SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

1.1 Product Name

STROZOLE

Omeprazole Capsules BP 20 mg

1.2 Strength

Omeprazole BP 20 mg

1.3 Pharmaceutical Form

Capsules for Oral Administration

2. Quality and Quantitative Composition

2.1 Qualitative Declaration

Each Hard gelatin Capsules Contains:

Omeprazole BP 20 mg

(As enteric coated granules)

Excipients q.s.

2.2 Quantitative Declaration

Sr. No	Ingredients	Specification	Quantity per Capsule (mg)	Overages (%)	Standard Quantity Per Batch (Kg)	Functions
1.	Omeprazole 7.5% enteric coated granules	BP	272	2	27.200	Active Pharmaceutical Ingredient
Average fill weight of capsule 272.00 mg						
2.	Empty hard gelatin capsule	BP	1	--	1,00,000	Capsule Shell
Average weight of filled capsule 335.00 mg						

* 2% Overages have been added to compensate the process loss.

3. Pharmaceutical Form

Description:

Transparent pink (cap) / colourless (body) hard gelatin capsules of size '2' containing white to off white coloured spherical granules.

4. Clinical Particulars

4.1 Therapeutic indications

Treatment and Prevention of relapse of duodenal ulcers

Treatment and Prevention of relapse of gastric ulcers

In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease.

Treatment of NSAID-associated gastric and duodenal ulcers

Treatment of reflux oesophagitis

Treatment of symptomatic gastro-oesophageal reflux disease

Treatment of Zollinger-Ellison syndrome

4.2 Posology and Method of Administration

For the relief of Acid-related Dyspepsia

Omeprazole is given in usual doses of 10 or 20 mg daily orally for 2 to 4 weeks.

Gastroesophageal Reflux Disease (GERD)

The usual dose is 20 mg orally once daily for 4 weeks, followed by a further 4 to 8 weeks if not fully healed.

Refractory Esophagitis

A dose of 40mg daily may be used. Maintenance therapy after healing of esophagitis is 20 mg once daily, and for acid reflux is 10 mg daily.

Peptic Ulcer Disease

A single dose of 20mg daily, or 40 mg in severe cased, is give. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer.

For eradication of Helicobacter pylori in Peptic Ulceration

Omeprazole may be combined with antibacterials in dual or triple therapy. Effective triple therapy regimens include Omeprazole 20mg twice daily or 40mg once daily combined with:

Amoxicillin 500mg and Metronidazole 500mg, both three times daily; Clarithromycin 250mg and Metronidazole 500mg (or Tinidazole 500mg) both twice daily;

or with Amoxicillin 1 g and Clarithromycin 500mg, both twice daily. These regimens are given 1 week. Dual therapy regimens such as Omeprazole 20mg twice daily or 40mg daily with either Amoxicillin 750mg to 1 gram twice daily or Clarithromycin 500mg three times daily, are less effective and must be given for 2 weeks. Omeprazole alone may be continued for a further 4 to 8 weeks.

Treatment of NSAID-associated Ulceration

Doses of 20mg dialy orally are used; a dose of 20mg daily may also be used for prophylaxis in patients with a history of gastroduodenal lesions who require continued NSAID treatment.

Zollinger-Ellison Syndrome

The initial recommended dosage is 60mg orally once daily, adjusted as required. The majority of patients are effectively controlled by doses in range 20 to 120mg, but doses up to 120mg three times daily have been used. Daily doses above 80mg should be given as divided doses.

Prophylaxis of acid aspiration during general anesthesia

Omeprazole is also used for the prophylaxis of acid aspiration during general anesthesia, in a dose of 40mg the evening before surgery and a further 40mg two to six hours before the procedure.

Dosage for Children

For the treatment of gastroesophageal reflux disease in children 1 year of age and over are determined by body-weight as follows: 10 to 20kg: 10 mg once daily; over 20mg once daily. These doses may be doubled if necessary. Treatment may be given for 4 to 12 weeks.

