AVOLAC®

Lactulose Oral Solution USP

Composition:
Each 5 ml oral solution contains Lactulose USP 3.35 g.

Properties and Effectiveness:
Lactulose which is not broken down in the stomach and small intestine, begins its action in the large intestine where it is broken down primarily by intestinal bacteria. In this degradation process, lactic acid is produced, this in turn supports the growth of intestinal bacteria, important for humans and hinders the growth of putrefactive bacteria. Thus normalization of intestinal flora (eubiosis) results. In addition, the increase in metabolic degradation products in the blood which can not be sufficiently detoxified by the liver is reduced.
Lactulose improves the transfer of Calcium Salts and Phosphates from the intestines, stimulates intestinal peristalsis and leads to a softening of the stool. It also leads to healing and improvement in gum diseases through normalization of metabolic processes in the parodontal region.
Even long-term use of **AVOLAC®** does not lead to habituation and thus there is no loss of efficacy.

Indications:
1. Constipation (chronic constipation):
In every case of chronic constipation, initial treatment should consist of a diet rich in fiber (vegetables, salads, fruits, supplements of linseeds, wheat germ etc.) a generous amount of liquids and much physical exercise.
AVOLAC® is only to be taken when these measures prove insufficient.
2. Intestinal flora disturbances:
- damage to intestinal flora, following therapy with broad spectrum antibiotics
- gallbladder diseases
- intestinal diseases (colitis, diverticulosis, megacolon)
3. Increased blood ammonia levels
(hyperammonemia in hepatopathy, portal systemic encephalopathy, precoma, coma)
4. Diseases of the gums and the parodontic apparatus
(paradontosis, bleeding from the gums, inflammation, dystrophy)
5. Precoma.

Dosage & Administration:
Dosage should be followed accurately unless otherwise specified.
1. In constipation (chronic constipation):
Due to the fact that every organism responds differently to **AVOLAC®**, each patient must determine his/her own optimal dose in the course of time.

	Initially	**In long-term therapy**
Adults	: 3-6 tea-spoons daily	1.5-6 tea-spoons daily
Children upto 14 years	: 3 tea-spoons daily	1-2 tea-spoons daily
Infants and toddlers	: 1-2 tea-spoons daily	1 tea-spoon daily

With **AVOLAC®** a prompt laxative effect may be achieved by drinking a mixture of 3-9 tea-spoons in1/8-1/4 liter water, coffee, tea, fruit juice, or milk on an empty stomach after getting up in the morning. Normally, defecation takes place approximately 2 hours later in the form of a fluid pulpy mass (increased defecation reflex).
2. In damaged intestinal flora (e.g. following long-term antibiotic treatment):
Adults : 1-2 tea-spoons daily
Children : 1 tea-spoon daily
3. For reduction of blood ammonia level (In hepatopathy):
A maximum of 60-100 g Lactulose daily, that is, 18-30 tea-spoons
4. In precoma: A maximum of 100 g Lactulose daily, that is 30 tea-spoons **AVOLAC®** spread over the course of the day.
5. Diseases of the gums and the parodontic apparatus (paradontopathy):
Adults : 3-6 tea-spoons **AVOLAC®** daily.

Pregnancy and Lactation:
Studies show that Lactulose has no adverse effects.
Decisions regarding use during pregnancy and lactation must be made by a registered physician.

Drug Interactions:
The glycosidic effect of cardiac glycosides can be intensified by potassium deficiency in abuse.

Contraindications:
Hypersensitivity to either galactose and or lactose, galactose-free diet. Gastro-cardiac symptom complex (heart problems stemming from the gastro-intestinal tract), suspected intestinal obstruction.

Side Effects:
Occasionally flatulence can occur at the beginning of treatment, this is rapidly eliminated by reducing the dose and or taking the daily dose in several smaller individual portions spread over the course of the day. Overdosage can result in diarrhoea. In abuse : loss of electrolytes (primarily Potassium)

Special note of warning concerning safe application:
Consult a doctor in case of pregnancy or side effects. **AVOLAC®** contains a maximum of 11 % galactose and a maximum of 2 % tagatose. This is to be taken into account in patients requiring a galactose-free diet. Diarrhoea may occur in case of overdoses. In such a case, lactulose use should be discontinued and care should be taken that the patient has an adequate supply of water and mineral. While undergoing therapy with **AVOLAC®**, foods that cause flatulence and excessive intake of carbonated drinks should be avoided.
In treating dysbacteria (disturbances of intestinal flora), a periodic course of treatment with **AVOLAC®** (6-8 weeks) is generally recommended. Only after this period of time can the desired change in the intestinal environment be achieved. If **AVOLAC®** is taken with or after meals, the laxative effects is reduced and the dose must be increased. The stool regulating effect of **AVOLAC®** may last several days in some patients. Thus **AVOLAC®** needs only be taken every 2nd or 3rd day in such cases.

Storage:
- Protect from light.
- Store below 30°C.
- Keep out of the reach of children.

Packing:
100 ml & 200 ml.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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