

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

UNIENZYME

1. Generic Name

Fungal Diastase, Papain & Activated Charcoal Tablets

2. Qualitative and quantitative composition

Each sugar coated tablet contains:

Fungal Diastase (1:800) I.P..... 100 mg

(Derived from *Aspergillus Oryzae*)

Papain I.P..... 60mg

Activated Charcoal I.P..... 75mg

(Appropriate Overages added)

Printing Colour: Titanium Dioxide I.P.

The excipients used are Colloidal Silicon Dioxide, Microcrystalline Cellulose, Dibasic Calcium Phosphate Dihydrate, Lactose Monohydrate, Gum Acacia, Gelatin, Sodium Benzoate, Talc, Magnesium Stearate, Shellac, Isopropyl Alcohol, Castor Oil, Calcium Carbonate, Sugar, Vegetable Charcoal Fine, Carnauba Wax, Edible Ink White.

3. Dosage form and strength

Dosage form: Sugar coated tablet

Strength: Fungal Diastase 100 mg, Papain 60mg and Activated Charcoal 75mg.

4. Clinical particulars

4.1 Therapeutic indication

This is indicated as symptomatic relief of functional dyspepsia and other gastrointestinal disorders which usually manifest with symptoms of bloating, belching, flatulence, abdominal discomfort or feeling of abdominal fullness.

4.2 Posology and method of administration

Dose: 2 Tablets after major meal or As directed by the physician.

4.3 Contraindications

UNIENZYME is contraindicated in patients with known hypersensitivity to any of the ingredients of the formulation.

4.4 Special warnings and precautions for use

History of the allergy, impairment of hepatic or renal function, G6-PD deficiency. To get periodic blood check & liver function tests to be done.

UNIENZYME is used with caution in patients with an allergy to fig and kiwi. Do not exceed the stated dose. Check the expiry date on the pack and do not use after expiry.

4.5 Drugs interactions

Not available

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Teratogenic effects

Pregnant and lactating women.

Patient with known hypersensitivity to any of ingredients of our Multi-enzyme preparation with MPS tablet

Flatulence, bloating belching, Dyspepsia, abdominal discomfort, Fullness heart burn

Pregnancy Category C:

Animal reproduction studies have not been conducted with UNIENZYME. It is also not known whether UNIENZYME can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The risk and benefit of UNIENZYME should be considered in the context of the need to provide adequate nutritional support to a pregnant woman with exocrine pancreatic insufficiency. Adequate caloric intake during pregnancy is important for normal maternal weight gain and fetal growth. Reduced maternal weight gain and malnutrition can be associated with adverse pregnancy outcomes. Patients should notify their healthcare professional if they are pregnant or are thinking of becoming pregnant during treatment with UNIENZYME.

Nursing Mothers

It is not known if UNIENZYME is excreted in human milk. Patients should notify their healthcare professional if they are breast-feeding.

Pediatric Use

The short-term safety and efficacy of UNIENZYME were assessed in a single, randomized, double-blind, placebo-controlled, crossover study of 32 patients with exocrine pancreatic insufficiency due to cystic fibrosis, including 12 patients between 12 and 18 years of age. The safety and efficacy in 12 to 18-year-old patients in this study were similar to adult patients.

The safety and efficacy of pancreatic enzyme products with different formulations of UNIENZYME consisting of the same active ingredient (lipases, proteases, and amylases) for treatment of children with exocrine pancreatic insufficiency due to cystic fibrosis have been described in the medical literature and through clinical experience.

4.7 Effects on ability to drive and use machines

Not available

4.8 Undesirable effects

Side Effect	
Events	No of patients (%)
Nausea	3 (3.3')

Skin Problems	2 (2.2%)
Total patients	3 (5.5%)

Nausea, hypersensitivity reactions and extensive destruction of the oesophageal wall with perforation may occur. Symptoms of side effects, if any, should subside after discontinuing the medicine. If symptoms persist, please consult the physician.

