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Faast®+

(Omeprazole + Sodium Bicarbonate)

Capsule

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COMPOSITION:

Faast + 20/1100 Capsule:

Each capsule contains:

Omeprazole BP ..... 20 mg.

Sodium Bicarbonate BP ..... 1100 mg.

Product Specs.: CCL Pharmaceuticals

Faast + 40/1100 Capsule:

Each capsule contains:

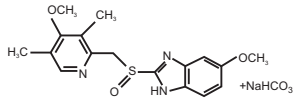
Omeprazole BP ..... 40 mg.

Sodium Bicarbonate BP ..... 1100 mg.

Product Specs.: CCL Pharmaceuticals

DESCRIPTION:

Faast + (Omeprazole/Sodium Bicarbonate) is a combination of **Omeprazole,** a proton-pump inhibitor, and sodium bicarbonate, an antacid. **Omeprazole** is a substituted benzimidazole,5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1*H*-benzimidazole, a racemic mixture of two enantiomers that inhibits gastric acid secretion. Its empirical formula is $C_{17}H_{19}N_3O_3S$, with a molecular weight of **Omeprazole** 345.417g/ml.



CLINICAL PHARMACOLOGY:

Omeprazole is acid labile and thus rapidly degraded by gastric acid. **Faast + (Omeprazole/Sodium Bicarbonate)** Capsules are immediate-release formulations that contain sodium bicarbonate which raises the gastric pH and thus protects **Omeprazole** from acid degradation.

Pharmacokinetics:

Absorption: The absorption of **Omeprazole** is rapid, with mean peak plasma levels (% CV) of **Omeprazole** being 1954 ng/mL (33%) and 1526 ng/mL (49%), respectively, and time to peak of approximately 30 minutes (range 10-90 min) after a single-dose or repeated-dose administration.

Following single or repeated once daily dosing, peak plasma concentrations of **Omeprazole** from **Omeprazole/Sodium Bicarbonate** are approximately proportional from 20 to 40 mg doses, but a greater than linear mean AUC (three-fold increase) is observed when doubling the dose to 40 mg. The bioavailability of **Omeprazole** from **Omeprazole/Sodium Bicarbonate** increases upon repeated administration.

Distribution: **Omeprazole** is bound to plasma proteins. Protein binding is approximately 95%.

Metabolism: Following single-dose oral administration of **Omeprazole,** the majority of the dose (about 77%) is eliminated in urine as at least six metabolites. The remainder of the dose was recoverable in feces. This implies a significant biliary excretion of the metabolites of **Omeprazole.**

Excretion: Following single-dose oral administration of **Omeprazole,** little if any, unchanged drug is excreted in urine. The mean plasma **Omeprazole** half-life in healthy subjects is approximately 1 hour (range 0.4 to 3.2 hours) and the total body clearance is 500-600 mL/min.

Special Populations:

Geriatric: The elimination rate of **Omeprazole** was somewhat decreased in the elderly and bioavailability was increased. The plasma clearance of **Omeprazole** was 250 mL/min (about half that of young subjects). However, no dosage adjustment is necessary in the elderly.

Pediatric: The pharmacokinetics of **Faast + (Omeprazole/Sodium Bicarbonate)** have not been studied in patients < 18 years of age.

Gender: There are no known differences in the absorption or excretion of **Omeprazole** between males and females.

Hepatic insufficiency: In patients with chronic hepatic disease, the bioavailability of **Omeprazole** from a buffered solution increased to approximately 100% compared to an I.V. dose, reflecting decreased first-pass effect, and the mean plasma half-life of the drug increased to nearly 3 hours compared to the mean half-life of 1 hour in normal subjects. Plasma clearance averaged 70 mL/min compared to a value of 500-600 mL/min in normal subjects.

Renal insufficiency: In patients with chronic renal impairment, whose creatinine clearance ranged between 10 and 62 mL/min/1.73 m^2, the disposition of **Omeprazole** from a buffered solution was very similar to that in healthy subjects, although there was a slight increase in bioavailability. Because urinary excretion is a primary route of excretion of **Omeprazole** metabolites, their elimination slowed in proportion to the decreased creatinine clearance.

INDICATIONS:

Duodenal ulcer: **Faast + (Omeprazole/Sodium Bicarbonate)** is indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Gastric ulcer: **Faast + (Omeprazole/Sodium Bicarbonate)** is indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer.

