thereby reducing incontinence and urgency. Additionally, loperamide will prolong mouth-to-cecum transit time without affecting gastric emptying.

Loperamide has an antidiarrhoeal effect. It slows gastro-intestinal motility by effects on the circular and longitudinal muscles of the intestine. It binds to opioid receptors in brain homogenates and intestinal strips. Its constipating action is probably due, at least in part, to actions at these receptors

5.2Pharmacokineticproperties

Absorption
Loperamide is not well absorbed from the gastrointestinal tract. Most ingested loperamide is absorbed from the gut, but as result of significant first passmetabolism, systemic bioavailability is only approximately 0.3%.

Blood Concentration
Concentrations of loperamide in plasma peak about 4 hours after ingestion of large doses.

Half-life
Theeliminationhalf-lifeofloperamideisabout10hours.

Distribution
Loperamide does not penetrate well into the brain. Little intact drug reaches the systemic circulation Gastrointestinal Tract: 85%, Liver: 5%, Tissues: 0.04 to 0.2%. The plasma protein binding of loperamide is 95%, mainly to albumin.

ProteinBinding
About97%isboundto plasma protein.

Metabolism
Loperamide undergoes first-pass metabolism in the liver. Loperamide undergoes significant first pass metabolism in the liver. Oxidative N-demethylation is the main metabolic pathway for loperamide, and is mediated mainly through CYP3A4 and CYP2C8. Oxidative N-dealkylation may be another pathway. Due to this very high first pass effect, plasma concentrations of unchanged drug remain extremely low.

Excretion
Excreted predominantly in the faeces. The half-life of loperamide in man is 10.8 hourswith arangeof9-14 hours. Approximately50%ofan orallyadministered dose is excreted unchanged, primarily in the faeces, there is slight urinary excretion.

5.3PreclinicalSafetyData

NOT APPLICABLE

6.PHARMACEUTICALPARTICULARS

List ofexcipeints

Corn Starch
Lactose Monohydrate
ColloidalSiliconDioxide
Polyvinylpyrrolidone
Polysorbate 80
Magnesium Stearate

Incompatibilities
NOT APPLICABLE

Shelflife
3 yearsfromdateofmanufacture

Specialprecautionforstorage
Storebelow30˚C.Protectfrommoisture.

Natureandcontentsofcontainer

Blister Pack

Type	:	Push-throughblisterpack;thepackageconsistsofatransparent themoformable plastic material and a heat-sealable lacquered backing material.
Material	:	Thermoformableplasticmaterial:PolyvinylChloride(PVC) Backing Material : Aluminium Foil

Specialprecautionsfordisposalandotherhandling
NOT APPLICABLE

7.MARKETINGAUTHORISATIONHOLDERADDRESS

Name : HOVID BHD.,
Address : 121,JalanTunkuAbdulRahman (Jalan Kuala Kangsar),30010Ipoh,Perak, Malaysia.

ManufacturerName:

Name	:	HOVID Bhd.
Address	:	Lot56442,7½ Miles, JalanIpoh/Chemor, 31200 Chemor, Perak., Malaysia.

8. MARKETINGAUTHORISATIONNUMBER

HOV/MAL/0030

9. DATEOFFIRSTREGISTRATION/RENEWALOFTHEAUTHORISATION

May 2017

10. DATEOFREVISIONOFTHETEXT

April2020