

Summary of Product Characteristics

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

ARISTOZYME LIQUID {DIASTASE & PEPSIN LIQUID}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION :

Each 5 ml contains:

Diastase 50 mg

Pepsin BP 10 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM: LIQUID.

Pale yellow coloured, clear liquid with pineapple flavour and sweet taste.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Aristozyme liquid is indicated in dyspepsia, epigastric distress and indigestion.

4.2 Posology and method of administration:

Adults: One – two teaspoonfuls twice daily after meals. Children: 2.5ml – 5ml
Twice daily after meals.

4.3 Contraindications:

None reported.

4.4 Special warnings and precautions for use: None reported.

4.5 Interaction with other medicinal products and other forms of interaction:

None reported.

4.6 Fertility, Pregnancy and lactation: None reported.

4.7 Effects on Ability to drive & Use Machines: None reported.

4.8 Adverse effects: None reported.

4.9 Overdosage and Treatment of Overdosage: None reported.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties: Pharmacotherapeutic group:

ATC code: Diastase :A09AA01 ; Pepsin: A09AA04

Mechanism of action:

Diastase (Amylase): Diastase is mixed with food and passed through stomach into the intestine. Diastase breaks down starch into pairs of sugar molecules which are then split by enzyme lipase so that individual sugar molecules are absorbed. The sugars are all carried to the liver in the blood stream. The liver changes all the compounds into glucose. *Pepsin:* Pepsin contains proteolytic enzymes secreted by the stomach, which control the degradation of proteins into proteoses and peptones. It hydrolyses polypeptides including those with bonds adjacent to aromatic or dicarboxylic L-amino- acid residues. pharmacology (summary of pharmacodynamics and pharmacokinetics): The digestive system depends on the enzymes that are produced by the organs attached to the digestive tract to bring about a chemical reaction involved in digestion.

When the food is chewed the saliva produce enzyme ptyalin, which starts acting on the carbohydrate. Amylase present in the saliva starts acting on carbohydrate.

Pharmacodynamic properties: After food reaches the stomach, the hormone gastrin stimulates the stomach cells to release hydrochloric acid and pepsin, and it is converted to peptones. When acidity reaches a certain point, gastrin production ceases. Protein are broken down by enzyme pepsin to peptones. The hormones cholecystokinin and secretion triggers the release of pancreatic juices which neutralizes the acidic chyme. Bile released from gall bladder breaks down fat globules. Pancreatin juice has three types of enzymes Trypsin, Lipase and Amylase. Trypsin breaks down peptones. Lipase breaks down fat into smaller molecules of glycerol and fatty acids. Amylase breaks down carbohydrates to maltose. When digested food comes into contact with villi, the glycerol, fatty acid and dissolved vitamins enter the lactal are carried through into the lymphatic system and then are poured into the blood stream.

Amino acids from protein are digested and sugar from carbohydrate and mineral like calcium, iron, iodine are absorbed directly into villi. These capillaries lead into the hepatic portal vein which transports the food directly to the liver. This in turn filters out some substances for its own use and remainder passes into body's general circulation.

5.0 PHARMACOLOGICAL PROPERTIES: [CONTD]

5.2 Pharmacokinetic properties:

Pharmacokinetics: The digestive system depends on the enzymes that are produced by the organs attached to the digestive tract to bring about a chemical reaction involved in digestion. When the food is chewed the saliva produce enzyme ptyalin, which starts acting on the carbohydrate. Amylase present in the saliva starts acting on carbohydrate. After food reaches the stomach, the hormone gastrin stimulates the stomach cells to release hydrochloric acid and pepsin, and it is converted to

peptones. When acidity reaches a certain point, gastrin production ceases. Protein are broken down by enzyme pepsin to peptones.

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5.3 Preclinical safety data:

No data available.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

Sucrose, Anhydrous Citric acid, Chloroform, Sodium Hydroxide (flakes), Propyl hydroxybenzoate, Methyl hydroxybenzoate, Glycerol, Liquid Sorbitol, Caramel, Flavour Pineapple Singapore, Flavour A.P. No. 1, Purified Siliceous Earth & Purified Water.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life :

18 Months.

6.4 Special precautions for storage:

Store at a temperature not exceeding 25°C.

KEEP OUT OF REACH OF CHILDREN

PROTECT FROM MOISTURE & LIGHT.

6.5 Nature and contents of container:

200 ml amber glass Bottle sealed with PP cap along with measuring cup , packed in a printed carton along with a pack insert.

6.6 Instructions for use and handling: No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER:

ARISTO PHARMACEUTICALS PRIVATE LIMITED.

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Off Veera Desai Road, ANDHERI (W), MUMBAI 400 053, INDIA.

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8. Marketing authorization number(s) issued by Ethiopian FDA:

05901/07498/REN/2020

9. Date of first authorization/renewal of the authorization:

29-04-2021

10. DATE OF REVISION OF THE TEXT:

04-07-2023.