Treatment of Gastroesophageal Reflux Disease (GERD):

Symptomatic GERD: **Faast + (Omeprazole/Sodium Bicarbonate)** is indicated for the treatment of heart burn and other symptoms associated with GERD.

Erosive Esophagitis: **Faast + (Omeprazole/Sodium Bicarbonate)** is indicated for the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy. ***Maintenance of healing of erosive Esophagitis:*** **Faast + (Omeprazole/Sodium Bicarbonate)** is indicated to maintain healing of erosive esophagitis.

DOSAGE AND ADMINISTRATION:

Since both the 20 mg and 40 mg **capsules** contain the same amount of sodium bicarbonate (1100 mg), two capsules of 20 mg are not equivalent to one capsule of **Faast + (Omeprazole/Sodium Bicarbonate)** 40 mg therefore two 20 mg capsules of **Faast + (Omeprazole/Sodium Bicarbonate)** should not be substituted for one capsule of **Faast + (Omeprazole/Sodium Bicarbonate)** 40 mg. **Faast + (Omeprazole/Sodium Bicarbonate)** should be taken on an empty stomach at least one hour before a meal. For patients receiving continuous NG/OG tube feeding, enteral feeding should be suspended approximately 3 hours before and 1 hour after administration of **Faast + (Omeprazole/Sodium Bicarbonate).**

Table: Recommended Doses of Faast + (Omeprazole/Sodium Bicarbonate) by Indication for Adults 18 Years and Older

Indication	Recommended Dose	Frequency
Short-Term Treatment of Active Duodenal Ulcer	20 mg / 1100	Once daily for 4 weeks *
Benign Gastric Ulcer	40 mg / 1100	Once daily for 4-8 weeks
Gastroesophageal Reflux Disease (GERD)		
Symptomatic GERD(with no esophageal erosions)	20 mg / 1100	Once daily for up to 4weeks *
Erosive Esophagitis	20 mg / 1100	Once daily for 4-8 weeks
Maintenance of Healing of Erosive Esophagitis	20 mg / 1100	Once daily

* Most patients heal within 4 weeks. Some patients may require an additional 4 weeks of therapy.

ADMINISTRATION:

Faast + (Omeprazole/Sodium Bicarbonate) Capsules should be swallowed intact with water.

DO NOT USE OTHER LIQUIDS. DO NOT OPEN CAPSULE AND SPRINKLE CONTENTS INTO FOOD.

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SIDE EFFECTS:

Body as a whole: Allergic reactions including rarely anaphylaxis, fever, pain, fatigue, malaise, abdominal swelling.

Cardiovascular: Chest pain or angina, tachycardia, bradycardia, palpitation, elevated blood pressure, and peripheral edema.

Gastrointestinal: Pancreatitis (some fatal), anorexia, irritable colon, flatulence, fecal discoloration, esophageal candidiasis, mucosal atrophy of the tongue, dry mouth, stomatitis. During treatment with **Omeprazole,** gastric fundic gland polyps have been noted rarely. These polyps are benign and appear to be reversible when treatment is discontinued. Gastroduodenal carcinoids have been reported in patients with Zollinger-Ellison syndrome on long-term treatment with **Omeprazole.** This finding is believed to be a manifestation of the underlying condition, which is known to be associated with such tumors.

Hepatic: Mild and rarely marked elevations of liver function tests [ALT (SGPT), AST (SGOT), γ-glutamyl transpeptidase, alkaline phosphatase and bilirubin (jaundice)]. In rare instances, overt liver disease has occurred, including hepatocellular, cholestatic, or mixed hepatitis, liver necrosis (some fatal), hepatic failure (some fatal), and hepatic encephalopathy.

Metabolic/Nutritional: Hyponatremia, hypoglycemia, and weight gain.

Musculoskeletal: Muscle cramps, myalgia, muscle weakness, joint pain, and leg pain.

Nervous system/Psychiatric: Psychic disturbances including depression, agitation, aggression, hallucinations, confusion, insomnia, nervousness, tremors, apathy, somnolence, anxiety, dream abnormalities; vertigo; paresthesia; and hemifacial dysesthesia.

Respiratory: Epistaxis, pharyngeal pain.

