SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

UNIENZYME cMPS TABLETS

1. Name of the Medicinal Product
UNIENZYME cMPS Tablets

2. Qualitative & Quantitative Composition
Fungal Diastase (1:800) …… 20 mg
Papain USP …….. 30 mg
Simethicone USP ……..... 50 mg
Activated Charcoal BP ……. 75 mg
Nicotinamide BP …….. 25 mg

3. Pharmaceutical Form
Tablet

4 Clinical Particulars
4.1 Therapeutic Indications
Symptomatic relief in digestive disorders manifested by dyspepsia, belching, abdominal discomfort or feeling of abdominal fullness.

4.2 Posology and method of administration
Adults and children, older then 7 years, are prescribed of 1 tablet along with water 1-2 times a day after food. The term of treatment depends on the course of the disease in patient.

4.3 Contraindications
Hypersensitivity to any of the ingredients. Nicotinic acid is contraindicated in hepatic dysfunction, intestinal obstruction and active peptic ulcer.__

4.4 Special Warnings and Special Precautions for use
The preparation contains lactose, therefore patients with rare genetic forms of galactose intolerance, lactase deficiency or glucose-galactose malabsorption syndrome should not use the preparation.
The preparation contains sucrose, which should be considered in patients with diabetes.
Activated charcoal may color the faeces black.
Nicotinic acid should be given cautiously to patients with a history of peptic ulcer disease and to patients with diabetes mellitus, gout or impaired liver function.

4.5Interaction with other medicinal products and other forms of interaction
Activated charcoal has the potential to reduce the absorption of many drugs from the gastro-intestinal tract. Hereby it is better to avoid the simultaneous oral therapy. Hence the medicine should be administrated 2 hours before or 1 hour after administration of other medicine, especially in case of administration of oral antidotes as methionine. Nicotinic acid may increase requirement of insulin or oral hypoglycemics.
Activated charcoal diminishes the action of ipecacuanha and other emetics during simultaneous oral administration.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

UNIENZYME cMPS TABLETS

4.6 Pregnancy and Lactation
It is not recommended to use the preparation during pregnancy and lactation.

4.7 Effects on ability to drive and use machines
The preparation does not influence on ability to drive and perform works, which require heightened attention.

4.8 Undesirable Effects
Caused by Nicotinamide: in particular cases may occur allergic reactions in the form of dermahemia, rash (fine pots, menocelis, urticaria), sometimes itching, hypersensitivity or idiosyncratic reactions. High doses of nicotinic acid may cause stomach ache, activation of the gastric ulcer and duodenum, nausea, vomiting, diarrhea, warm sensation into limbs, dry skin, hypotension, short-term head ache, arrhythmia, impaired glucose tolerance.
Caused by activated charcoal: may occur constipation, diarrhea, nausea, vomiting; during long-term use of preparation may be generated the deficiency of vitamins, hormones, fats, proteins, which require relevant medicinal correction.
Adverse reactions of fungal diastase, papain, simethicone (MPS) were not observed.

4.9 Overdose
To the best of our knowledge, no instances of deliberate or accidental overdose have been reported. Nicotinamide overdose can cause stomach pain, increasing of peristalsis; possible nausea, sometimes vomiting. In the event of overdosage, supportive and symptomatic therapy is indicated after stomach lavage.

5 Pharmacological Properties
5.1 Pharmacodynamic Properties
Fungal diastase. It is an enzyme obtained from the growth of a strain of Aspergillus oryzae. It contains two types of amylases namely, alpha amylase and beta amylase. These amylases have specific activity to convert starch into dextrose, maltose. The amylolytic activity ratio of fungal diastase in tablets is 1:800. It means that, one part of fungal diastase digests 800 parts of cooked starch that is consumed with meal. Fungal diastase also has some protease action and some lipase activity. This means that some digestive action is seen on proteins and fats.
Papain. It is a proteolytic enzyme or mixture of enzymes, which have plant origin. Papain is prepared from the juice of the unripe fruit of Carica Papaya. The enzyme consists chiefly of a mixture of papain and chymopapain, which digest proteins to enzymes.