4.9 Overdose

Not available

5. Pharmacological properties

Not available

6. Nonclinical properties

Not available

7. Description

UNIENZYME is a combination of Papain, Fungal Diastase and Activated charcoal. Papain is an enzyme obtained from the juice of the unripe fruit of *Carica papaya* Linn. that digests protein and catalyses the breakdown of proteins by hydrolysis. It is sparingly soluble in water. Fungal Diastase is a potent, dependable and powerful enzyme complex obtained from *Aspergillus oryzae*. Fungal Diastase is a starch degrading enzyme. It helps in digestion of starch and carbohydrates from the diet into simple polysaccharides and sugar.

Unienzyme tablets are black coloured, oval shaped, sugar coated tablets, having UNIENZYME printed in white along one side. The excipients used are Colloidal Silicon Dioxide, Microcrystalline Cellulose, Dibasic Calcium Phosphate Dihydrate, Lactose Monohydrate, Gum Acacia, Gelatin, Sodium Benzoate, Talc, Magnesium Stearate, Shellac, Isopropyl Alcohol, Castor Oil, Calcium Carbonate, Sugar, Vegetable Charcoal Fine, Carnauba Wax, Edible Ink White.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not available

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

UNIENZYME is available in Alu-Alu Strip pack of 15 tablets.

8.4 Storage and handing instructions

Store in a cool and dry place

9. Patient Counselling Information

Package leaflet: information for the patient

UNIENZYME

Fungal Diastase 100 mg, Papain 60mg and Activated Charcoal 75mg

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. What UNIENZYME is and what it is used for
2. What you need to know before you take UNIENZYME
3. How to take UNIENZYME
4. Possible side effects
5. How to store UNIENZYME
6. Contents of the pack and other information

1. What UNIENZYME is and what it is used for

Unienzyme is combination of fungal diastase, papain and activated charcoal.

• Fungal diastase

- Starch digesting capacity is reasonably good over wide range of pH (3.5-7.0) with *maximum activity at pH 5*
- Can be reactivated in intestine after its inactivation in acidic environment of stomach
- *Assists and complement salivary and pancreatic amylase* in assimilations of heavy carbohydrates food (most common component of food)
- In saccharification, *fungal source α -amylase have high efficiency compared to bacterial enzyme*
- No known contraindications
- Does not exert any systemic pharmacological effects

Role of papain

- PAPAINE is a proteolytic enzyme
- It is obtained from the juice of unripe fruit of *Carica papaya*
- Action similar to pepsin which is a normal enzyme secreted in the stomach for protein breakdown\
- It hydrolyzes polypeptides, amides and esters especially with bonds of leucine and glycine
- **Advantage over pepsin**
- Conserves protein degrading activity over wide range of PH.
- Pepsin is completely inactive at $\text{pH} > 4.5$
- Thus papain is active at both acid and alkaline pH

- Maximum Activity at pH 5 to 8

Role of activated charcoal

- Gas adsorbent of high capacity.
- Its highly porous surface adsorbs gases, poorly soluble substances and toxins.
- Reduces the volume of intestinal gas, providing relief of symptoms and reducing or eliminating flatulence.
- Also adsorbs microbial metabolites and toxins which may generate gas, thus reducing gas production, especially of hydrogen and methane.

Unienzyme is indicated as symptomatic relief of functional dyspepsia and other gastrointestinal disorders which usually manifest with symptoms of bloating, belching, flatulence, abdominal discomfort or feeling of abdominal fullness. for abdominal syndrome with flatulence in patients with diseases of digestive tract.

Possibilities of differential approach to the treatment of patients with Meteorism. Meteorism is a symptom that refers to a swollen abdomen, generated by the increase in the amount of intestinal gas, exerting more pressure than usual inside the digestive system, causing various discomforts, especially more or less intense pain and flatulence to eliminate the gas.

Advantages of UNIENZYME

- Superior digestive supplement for optimal digestion.
- Relieves indigestion (including acidity) and gas, is the complete solution for symptoms in indigestion.
- Better than antacids when used in treatment of indigestion.
- Unienzyme has natural ingredients which helps in the digestion of food and relieves associated symptoms including acidity.
- Contains activated charcoal, which removes gas in lower part of GIT.
- Not absorbed in body and can be taken for long duration, if required.
- Recommended in patients with heart, or kidney disease and also in patients having hypertension.
- Good clinical evidence available for Unienzyme in different ethnic population (Indian, Russian).