Skin: Rash and rarely cases of severe generalized skin reactions including toxic epidermal necrolysis (TEN; some fatal), Stevens-Johnson syndrome and erythema multiforme (some severe) purpura and/or petechiae (some with rechallenge), skin inflammation, urticaria, angioedema, pruritus, photosensitivity, alopecia, dry skin, and hyperhidrosis.

Special senses: Tinnitus, taste perversion.

Ocular: Blurred vision, ocular irritation, dry eye syndrome, optic atrophy, anterior ischemic optic neuropathy, optic neuritis and double vision.

Urogenital: Interstitial nephritis (some with positive rechallenge), urinary tract infection, microscopic pyuria, urinary frequency, elevated serum creatinine, proteinuria, hematuria, glycosuria, testicular pain and gynecomastia.

Hematologic: Rare instances of pancytopenia, agranulocytosis (some fatal), thrombocytopenia, neutropenia, leukopenia, anemia, leucocytosis, and hemolytic anemia have been reported. The incidence of clinical adverse experiences in patients greater than 65 years of age was similar to that in patients 65 years of age or less. Additional adverse reactions that could be caused by sodium bicarbonate include metabolic alkalosis, seizures, and tetany.

DRUG INTERACTIONS:

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including **Omeprazole,** and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with proton pump inhibitors and warfarin may need to be monitored for increases in INR and prothrombin time. Because of its profound and long-lasting inhibition of gastric acid secretion, it is theoretically possible that **Omeprazole** may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g. ketoconazole, ampicillin esters, and iron salts). Concomitant administration of **Omeprazole** and atazanavir has been reported to reduce the plasma levels of atazanavir. Concomitant administration of **Omeprazole** and tacrolimus may increase the serum levels of tacrolimus. Co-administration of **Omeprazole** and clarithromycin have resulted in increases of plasma levels of **Omeprazole,** clarithromycin and 14-hydroxy-clarithromycin.

WARNINGS: No information provided.

PRECAUTIONS:

General:

Symptomatic response to therapy with **Omeprazole** does not preclude the presence of gastric malignancy. The sodium content of **Faast + (Omeprazole/Sodium Bicarbonate)** products should be taken into consideration when administering to patients on a sodium restricted diet. **Sodium Bicarbonate** is contraindicated in patients with metabolic alkalosis and hypocalcemia. **Sodium Bicarbonate** should be used with caution in patients with Bartter's syndrome, hypokalemia, respiratory alkalosis and problems with acid-base balance. Long-term administration of bicarbonate with calcium or milk can cause milk-alkali syndrome.

Pregnancy:

Pregnancy Category C:

There are no adequate and well-controlled studies in pregnant women. Because animal studies and studies in humans cannot rule out the possibility of harm. **Omeprazole** should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Nursing mothers: **Omeprazole** is excreted in human milk, because of the potential for serious adverse reactions in nursing infants from **Omeprazole** and because of the potential for tumorigenicity shown for **Omeprazole** in rat carcinogenicity studies, a decision should be taken to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. In addition, **Sodium Bicarbonate** should be used with caution in nursing mothers.

Pediatric use: Clinical studies have been conducted evaluating delayed-release **Omeprazole** in pediatric patients. There are no adequate and well-controlled studies in pediatric patients with **Faast + (Omeprazole/Sodium Bicarbonate)**.

Geriatric use: Pharmacokinetic studies with buffered **Omeprazole** have shown the elimination rate was somewhat decreased in the elderly and bioavailability was increased. The plasma clearance of **Omeprazole** was 250 mL/min (about half that of young subjects). However, no dosage adjustment is necessary in the elderly.

OVERDOSE:

Reports have been received of overdosage with **Omeprazole** in humans. Doses ranged up to 2400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience. No specific antidote for **Omeprazole** overdosage is known. **Omeprazole** is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive. As with the management of any overdose, the possibility of multiple drug ingestion should be considered. In addition, a **Sodium Bicarbonate** overdose may cause hypocalcemia, hypokalemia, hypernatremia and seizures.

CONTRAINDICATIONS:

Faast + (Omeprazole/Sodium Bicarbonate) is contraindicated in patients with known hypersensitivity to any components of the formulation.

INSTRUCTIONS

- Store below 30ºC.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Faast + 20/1100 Capsule: : Pack of 2 x 7 capsules.

Faast + 40/1100 Capsule: : Pack of 2 x 7 capsules.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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