SUMMARY OF PRODUCT CHARACTERISTICS

Summary Product Characteristics (SPC)

1.Name of the medicinal product

EVAC

2. Qualitative and Quantitative composition:

Each 5 ml contains: Lactulose Concentrate USP Equivalent to Lactulose 3.35gm

Excipients: Refer to section 6.1

3. Pharmaceutical Form: Solution.

4. Clinical Particulars:

4.1 Therapeutic Indications:

Constipation: Particularly when associated with laxative habituation or for those patients in whom constipation presents a special problem e.g. children, obstetrics and post-surgical patients

Portal systemic encephalopathy (PSE): Treatment and prevention of hepatic coma or Precoma stages where hyperammonaemia is present

4.2 Posology and method of administration:
a) Constipation
Dosage may vary widely with the severity of the condition. A relatively large initial dose should be followed by a smaller maintenance dose after the first three days of treatment. Only one dose daily needs to be taken, preferably after breakfast.
Recommended dosages are as follows.

Usual Starting dose

Adults:	30mL (6 x 5 mL spoonful)
Children (6-14 years):	15mL (3 x 5mL spoonful)
Children (1-5 years):	10mL (2 x 5mL spoonful)
Infants:	5mL (1 x 5mL spoonful)

Maintenance dose

Adults:	15-30mL (3-6 x 5mL spoonful)
Children (6-14 years):	10-15mL (2-3 x 5mLspoonful)
Children (1-5 years):	5-10mL (1-2 x 5mL spoonful)
Infants:	2.5-5mL (1/32-1 x 5mL spoonful)

b) Portal systemic encephalopathy
Initial dose of 30mL-50mL three times daily subsequently adjust the dose to produce two or three soft stool daily

c) Chronic portal hypertension and Hepatic Encephalopathy
The usual maintenance dose is 30 to 45 mL (6 to 9 medicine measures) three or four times daily; this is adjusted such that there are two or three soft stool daily and a faecal pH of 5 to 5.5. Therapy can be initiated with hourly doses of 30 to 45mL (6 to 9 medicine measures) if indicated.
Route of administration: Oral

4.3 Contraindications:
- Galactosaemia, including patients on galactose free diet, and in patients with intestinal obstruction.

4.4 Special warning and precaution for use:
Lactose may cause abdominal discomfort associated with flatulence or cramps. Nausea and vomiting has been reported following high doses. Prolonged use or overdose may result in diarrhea with excessive loss of water and electrolytes, particularly potassium.
Care should be taken in patients with lactose intolerance or in diabetic patients because of the presence of some free galactose and lactose
For management of chronic portal hypertension and encephalopathy other laxatives should not be employed concurrently in order to avoid inadequate acidification of stool.

4.5 Interaction with other medicinal products and other forms of interaction:
Due to the lowering the pH in the colon, drugs that have a colon pH dependent release (such as 5-ASA agents) may be inactivated.

4.6 Pregnancy and Lactation:
This medicine may be used as prescribed during pregnancy and lactation.

4.7 Effects on the ability to drive and use machines:
Not relevant.

4.8 Undesirable effects:
Flatulence may occur during the first few days of treatment. As a rule it disappears after a couple of days. When dosages higher than instructed are used, belly ache and diarrhoea may occur. In such a case the dosage should be decreased. If high doses (normally only associated with PSE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhoea.

4.9 Overdose

Prolonged use or excessive dosage may result in diarrhea with excessive loss of water and electrolytes, particularly potassium.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives.
ATC code: Lactulose- A06AD11

Lactulose is synthetic disaccharide derivative of lactose and acts by its osmotic properties in the luminal fluid. The primary osmotic effect of lactulose which is not absorbed in the upper intestines, may be augmented in the distal ileum and colon by the bacteria metabolism of the disaccharide to lactate and other organic acids that are partially absorbed. There is speculation that the concomitant reduction of luminal pH enhances motility and secretion.
The increased osmotic activity in the lumen that follows administration of lactulose results in modest accumulation of fluid and passage of soft, formed faeces in 1 to 3 days. Another important aspect of the action of lactulose is reduction of intestinal absorption of ammonia, presumably because of reduced production and increased utilization of ammonia by intestinal bacteria and enhanced excretion of ammonia in faeces.

5.2 Pharmacokinetic properties

Following oral administration, a negligible amount of lactulose is absorbed in the gastro intestinal tract. It passes essentially unchanged into the large intestine where it is metabolized by saccharolytic bacteria, forming simple organic acids such as lactic acid and acetic acid. Urinary excretion has been reported to be 3% or less.

5.3 Pre-clinical Safety:

The results of acute, sub-chronic and chronic toxicity studies in various species indicate that the compound has very low toxicity. The effects observed, appear to be more related to the effect of bulk in the gastrointestinal tract than to a more specific toxic activity. In reproduction and teratology experiments in rabbits, rats or mice no adverse effects were found.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

No excipients are used in the manufacturing of Lactulose Solution USP.

6.2 Incompatibilities: None.

6.3 Shelf Life: 24 months.

6.4 Special Precautions for storage:
Store in cool dry at temperatures not exceeding 30°C. Keep out of reach of children. Do not refrigerate

6.5 Nature and contents of container:
100ml amber coloured PET bottle contained in a unit carton with literature insert

6.6 Special precautions for disposal and other handling
None

7. Registrant:

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