Method of Administration

Omeprazole should be taken immediately before a meal, preferably in the morning. If you forget to take a dose of Omeprazole, take it as soon as you remember. If it is almost time for your next dose, skip the one you forgot and continue with your regular schedule. Do not take a double dose.

4.3 Contraindications

Omeprazole should not be used to patients who are/have:

1. Chronic, current or history of hepatic disease;
2. Presence of gastric malignancy;
3. Pregnancy and lactation;
4. Sensitive to Omeprazole or any component of the capsules;
5. Children: Safety and efficacy for children are not established.

4.4 Special warning and precautions for use

Pregnancy and Lactation

Animal studies with Omeprazole have shown toxic effects in developing fetuses, but no such problems have been reported in humans. However, as with most drugs, pregnant women, and those who might become pregnant, should not use Omeprazole unless its advantages clearly outweigh its possible dangers.

Because of tumorigenic potential of Omeprazole in animals at high doses, a decision should be made on whether nursing should be discontinued or the medicament withdrawn taking into account the importance of Omeprazole to the mother.

Elderly

Elderly exhibit the same side effects seen in younger adults. However, older adults are likely to have age-related reduction in kidney and/or liver function, which could account or increased amounts of drug in the bloodstream. Report any unusual side effects to your doctor.

4.5 Interaction with other medicinal products and other forms of interactions

1. Omeprazole and other proton pump inhibitors are metabolized by cytochrome P450 system, primarily by isoenzyme CYP2C19, and to a smaller extent by CYP3A4. Inhibitors or inducers of these isoenzymes may affect exposure to Omeprazole and other proton pump inhibitors. In turn, proton pump inhibitors may alter the metabolism of some drugs metabolized by these enzymes.
2. Omeprazole may prolong the elimination of diazepam, phenytoin, and warfarin by slowing the breakdown of these drugs by liver. It may also interact with other drugs broken down by the liver.
3. Omeprazole and other proton pump inhibitors can reduce the absorption of drugs such as dasatinib, ketoconazole, itraconazole, ampicillin and iron, whose absorption is dependent on the acid gastric pH.
4. With voriconazole, the plasma concentration of both drugs may be increased.
5. Omeprazole and other proton pump inhibitors should be used with atazanavir, as it substantially reduces exposure to atazanavir.
6. The use of Omeprazole with drugs that reduce the production of blood cells by the bone marrow may increase their effect.
7. Exclude the presence of gastric malignancy, as treatment with Omeprazole may delay diagnosis by alleviating symptoms.

4.6 Pregnancy and lactation

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4.7 Effects on ability to drive and use machine

Omeprazole is not likely to affect the ability to drive or use machines. Adverse drug reactions such as dizziness and visual disturbances may occur. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

The most common side effects (1-10% of patients) are headache, abdominal pain, constipation, diarrhoea, flatulence and nausea/vomiting.

The following adverse drug reactions have been identified or suspected in the clinical trials programme for omeprazole and post-marketing. None was found to be dose-related. Adverse reactions listed below are classified according to frequency and System Organ Class (SOC). Frequency categories are defined according to the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), Not known (cannot be estimated from the available data).

SOC/frequency	Adverse reaction
Blood and lymphatic system disorders	
Rare:	Leukopenia, thrombocytopenia
Very rare:	Agranulocytosis, pancytopenia
Immune system disorders	
Rare:	Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock
Metabolism and nutrition disorders	
Rare:	Hyponatraemia
Not Known:	Hypomagnesaemia
Psychiatric disorders	
Uncommon:	Insomnia
Rare:	Agitation, confusion, depression
Very rare:	Aggression, hallucinations
Nervous system disorders	
Common:	Headache
Uncommon:	Dizziness, paraesthesia, somnolence
Rare:	Taste disturbance
Eye disorders	
Rare:	Blurred vision