Papain has a proteolytic activity, which is like that of the natural enzyme pepsin. The advantage of papain over pepsin is that it is active over a wide pH range of 3 to 10.5 as compared to pepsin (which is not active above a pH of 4.5).
Papain therefore is active in different pH value. Hence it is useful even in conditions of achlorhydria or hypochlorhydria. It is thus used as one of the ingredients in enzyme preparations to aid in protein digestion.
Nicotinamide. Nicotinamide acts as a co-enzyme in the carbohydrate metabolism. Nicotinamide coenzymes (NAD and NADP) are essential for vital activity of all tissues. The essential function

of these coenzymes is a participation in tissue respiration (first link of respiratory chain) and cell energy metabolism. Usually, the insufficient quantity of this compound occurs under unbalanced diet in older patients. Lack of Nicotinamide may cause reducing of acid in the stomach, which has an effect on digestion and intestinal absorption; lactose intolerance, which is one of the mechanisms, causing diarrhea, may occur due to lack of Nicotinamide.
Simethicone (dimethylpolysiloxane) – non-toxic surface-active inert substance, which has defoaming properties, based on silica. Simethicone reduces the intestinal gas generation. It acts by lowering surface tension of gas bubbles, which occur in intestinal track under flatulence. Released gas is absorbed or expelled naturally. Simethicone does not influence on gastric secretion and absorption of nutrient materials. Simethicone reduces the bloating and pain, caused by higher flatulence.
Simethicone essentially improves the condition under flatulence, air swallowing, indigestion, absorbing and clearance.
Thus, the given component is an effective additive to the enzyme constituents of preparation.
Activated Charcoal. It is an enterosorbent. Specially prepared charcoal has high surface activity, adsorbs gases, alkaloids, endo- and exotoxins and other chemical compounds. Activated charcoal in the composition of Unienzyme® c MPS acts as enterosorbent and detoxicant, provides adsorbtion of gas and toxins, which occur under indigestion, adsorbs poorly soluble substances, reduces the volume capacity of intestinal track, and thereby produces relief from symptoms of flatulence and dyspepsia, acting complexly along with enzymes.
Thus, the preparation has all the necessary ingredients that will assist in proper digestion of the principle nutrients like carbohydrates, fats and proteins. Besides it also helps in relieving the associated complaints of indigestion like bloating, belching, abdominal fullness and flatulence.

5.2 Pharmacokinetic Properties

5.3 Preclinical Safety Data

---

6 Pharmaceutical Particulars

6.1 List of Excipients

Colloidal Anhydrous Silica BP
Microcrystalline Cellulose BP
Lactose BP
Acacia BP
Sodium Benzoate BP
Gelatin BP
Purified Talc BP
Magnesium Stearate BP
Carboxymethylcellulose Sodium BP
Microcrystalline Cellulose BP (Directly compressible)
Dichloromethane BP
Castor Oil BP
Calcium Carbonate BP

Vegetable Charcoal O. Sp.
Shellac BP
Sugar M30 O. Sp.
Carnauba Wax BP
White Bees Wax BP
Carbon Tetrachloride USP-NF
Industrial Methylated Spirit BP

6.2Incompatibilities
None

6.3Shelf Life
36 months

6.4Special Precautions for Storage
Store below 30°C.

6.5Nature and contents of container
a. Aluminum strip of 10 tablets; Such two strips are packed in carton along with pack insert.
b. Aluminum strip of 10 tablets; such two strips are packed in a carton along with pack insert. Further such five cartons are packed in printed outer carton.

6.6 Instructions for use and handling
Not Applicable

7 Marketing Authorization Holder
Unichem Laboratories Limited
Unichem Bhavan, Prabhat Estate, S.V. Road,
Jogeshwari (West), Mumbai 400 102 INDIA
Manufacturing site:
Unichem Laboratories Limited
C-31 , C-32 & D-10, Industrial Area,
Meerut Road, Ghaziabad 201 003,
India.

Marketing Authorization Number:

--

Date of first authorization/renewal of the authorization:

-

Date of revision of the text:

-