Bharat Parenterals Limited
Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

CONSTISTOP
SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product:

1.1 (Invented) name of the medicinal product:

Generic Name/INN Name: Lactulose Solution USP

Brand Name:

CONSTISTOP

1.2 Strength:

Each 15 ml contains:

Lactulose Concentrate USP eq. to

Lactulose 10 gm

Colour: Caramel

Aqueous Flavored Base

1.3 Pharmaceutical form:

Liquid Oral Solution

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2. Qualitative and Quantitative Composition:

Sr. No.	Ingredients.	Spec.	Std. Qty. (gm/15 ml)	Actual Quantity (gm/15 ml)	Function
1.	Lactulose concentrate 70 %*	USP	10.000	19.22	Active
2.	Sodium Hydroxy Methyl Benzoate	BP	0.015	0.015	Preservative
3.	Sodium Hydroxy Propyl Benzoate	BP	0.0030	0.0030	Preservative
4.	Citric Acid Anhydrous	BP	0.0063	0.0063	pH Adjustant
5.	Caramel colour	IH	0.0075	0.0075	Colouring agent
6.	Chocolate Flavour	IH	0.030	0.030	Flavoring agent
7.	Di-Sodium Edetate	BP	0.0003	0.0003	Chelating agent
8.	Purified Water	BP	q.s to 15 ml	q.s to 15 ml	Vehicle

Calculation for the Active Ingredient:

*The quantity of the Lactulose Concentrate USP has to be calculated as per the Assay
Lactulose concentrate USP (Limit: 95.0 % to 10.5.00 % i.e 66.5 % w/v to 73.5 % w/v)

Assay: 99.15 % i.e 69.405 % w/v, Weight/ml of lactulose concentrate USP = 1.334

$$A = \frac{10 \times 100}{\text{Assay (\% w/v assay i.e 66.5 \% w/v to 73.5 \% w/v)}}$$

$$= \frac{10 \times 100}{69.405}$$

= 14.408 ml

=14.408 ml ×1.334 wt/ml

= 19.22 gm

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3. Pharmaceutical form:

Dosage Form:

Liquid oral dosage form, Solution

Visual & Physical characteristics of the product:

A light brown colour liquid filled in amber color pet bottle.

4. Clinical particulars:

4.1 Therapeutic indications:

Symptomatic treatment of constipation

It is indicated in adults and in children and adolescents aged 7 to 18 years. For children below 7 years, other dosage forms are available.

4.2 Posology and method of administration:

The usual dose is 1 to 2 tablespoonful (15 to 30 ml, containing 10 g to 20 g of lactulose) daily. The dose may be increased to 60 ml daily if necessary. Twenty-four to 48 hours may be required to produce a normal bowel movement.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

- Use in patients with galactosaemia.

- Acute inflammatory bowel disease (ulcerative colitis, Crohn's disease), gastrointestinal obstruction or subocclusive syndromes, digestive perforation or risk of digestive perforation, painful abdominal syndromes of undetermined cause.

4.4 Special warnings and precautions for use:

In case of insufficient therapeutic effect after several days consultation of a physician is advised.

From the route of synthesis Constistop may contain small amounts of sugars

Patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose mal-absorption should not take this medicine.

Lactulose should be administered with care to patients who are intolerant to lactose.

Lactulose may contain more than 5 g lactose/galactose/epilactose depending upon the dose taken. This should be taken into account in patients with diabetes mellitus.

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For patients with gastro-cardiac syndrome lactulose should only be taken after consultation of a physician. If symptoms like meteorism or bloating occur in such patients after lactulose intake, the dose should be reduced or the treatment should be discontinued.
Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.
For elderly patients or patients that are in bad general condition and take lactulose for a more than 6 months period, periodic control of electrolytes is indicated.
During the therapy with laxatives it is recommended to drink sufficient amounts of fluids
Paediatric population
Use of laxatives in children should be exceptional and under medical supervision.
Lactulose should be administrated with caution in infants and small children with autosomal recessive hereditary fructose intolerance.
The defecation reflex may be altered during the treatment with lactulose.

4.5 Interaction with other medicinal products and other forms of interaction

Lactulose may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphotericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.
With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently can be inactivated.

4.6 Fertility, Pregnancy and lactation:

Pregnancy
Limited data on pregnant patients indicate neither malformative nor foeto/neonatal toxicity. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
The use of C may be considered during pregnancy if necessary.

Breast-feeding
Lactulose Solution can be used during breastfeeding.

4.7 Effects on ability to drive and use machines:

Lactulose Solution has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects:

Very common	≥ 1/10
Common	≥1/100 to < 1/10
Uncommon	≥1/1,000 to <1/100
Rare	≥1/10,000 to < 1/1,000
Very rare	< 1/10,000

Not known	cannot be estimated from the available data

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, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.

Gastrointestinal disorders

Very common (≥ 1/10):	Flatulence, abdominal pain,
Common (≥ 1/100 < 1/10):	Nausea and vomiting; if dosed too high, diarrhoea (sometimes including electrolyte imbalance).

4.9 Overdose:

Symptoms:
If the dose is too high, the following may occur: diarrhoea and abdominal pain.
Management: cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Drugs for constipation. Osmotically acting laxatives.

ATC code: A06A D11

Lactulose is a synthetic disaccharide formed from D-galactose and fructose. Lactulose as a prebiotic substance strengthens the growth of bifidobacteria and lactobacilli, whereas Clostridium and Escherichia coli may be suppressed.
In the colon lactulose is metabolised by bacterial enzymes to short chain fatty acids mainly lactic and acetic acid as well as methane and hydrogen. This effect leads to a decrease of the pH-value and an increase of the osmotic pressure in the colon. This causes stimulation of peristalsis and an increase of the water content of the faeces.

5.2 Pharmacokinetic properties:

Lactulose is practically not absorbed, because in man there is no corresponding disaccharidase available in the upper intestinal tract. Not being absorbed as such, it reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher dosages, a proportion may be excreted unchanged.

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6. Pharmaceutical particulars:

6.1 List of Excipients:

Sodium Hydroxy Methyl Benzoate, Sodium Hydroxy Propyl Benzoate, Citric Acid Anhydrous, Caramel colour, Chocolate flavour, Di sodium Edetate.

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

36 months

6.4 Special precautions for storage:

Store below 30°C. Protect from sunlight and moisture.

6.5 Nature and contents of container:

Primary Packing: 300 ml Amber Pet Bottle

Secondary Packing: Such a 1 Pet Bottle packed in a monocarton with package insert.

6.6 Special precautions for disposal:

No special requirements.

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

7. Applicant:

CHEZ RESOURCES PHARMACEUTICAL LIMITED.
Premises address: No. 7, Calabar Street, Onitsha, Anambra State, Nigeria.
E-mail: chezrespharm@gmail.com

Name and Address of manufacturer:
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