

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

SUMMARY OF CHARACTERISTICS OF PRODUCTS

1. NAME OF THE MEDICINAL PRODUCT

OMESHAL-D CAPSULES (Domperidone & Omeprazole Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr.No.	Approved Name (if any)	Quantity / capsule in mg
1.	Omeprazole BP (as Omeprazole Enteric Coated Pellets 10 % IH)	200.00
2.	Domperidone Maleate BP (as Immediate Release Pellets 16 % IH)	79.530
3.	Size “2” Empty hard Gelatin Capsules with opaque purple coloured cap & opaque white body IH	1 No.

Definitions:

BP: British Pharmacopoeia

IH: In-house Specification

3. PHARMACEUTICAL FORM

Capsules (Oral)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Omeshal D is useful in the treatment of the following condition:

- Gastro-esophageal reflux disease [digestive disease in which stomach acid or bile irritates esophagus (food pipe)] and
- Dyspepsia (indigestion) caused by gastroparesis (stomach cannot empty) and gastroesophageal reflux.

4.2 Posology and method of administration

Adult: 1 capsule of Omeshal D twice daily, before meals for 4-8 weeks.

4.3 Contraindications

Do not use Omeshal D Capsule in the following conditions:

- An allergy to any of the constituents of it.
- Bleeding, obstruction or perforation in the digestive tract.
- Prolactin-releasing pituitary tumour (prolactinoma).

4.4 Special warnings and precautions for use

Omeprazole to be used with care in patients taking warfarin or phenytoin.

Rule out the possibility of stomach cancer before starting the omeprazole therapy.

Domperidone can cause galactorrhoea (excessive or inappropriate production of milk) in females and less frequently gynaecomastia (enlargement of breasts) in males. A severe increase in blood pressure may occur in patients with phaeochromocytoma (a rare tumor of adrenal gland tissue), impaired function of kidney and at risk of water retention.

4.5 Interaction with other medicinal products and other forms of interaction

Please tell the health care provider if taking or have recently taken any of the following:

Diazepam, phenytoin, blood thinners (Coumadin), ampicillin, digoxin, iron preparations and ketoconazole, anticholinergic medicine, cimetidine, and sodium bicarbonate.

4.6 Pregnancy and lactation

Ask the health care provider for advice before taking any Omeshal D Capsules in pregnant or breast-feeding women. It is used during pregnancy only if the benefit justifies the potential risk to the fetus.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Omeprazole is well tolerated and safe in majority of patients. It may cause headache, stomach pain, nausea, vomiting, diarrhoea, constipation, flatulence, skin rash and giddiness (impaired balance), muscle or joint pain, urinary tract infection, and sleepiness.

Domperidone-Dry mouth, transient skin rash, itching, headache, diarrhoea and rarely nervousness.

4.9 Overdose

For Omeprazole symptoms of overdosage may include confusion, drowsiness, blurred vision, nausea, vomiting, headache, dry mouth. In case of Domperidone, symptoms of overdosage may include drowsiness, disorientation & extra pyramidal reactions especially in children.

Contact the health care provider immediately and say exactly how much quantity is taken. The health care provider will advise what to do. It is important to contact the health care provider even if one feels well.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Omeprazole is benzimidazole derivative and belongs to the proton pump inhibitors (PPI's) class of medicines. Domperidone is a peripheral dopamine D2-receptor antagonist (blocker).

ATC Code: Omeprazole: A02BC01 & Domperidone: A03FA03

Mechanism of action

Omeprazole permanently blocks the action of enzyme hydrogen potassium ATPase (H^+/K^+ ATPase or the proton pump) present in the stomach (a part of digestive tract) and inhibits the secretion of gastric acid.

Domperidone stimulates emptying of stomach contents and effectively relieves symptoms of reflux esophagitis [injury to mucosa of esophagus (food pipe) due to back flow of stomach content] by blocking peripheral dopamine D2-receptors. Domperidone is also effective in reducing nausea.

5.2 Pharmacokinetic properties

The absorption of Omeprazole is fast and 30-40% of the medicine enters into blood circulation.

The peak concentration in the plasma (fluid part of blood) is reached within 0.5 to 3.5 hours after the dose of 40 mg.

Domperidone is rapidly absorbed, with the peak plasma concentration is reached in approximately 1 hour after oral administration. It is altered chemically in the liver and eliminated from the body in the urine and faeces at 31% and 66% of the oral dose, respectively.

5.3 Preclinical safety data

Not Applicable

6.1 List of excipients

Size "2" Empty hard gelatin capsules with purple color cap & white opaque body.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

36 months (3 Years)

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

Omeshal-D Capsule is available in a strip pack of 10 capsules.

6.6 Special precautions for disposal and other handling

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

7. MARKETING AUTHORISATION HOLDER

Shalina Healthcare Nigeria Limited

8. DATE OF UPDATE OF TEXT

Every two years.