1. NAME OF THE MEDICINAL PRODUCT

ProctiCad (Lactitol monohydrate oral solution (10 gm/15 mL))

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 mL contains:
Lactitol Monohydrate BP/EP…… 10 mg
Benzoic Acid BP…… 0.0225 g
(As preservative)
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Solution.

Light orange, flavoured, viscous liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of Constipation

4.2 Posology and method of administration

Lactitol monohydrate oral solution may be administered diluted or undiluted. The dose should be titrated according to the clinical response. Lactitol may be given as a single daily dose or in two to three divided doses.

A single dose of Lactitol should be swallowed in one and should not be kept in the mouth for an extended period of time.

The posology should be adjusted according to the individual needs of the patient. The starting dose can be adjusted after adequate treatment effect individually (maintenance dose). Several days (23 days) of treatment may be needed in some patients before adequate treatment effect occurs. In case of single daily dose, this should be taken at the same time of the day, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.52 l/day, equal to 68 glasses).

For a precise dosing for babies, toddlers and children up to 6 years, it should be noted that not all included dose recommendations can be carried out with Lactitol and that other authorized products are available.

Constipation

	Starting dose		Maintenance dose	
Adults and adolescents over 14 years	15 - 45 ml daily	13 sachets, corresponding to 10 - 30 g Lactitol	15 - 30 ml daily	12 sachets, corresponding to 10 - 20 g Lactitol
Children (7 to 14 years)	15 ml Daily	1 sachet, corresponding to 10 g Lactitol	15 ml daily	1 sachet, corresponding to 10 g Lactitol

If diarrhoea occurs, the dosing regimen should be reduced.

In elderly patients and patients with renal or hepatic insufficiency no special dosage recommendations exist.

Duration of treatment:
The duration of treatment has to be adopted according to the symptoms.

4.3 Contraindications

Appendicitis

Lactitol Monohydrate is contraindicated in:

− 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.

− Hypersensitivity to the drug or any other component of the formulation

− Use in patients with galactosemia

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 Lactitol monohydrate oral solution may contain small amounts of sugars (Not more than 67 mg/ml lactose, 100 mg/ml galactose, 67 mg/ml epilactose, 27 mg/ml tagatose and 7 mg/ml fructose).
Patients with rare hereditary problems of galactose or fructose intolerance, lactase deficiency or glucosegalactose malabsorption should not take this medicine.
Lactitol monohydrate oral solution should be administered with care to patients who are intolerant to lactose.
The dose normally used should not pose a problem for diabetics.
15 ml of Lactitol contain 42.7 KJ (10.2 kcals) = 0.21 BU.
For patients with gastro-cardiac syndrome (Roemheld syndrome) Lactitol should only be

taken after consultation of a physician. If symptoms like meteorism or bloating occur in such patients after Lactitol 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 who take Lactitol 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 (1.52 l/day, equal to 6-8 glasses).

Children up to 6 years:
Use of laxatives in children should be exceptional and under medical supervision.
Lactitol 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 Lactitol.

4.5 Interaction with other medicinal products and other forms of interaction

Lactitol may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphothericin 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 (e.g. 5-ASA) can be inactivated.

4.6 Pregnancy and lactation

Limited data on pregnant patients indicate no 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 (see section 5.3).

The use of Lactitol monohydrate oral solution may be considered during pregnancy if necessary.

Lactitol monohydrate oral solution can be used during breastfeeding.

4.7 Effects on ability to drive and use machines

Lactitol Monohydrate has 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

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.

Investigations
Electrolyte imbalance due to diarrhoea.

4.9 Overdose

If the dose is too high, the following may occur:
Symptom: diarrhoea and abdominal pain.
Treatment: 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: Osmotically acting laxatives.
ATC code: A06A D11

Lactitol monohydrate is a synthetic disaccharide formed from D-galactose and fructose. In the colon lactitol monohydrate is metabolized by bacterial enzymes to short chained 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

Lactitol monohydrate is practically not absorbed, because in man there are no corresponding

disaccharidases available in the upper intestinal tract. Not being absorbed as such, it reaches the colon unchanged. There it is metabolized 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.

5.3 Preclinical safety data

Preclinical data based on studies of single and repeated dose toxicity reveal no special hazards for humans. A long-term animal study does not give reference to tumorigenic potential. Lactitol monohydrate was not teratogenic in mice, rats and rabbits. After oral administration systemic toxicity is not to be expected due to the pharmacological and pharmacokinetic properties of Lactitol.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactitol Monohydrate Oral Solution (10 gm/15 mL) contain following excipients:
Benzoic acid,
Propylene glycol,
Orange flavour,
Colour sunset yellow,
Colour ponceau 4R,
Citric acid monohydrate
Sodium citrate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two Years

6.4 Special precautions for storage

Store in a well closed container at a temperature not exceeding 30 ^{0}C.
• Keep all medicines out of reach of children.
• Avoid freezing.
• Avoid exposure to heat, light and humidity.
• Improper storage may deteriorate the medicine.

6.5 Nature and contents of container

Lactitol Monohydrate Oral Solution is proposed to be marketed in 50 ml, 100 ml & 200 ml Amber coloured PET bottles with silver coloured aluminium cap printed with CPL logo.

Each carton will contain 1 bottle.

6.6 Special precautions for disposal and other handling
No special instructions needed.

7. MARKETING AUTHORIZATION HOLDER
Cadila Pharmaceuticals Limited
1389, Dholka - 387810
District - Ahmedabad
Gujarat state,
India

8. MARKETING AUTHORISATION NUMBER(S)
New Registration

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION
New Registration

10.DATE OF REVISION OF THE TEXT
April' 2015