

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

UNIENZYME LIQUID

1. Generic Name

Digestive Enzymes

2. Qualitative and quantitative composition

Each 5 ml contains:

Diastase I.P. (1:1200)..... 50 mg

(Fungal Diastase derived from *Aspergillus Oryzae*.)

Digests not less than 60 g of cooked starch)

Pepsin I.P. (1: 3000)..... 10 mg

(Digests not less than 30 g of coagulated egg albumin)

Flavoured Syrupy base.....q.s.

Colour: Caramel

Appropriate overages of enzymes added to compensate probable loss on storage.

The excipients used are Refined Sugar, Methyl Paraben, Propyl Paraben, Sodium Benzoate, Sodium Chloride, Sodium Hydroxide, Citric Acid Monohydrate, Sorbitol, Colour Caramel, Essence Pineapple, Chloroform and Hyflo Supercell.

3. Dosage form and strength

Dosage form: Syrup

Strength: Diastase I.P. (1:1200)..... 50 mg, Pepsin I.P. (1: 3000)..... 10 mg

4. Clinical particulars

4.1 Therapeutic indication

UNIENZYME LIQUID is indicated in following conditions:

- Indigestion
- Digestive disorders
- Belching
- Pepsin insufficiency in elderly
- Anorexia
- Chronic illness (Convalescence patients)
- Impaired appetite.
- Pepsin insufficiency in elderly
- Anorexia
- Chronic illness (Convalescence patients)
- Impaired appetite

4.2 Posology and method of administration

Dosage

Adults: 5ml (1 teaspoonful) immediately after meal or as directed by the physician

Children: Half the adult dose

Shake well before use.

Method of administration

Oral use.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Not available.

4.5 Drugs interactions

Not available

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

Not available.

4.7 Effects on ability to drive and use machines

Not available

4.8 Undesirable effects

Prolonged use in patients ingesting low phosphate diet may cause osteomalacia, nausea, vomiting, constipation.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

By reporting side effects, you can help provide more information on the safety of this Medicine.

4.9 Overdose

Not available.

5. Pharmacological properties

5.1 Mechanism of Action

Fungal Diastase

The major amyolytic activity of diastase (Fungal Diastase) is on starch as alpha amylase and S-amylase (Saccharifying amylase), and has some proteolytic activity.

Pepsin:

Pepsin is a proteolytic enzyme which is secreted by the stomach and controls the degradation of proteins into proteoses and peptones.

5.2 Pharmacodynamic properties

Fungal Diastase

An enzyme catalyzing the hydrolysis of linkages of polysaccharides such as starch. Best quality of amylase (diastase) is available from *Aspergillus oryzae*. The major amyolytic activity of diastase (Fungal Diastase) is on starch as alpha amylase and S-amylase (Saccharifying amylase), and has some proteolytic activity in addition, it also contains

lipase, cellulose, pectinase and several other enzymes making it a rich source of enzyme complex which splits carbohydrates, proteins, fats and cellulosic constituents of food in their assimilable forms and thus greatly enhances digestive capacity. Amylase has been used as a digestant.

Pepsin:

Pepsin is a proteolytic enzyme which is secreted by the stomach and controls the degradation of proteins into proteoses and peptones. It hydrolysis polypeptides. Pepsin is a substance containing a proteolytic enzyme present in the gastric juice of animals and obtained from the membrane of the stomach of certain animals commonly used for food.

5.3 Pharmacokinetic properties

Not available.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Not available.

7. Description

UNIENZYME LIQUID is a preparation, which contains digestive enzyme Diastase for effective digestion of carbohydrates & pepsin for digestion of proteins. It aids in effective digestion.

Digestive Enzyme is Brownish yellow coloured liquid filled in amber coloured glass bottles & sealed with aluminium cap. The excipients used are Refined Sugar, Methyl Paraben, Propyl Paraben, Sodium Benzoate, Sodium Chloride, Sodium Hydroxide, Citric Acid Monohydrate, Sorbitol, Colour Caramel, Essence Pineapple, Chloroform and Hyflo Supercell.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable.

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

UNIENZYME LIQUID is available in 200ml pack.

8.4 Storage and handing instructions

Store at a temperature between 8°C to 25°C in a dark place.

Keep out of reach of children.

9. Patient Counselling Information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 in this leaflet:

- 9.1 What UNIENZYME LIQUID is and what it is used for
- 9.2 What you need to know before you take UNIENZYME LIQUID
- 9.3 How to take UNIENZYME LIQUID
- 9.4 Possible side effects
- 9.5 How to store UNIENZYME LIQUID
- 9.6 Contents of the pack and other information

9.1 What UNIENZYME LIQUID is and what it is used for

UNIENZYME LIQUID is a preparation, which contains digestive enzyme Diastase for effective digestion of carbohydrates & pepsin for digestion of proteins. It aids in effective digestion.

- UNIENZYME LIQUID is indicated in following conditions: Indigestion
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- Anorexia
- Chronic illness (Convalescence patients)
- Impaired appetite.

9.2 What you need to know before you take UNIENZYME LIQUID

Do not take UNIENZYME LIQUID:

- if you are allergic to any ingredients of this medicine,

Warnings and precautions

Talk to your doctor before taking UNIENZYME LIQUID.

Take special care with UNIENZYME LIQUID and tell your doctor if you:

- if you have any history of allergy.

Other medicines and UNIENZYME LIQUID

Tell your doctor if you are taking, or have recently taken, or might take any other medicines.

9.3 How to take UNIENZYME LIQUID

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Take UNIENZYME LIQUID every day for as long as your doctor prescribes it.

If you take more UNIENZYME LIQUID than you should

It is important to keep to the dose as prescribed by your doctor. If you have taken more UNIENZYME LIQUID than you should, see a doctor right away. Take the medicine pack with you.

If you forget to take UNIENZYME LIQUID

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking UNIENZYME LIQUID

If you stop taking UNIENZYME LIQUID, your symptoms may return. If your doctor decides to stop this medication, your dose may be decreased gradually over a few days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects mostly occur at the start of treatment and usually disappear within a few days with continued treatment.

- Nausea,
- Vomiting,
- Constipation,
- Prolonged use in patients ingesting low phosphate diet may cause osteomalacia.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

By reporting side effects, you can help provide more information on the safety of this Medicine.

9.5 How to store UNIENZYME LIQUID

- Store at a temperature between 8°C to 25°C in a dark place.
- Keep out of reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle/carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

9.6 Contents of the pack and other information

What UNIENZYME LIQUID contains

The active substances are Fungal Diastase and Pepsin.

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What UNIENZYME LIQUID looks like and contents of the pack

UNIENZYME LIQUID is available in 200ml pack.

10. Details of manufacturer

Manufactured in India by:

Biogenetic Drugs Pvt Ltd.

Jharmazri, Baddi, Dist. Solan (H.P.)

11. Details of permission or licence number with date

Mfg Lic No. MB-05/151 issued on 13.07.2015.

12. Date of revision

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IN/UNIENZYME LIQUID/APR-20/01/PI