Ear and labyrinth disorders	
Uncommon:	Vertigo
Respiratory, thoracic and mediastinal disorders	
Rare:	Bronchospasm
Gastrointestinal disordersz	
Common:	Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting
Rare:	Dry mouth, stomatitis, gastrointestinal candidiasis
Not Known	microscopic colitis
Hepatobiliary disorders	
Uncommon:	Increased liver enzymes
Rare:	Hepatitis with or without jaundice
Very rare:	Hepatic failure, encephalopathy in patients with pre-existing liver disease
Skin and subcutaneous tissue disorders	
Uncommon:	Dermatitis, pruritus, rash, urticaria
Rare:	Alopecia, photosensitivity
Very rare:	Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)
Not known:	Subacute cutaneous lupus erythematosus
Musculoskeletal and connective tissue disorders	
Uncommon:	Fracture of the hip, wrist or spine
Rare:	Arthralgia, myalgia
Very rare:	Muscular weakness
Renal and urinary disorders	
Rare:	Interstitial nephritis
Reproductive system and breast disorders	
Very rare:	Gynaecomastia
General disorders and administration site conditions	
Uncommon:	Malaise, peripheral oedema

Rare:	Increased sweating

4.9 Overdose

No specific antidote for Omeprazole overdosage is known. The drug is extensively protein bound and is, therefore, not readily dialyzed. Overdose symptoms are likely to be similar to Omeprazole's side effects. In the event of overdosage; treatment should be symptomatic and supportive. Call you local poison control centre or hospital emergency room for additional information.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Omeprazole is a substituted benzimidazole which suppresses gastric acid secretion. Omeprazole is activated at an acidic pH to a sulphenamide derivative that binds irreversibly to H+/K+ More

ATPase, an enzyme system found at the secretory surface of parietal cells. It hereby inhibits the final transport of hydrogen ions to the gastric lumen.

Therefore, Omeprazole has been referred to as an acid or proton pump inhibitor. Omeprazole inhibits basal and stimulated gastric acid secretion. The degree of inhibition of gastric acid secretion is related to the dose and duration of therapy.

5.2 Pharmacokinetic Properties

Omeprazole is rapidly but variably absorbed after oral doses. Absorption is not significantly affected by food. Omeprazole is acid-labile and the pharmacokinetics of the various formulation develop to improve oral bioavailability may vary. The absorption of Omeprazole also appears to be dose-dependent; increasing the dosage above 40mg has been reported to increase the plasma concentrations in non-linear fashion because of saturable first-pass hepatic metabolism. In addition, bioavailability is higher after long-term use. Bioavailability of Omeprazole may be increased in elderly patients, in some ethnic groups such as Chinese, and in patients with hepatic impairment, but is not markedly affected in patients with renal impairment. On absorption, Omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxyl-omeprazole, and to a small extent by CYP3A4 to form omeprazole sulfone. The metabolites are inactive, and are excreted mostly in the urine and to a lesser extent in bile. The elimination half-life from plasma is reported to be about 0.5 to 3 hours. Omeprazole is about 95% bound to plasma proteins.

5.3 Preclinical Safety Data

Gastric ECL-cell hyperplasia and carcinoids, have been observed in life-long studies in rats treated with omeprazole. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition. Similar findings have been made after treatment with H2-receptor antagonists, proton pump inhibitors and after partial fundectomy. Thus, these changes are not from a direct effect of any individual active substance.

6. Pharmaceutical Particulars

6.1 List of Excipients

"2" Size pink/clear transparent empty hard gelatin capsules

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special Precautions for storage

Store at a temperature not exceeding 30^0C. Protect from light & moisture.

6.5 Nature and Contents of Container

10 Capsules packed in Alu-Alu blister or

07 Capsules packed in Alu-Alu blister

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirement.

7. Marketing Authorization Holder / Manufacturer

GLOBAL ORGANICS LTD.

Plot -868, KM-34,

Lagos Abeokuta express way,

Lagos state,

NIGERIA

Marketing Authorization Numbers

NA

8. Date of revision of text

June 2018