2. What you need to know before you take UNIENZYME

Precautions and Warnings - When to avoid Unienzyme Tablet:

Patients with instances of abdominal bleeding must take a doctor's advice before taking the drug. Abnormal bleeding has been reported in many individuals consuming the tablet.

Professional advice is recommended as this drug is an over-the-counter drug.

Expiry and the manufacturing date should always be checked before using the tablet.

One should always make clear to the concerned physician if he or she is allergic to any if the ingredient of the tablet. People allergic to pork protein have also reported considerable side effects of the tablet. All these physiological reservations should be made crystal clear to the doctor beforehand.

Surgical aspects also need to be considered. Before having surgery, one should report the doctor or the dentist about each and every medicine one uses including herbal products, prescription drugs among other things.

Although there is no clear evidence of the enzyme affecting breast milk, one should always consult the doctor before breastfeeding when consuming this medicine.

Also, one should make clear to the doctor if one has a medical history of sudden swelling of the pancreas or abrupt worsening of any kind of long term pancreatic disorder.

As mentioned earlier, the drug contains inactive ingredients which may end up causing allergic reactions among other things. Therefore, one should always consult a doctor before taking the medication.

Another very important aspect to keep in mind is that one should not abruptly start, stop, or alter the course of the medication without the professional approval of the doctor.

Unienzyme Interactions:

- It may interact with the class of tricyclic antidepressants.
- It may also interact with Acarbose, acetaminophen, alcohol, digoxin and Miglitol.
- Apart from that, the drug may also interact with theophylline, thimerosal topical and Silva Sorb.
- The medicine may also interact with silver sulphadiazine topical.
- It is important to keep in mind that one should always list all medical products one uses such as herbal products, prescription drugs among other things.
- The drug usually interacts with herbal products and therefore one should proceed according to the advice of the doctor.

3. How to take UNIENZYME

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dose: 2 Tablets after major meal or as directed by the physician.

4. Possible side effects

- **Like all medicines, this medicine can cause side effects, although not everybody gets them.**
- **Contact your doctor immediately if you experience:**
- Some of the most common side effects of the medicine may include constipation, dark feces, excruciating micturition, skin irritation, and nausea.
- Apart from these, this medicine may also cause stomach ache and diarrhea.
- Although a very serious allergic reaction to Unienzyme is rare, medical intervention should be sought right away if symptoms such as rash, skin irritation, dizziness, breathing troubles, etc. are experienced.
- Abdominal distress and joint pain are also reported in certain cases.
- Medicine that may show an adverse effect if taken alongside the Unienzyme:

- Digoxin, SilvaSorb
- Tricyclic antidepressants
- Theophylline
- Miglitol
- Acetaminophen
- Silver sulfadiazine topical
- Thimerosal topical
- Acarbose

5. How to store UNIENZYME

Store in a cool and dry place. Keep out of reach of children

6. Contents of the pack and other information

The active substances are: activated charcoal, papain, and fungal diastase

Other ingredients: The excipients used are Colloidal Silicon Dioxide, Microcrystalline Cellulose, Dibasic Calcium Phosphate Dihydrate, Lactose Monohydrate, Gum Acacia, Gelatin, Sodium Benzoate, Talc, Magnesium Stearate, Shellac, Isopropyl Alcohol, Castor Oil, Calcium Carbonate, Sugar, Vegetable Charcoal Fine, Carnauba Wax, Edible Ink White.

UNIENZYME is available in Alu-Alu Strip pack of 15 tablets.

7. Details of manufacturer

Manufactured by:

Unichem Laboratories Ltd.

Unit-II, Village Bhatauli Kalan, Baddi, Dist. Solan (H.P.) – 173205

Torrent Pharmaceuticals Ltd.

Unit III, NH-10, Village: Bagheykhola, P.O.: Majhitar, Rangpo, East District, Gangtok, Sikkim-737136

8. Details of permission or licence number with date

Mfg Lic No. MNB/04/91 issued on 05.12.2017

Mfg Lic No. M/543/2010 issued on 19.01.2018

9. Date of revision

Not Applicable

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

Intrad-382 721, Dist. Mehsana, INDIA.

IN/UNIENZYME/ 100, 60, 75 mg/May-19/01/PI