SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PRODUCT

Cimetidine 400 mg Film-Coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Cimetidine	400 mg

Kindly refer to Section 6.1 for excipient.

3. PHARMACEUTICAL FORM

Oblong, pale yellow film-coated tablet, convex faces and break-bar embossed on one face.

4. CLINICAL PARTICULARS

Therapeutic indication

Cimetidine is indicated in the:

- Prophylaxis and treatment of duodenal ulcer.
- Short-term treatment of active benign gastric ulcer.
- Treatment of pathological gastric hypersecretion states, such as Zollinger-Ellison syndrome.
- Treatment of acute gastroesophageal reflux disease.
- Treatment of upper gastrointestinal bleeding.

4.2 Posology and Method of administration

Route of administration is oral.

Duodenal or benign gastric ulcer:

A single daily dose of 800 mg at bedtime, or 400 mg twice a day with breakfast and at bedtime, or 200 mg three times a day with meals and 400 mg at bedtime (1.0 g/day), or 400mg four times a day with meals and at bedtime (1.6 g/day).

Treatment should be given initially for at least four weeks (six weeks in benign gastric ulcer).

Oesophageal reflux disease:

400 mg four times a day, with meals and at bedtime, for 4 to 8 weeks.

Gastric hypersecretion states (eg Zollinger-Ellison Syndrome):

400 mg four times a day.

The total daily dose should not exceed 2.4 g. Dosage should be reduced in patients with impaired renal function. Antacids can be made available to all patients until symptoms disappear.

Children (more than one year old):

Oral, 25 - 30 mg/kg of body weight per day in divided doses.

Contraindication

- Avoid in patients known to be hypersensitive to histamine H2-receptors antagonists.
- It should not be used in nursing mothers.

Warnings and precautions

- Caution in patients with cirrhosis, history of portal systemic encephalopathy, hepatic and renal function impairment.
- Safety for use in pregnancy has not been established.
- Dosage should be reduced in patients with impaired renal function.
- Care should be taken in patients with a history of peptic ulcer, particularly the elderly.

Drug Interactions

Concurrent use with the following drugs requires careful monitoring:

- Theophylline, phenytoin, lidocaine, anti-arrhythmias, benzodiazepines, some beta-blockers and some vasodilators.
- Adjustment to anti-coagulant medications may be necessary during and after cimetidine therapy to prevent bleeding due to anti-coagulant potentiation.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Main Side/ Adverse Effects

Diarrhoea, dizziness, tiredness, rashes. Reversible confusional states, especially in the elderly or in seriously ill patients such as those with renal failure, gynaecomastia and impotence have occasionally occurred.

4.9 Overdose

Clinical features:

Allergic reaction, bradycardia or tachycardia, bronchospasm, confusion, neutropenia or other blood dyscrasias and fever may occur.

Treat overdosage by emesis or gastric lavage; artificial respiration in the event of respiratory failure and administration of beta-blocker to control tachycardia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cimetidine inhibits basal and nocturnal gastric acid secretion by competitive inhibition of the action of histamine at the histamine H2-receptors. It also inhibits gastric acid secretion stimulated by food, betasole, pentagastrin, caffeine, insulin and physiological vagal reflex

5.2 Pharmacokinetic properties

Cimetidine is well absorbed from the gastrointestinal tract and is weakly bound to plasma proteins. It is partially metabolised in the liver and most of an oral dose of cimetidine is excreted unchanged in the urine.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

List of excipients

Dodecyl Sulphate Sodium Salt (Sodium Lauryl Sulphate)
Cornstarch
Polyvinylpyrrolidone K-25
Microcrystalline Cellulose PH101
Magnesium Stearate
Pregelatinised Cornstarch
Sodium Starch Glycolate
Propylene Glycol
Isopropyl Alcohol
Iron Oxide Yellow
Talc
Titanium Dioxide
Hydroxypropyl Methylcellulose E-5
Hydroxypropyl Methylcellulose E-15

Incompatibilities

NOT APPLICABLE

Shelf life

3 years from date of manufacture

Special precaution for storage

Store below 30°C. Protect from light and moisture.

Nature and contents of container

Primary Packaging			
1	PVC film		
	Appearance	:	Clear transparent film
	Thickness	:	0.25 ± 0.02 mm
	Shrinkage	:	Not more than 8.0%
	Grammage	:	318.25 to 351.75 g/m2
2	Aluminium foil		
	Description	:	Aluminium foil with high slip primer on bright surface and heat seal on matt surface.
	Thickness	:	25 - 31 micron
	Grammage	:	57.6 – 70.4 gsm
Secondary Packaging			
1	Type	:	Unit box
	Material	:	Paper carton

6.6 Instructions for use and handling <and disposal>

NOT APPLICABLE

7. MARKETING AUTHORISATION HOLDER

Name: HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Manufacturer Name :

Name	:	HOVID Bhd.
Address	:	Lot 56442, 7 ½ Miles, Jalan Ipoh / Chemor, 31200 Chemor, Perak., Malaysia.

8. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

HOV/MAL/014

9. DATE OF FIRST AUTHORISATION\

November 2003

10. DATE OF REVISION OF THE TEXT

October 2019