

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

UNIENZYME DROPS

1. Generic Name

Digestive Enzymes

2. Qualitative and quantitative composition

Each ml contains:

Fungal Diastase (1:800) I.P..... 20mg

Caraway Oil I.P..... 400mcg

Cinnamon Oil I.P..... 200mcg

Cardamom Oil I.P..... 400mcg

Simethicone I.P.....40mg

Papain I.P.....10mg

Flavoured syrupy baseq.s.

Colour: Sunset Yellow FCF

The excipients used are Sorbitol, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Benzoate, Xanthan Gum, Sodium Saccharin, Sodium Hydroxide, Citric Acid Monohydrate, Glycerin, Aspartame, Chloroform, Colour Sunset Yellow and Flavour Peppermint.

3. Dosage form and strength

Dosage form: Syrup

Strength: Fungal Diastase (1:800) 20mg, Caraway Oil 400mcg, Cinnamon Oil 200mcg, Cardamom Oil 400mcg, Simethicone 40mg, Papain 10mg

4. Clinical particulars

4.1 Therapeutic indication

Colic, distension, gas griping pain due to indigestion and flatulence.

4.2 Posology and method of administration

For paediatric use

Dosage

For infant less than 1 year: 0.5ml (about 10 drops) daily.

For children above 1 year: 0.5ml (about 10 drops) twice daily.

Shake well before use

To be diluted with water or as directed by Physician.

Method of administration

Oral use.

4.3 Contraindications

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

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

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

5.1 Mechanism of Action

Not available.

5.2 Pharmacodynamic properties

Not available.

5.3 Pharmacokinetic properties

Not available.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Not available.

7. Description

UNIENZYME DROPS is Orange coloured liquid filled in amber coloured glass bottle, sweet with peppermint flavor having PP cap 22 mm black base printed with silver colour. The excipients used are Sorbitol, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Benzoate, Xanthan Gum, Sodium Saccharin, Sodium Hydroxide, Citric Acid Monohydrate, Glycerin, Aspartame, Chloroform, Colour Sunset Yellow and Flavour Peppermint.

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 DROPS is available in Bottle pack of 15ml.

8.4 Storage and handing instructions

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

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 DROPS is and what it is used for

9.2 What you need to know before you take UNIENZYME DROPS

9.3 How to take UNIENZYME DROPS

9.4 Possible side effects

9.5 How to store UNIENZYME DROPS

9.6 Contents of the pack and other information

9.1 What UNIENZYME DROPS is and what it is used for

UNIENZYME DROPS is a preparation, which contains fungal diastase, caraway, cinnamon, cardamom, simethicone and papain.

UNIENZYME DROPS is indicated for colic, distension, gas griping pain due to indigestion and flatulence.

9.2 What you need to know before you take UNIENZYME DROPS

Do not take UNIENZYME DROPS:

- if you are allergic to any ingredients of this medicine

Warnings and precautions

Talk to your doctor before taking **UNIENZYME DROPS**.

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

- if you have any history of allergy.

Do not exceed the stated dose. Check the expiry date on the pack and do not use after expiry.

Other medicines and UNIENZYME DROPS

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

9.3 How to take UNIENZYME DROPS

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 DROPS every day for as long as your doctor prescribes it.
- Shake well before use.
- To be diluted with water or as directed by Physician.

If you take more UNIENZYME DROPS than you should

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

If you forget to take UNIENZYME DROPS

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 DROPS

If you stop taking UNIENZYME DROPS, 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,
- 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.

9.5 How to store UNIENZYME DROPS

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

The active substances are fungal diastase, caraway, cinnamon, cardamom, simethicone and papain.

Each ml contains:

Fungal Diastase (1:800) I.P..... 20mg

Caraway Oil I.P..... 400mcg

Cinnamon Oil I.P..... 200mcg

Cardamom Oil I.P..... 400mcg

Simethicone I.P..... 40mg

Papain I.P..... 10mg

Flavoured syrupy base ... qs

Colour : sunset yellow FCF.

The other ingredients are: Sorbitol, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Benzoate, Xanthan Gum, Sodium Saccharin, Sodium Hydroxide, Citric Acid Monohydrate, Glycerin, Aspartame, Chloroform, Colour Sunset Yellow and Flavour Peppermint.

What UNIENZYME DROPS looks like and contents of the pack

UNIENZYME DROPS is available in Bottle pack of 15ml.

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 12.12.2017

12. Date of revision

NA

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

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