Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

AVOLAC Oral solution (LACTULOSE SOLUTION USP).

2. Qualitative and quantitative composition

Each 5mL contains:
Lactulose concentrate USP
Eq. to Lactulose……3.35gm
For a full list of excipients, see section 6.1

3. Pharmaceutical form

Oral solution.
Clear brown colour viscous solution.

4. Clinical particulars

4.1 Therapeutic indications

AVOLAC is used for indicated that for the treatment of constipation and for the treatment of hepatic encephalopathy (HE); hepatic coma.

4.2 Posology and method of administration

The lactulose solution may be administered diluted or undiluted. Each dose may if necessary be taken with water or fruit juices, etc. Each dose of lactulose 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. In case of single daily dose, this should be taken at the same time, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5–2 litres, equal to 6-8 glasses) during the day. For lactulose in bottles the measuring cup may be used. For lactulose in 15 ml single dose sachets the corner of the sachet should be torn off and contents taken immediately.

Dosing in constipation:

Lactulose may be given as a single daily dose or in two divided doses, for lactulose in bottles the measuring cup may be used. After a few days the starting dosage may be adjusted to the maintenance dose based upon treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs. Lactulose oral solution in bottles or 15 ml single dose sachets:

	Starting dose daily	**Maintenance dose daily**
Adults and adolescents	15-45 mL, corresponding to 1-3 sachets	15-30 mL, corresponding to 1-2 sachets
Children (7- 14 years)	15 mL, corresponding to 1 sachet	10- 15 mL, corresponding to 1 sachet*
Children (1-6 years)	5- 10mL	5- 10mL
Infants under 1 year	Up to 5mL	Up to 5mL

* If the maintenance dose is below 15 ml, lactulose in bottles should be used. For a precise dosing for infants and children up to 7 years lactulose in bottles should be used.

Dosing in HE (for adults only):

Starting dose: 3 to 4 times daily 30-45 ml (6-9 x 5 ml spoonfuls) or 2-3 sachets. This dose may be adjusted to the maintenance dose to achieve two or three soft stools each day.

Paediatric population

The safety and efficacy in children (newborn to 18 years of age) with HE have not been established. No data are available.

Elderly patients and patients with renal or hepatic insufficiency No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

4.3 Contraindications

AVOLAC is contraindicated

- Hypersensitivity to the active substance or any of the ingredients.
- Galactosaemia.
- Gastro-intestinal obstruction, digestive perforation or risk of digestive perforation.

4.4 Special warnings and precautions for use

Consultation of a physician is advised in case of:

- Painful abdominal symptoms of undetermined cause before the treatment is started.
- Insufficient therapeutic effect after several days.

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

The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of HE is usually much higher and may need to be taken into consideration for diabetics.

Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.

This product contains lactose, galactose and small amounts of fructose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Paediatric population

Use of laxatives in children should be exceptional and under medical supervision. It should be taken into account that the defaecation reflex could be disturbed during the treatment.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with Lactulose.

4.6 Pregnancy and Lactation

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to Lactulose is negligible. AVOLAC can be used during pregnancy.

Lactation
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Lactulose is negligible. AVOLAC can be used during breast-feeding.
Fertility
No effects are to be expected, since systemic exposure to Lactulose is negligible.

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

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, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased. If high doses (normally only associated with hepatic encephalopathy, HE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhoea. Dosage should then be adjusted to obtain two or three formed stools per day.
Tabulated list of adverse reactions
The following undesirable effects have been experienced with the below indicated frequencies in Lactulose-treated patients in placebo-controlled clinical trials:

- 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)

Paediatric population The safety profile in children is expected to be similar as in adults.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacy and Poisons Board- Pharmacovigilance Electronic Reporting System (PvERS); https://pv.pharmacyboardkenya.org .

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.
No specific antidote. Symptomatic treatment should be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives,
ATC code: A 06AD11

Mechanism of Action

Lactulose is a synthetic disaccharide formed from D-galactose and fructose. In the colon Lactulose 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.

In the colon lactulose is broken down by colonic bacteria into low molecular organic acids. These acids lead to a lowering of pH in the colonic lumen and via an osmotic effect to an increase of the volume of colonic contents. These effects stimulate peristalsis of the colon and return the consistency of the stool. The constipation is cleared and the physiological rhythm of the colon is reinstated.

In hepatic encephalopathy (HE) the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect, and alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis.

5.2 Pharmacokinetic properties

Lactulose is poorly absorbed after oral administration and 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

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

Sodium benzoate BP
Essence Orange sweet IHS
Sodium Methyl Paraben BP
Sodium Propyl Paraben BP

Colour Caramel IHS

6.2 Incompatibilities
Not applicable

6.3 Shelf-Life
24 Months

6.4 Special Precautions for storage
Store in cool, dry and dark place below 30° C. Protect from light. Keep out of the sight and reach of children.

6.5 Nature and Content of container
AVOLAC is packed in 100 ml & 200 ml amber coloured PET bottle packed in printed carton along with package insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
NEXTGEN PHARMACEUTICALS (K) LTD,
Address: 2259/218 Karen Road, Golden Ivy Plaza (1st FL) Nairobi,
Country: KENYA.
Telephone: 0791578060
E-Mail: info@nextgenpharma.co.ke

8. Marketing Authorization Number
H2019/CTD4656/807ER

9. Date of first authorization/renewal of the authorization
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10. Date of revision of the text
12 JUNE, 2026