

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Endofalk powder for oral solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### 1 sachet contains:

Potassium chloride 0.185 g  
Sodium chloride 1.400 g  
Sodium hydrogen carbonate 0.715 g  
Macrogol 3350 52.500 g

### 1 litre reconstituted solution contains:

Potassium chloride 0.370 g  
Sodium chloride 2.800 g  
Sodium hydrogen carbonate 1.430 g  
Macrogol 3350 105 g

### 1 litre reconstituted solution corresponds to:

Potassium 5 mmol/l  
Sodium 65 mmol/l  
Chloride 53 mmol/l  
Hydrogen carbonate 17 mmol/l  
Macrogol 3350 31 mmol/l

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Powder for oral solution  
White powder

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For emptying the bowel before colonoscopy.

### 4.2 Posology and method of administration

Posology

For complete cleansing of the bowel 3 or a maximum of 4 litres Endofalk solution have to be consumed. 1 sachet is equivalent to ½ litre of solution.

Method of administration

The solution is drunk in portions of 200 - 300 ml every 10 minutes until the rectal outflow is clear. The solution is taken over a period of about 4 hours, generally on the day of the investigation. Alternatively, the entire quantity can be given on the previous evening, or part on the previous evening and the remainder in the morning of the examination day.

The patient should not eat any solid food from 2 - 3 hours before administration of Endofalk until after the examination.

Paediatric population

There is no sufficient experience with the use of Endofalk in children. Therefore Endofalk should not be administered in children.

***Preparation of solution***

The solution should be freshly prepared immediately before use. Dissolve the contents of 2 sachets in 500 ml of lukewarm tap-water or cooled boiled water. Subsequently dilute to 1 litre with water. Care should be taken that the sachets are completely emptied for the preparation of the solution. The prepared solution can be put into a refrigerator after preparation to cool as the cooled solution is more palatable to drink.

**4.3 Contraindications**

- Hypersensitivity to the active substances, other macrogols or any of the excipients listed in section 6.1
- Ileus and suspected ileus
- Gastro-intestinal obstruction or perforation
- Danger of gastro-intestinal perforation
- Hyperflorid colitis
- Toxic megacolon
- Disorders of emptying of the stomach.

Endofalk should not be administered to unconscious patients or those with impaired consciousness, general weakness and patients with a tendency to aspiration or regurgitation or impaired swallowing reflex.

**4.4 Special warnings and precautions for use**

Endofalk should only be administered under medical supervision in patients with reflux oesophagitis or pre-existing cardiac arrhythmias, suspected or known S-A block or sick sinus syndrome and in elderly patients.

Endofalk may be used in patients with chronic inflammatory intestinal diseases (except for the highly florid stages and toxic megacolon), but caution is necessary and medical supervision is advisable.

Endofalk should not be used in patients with kidney and heart failure (grade III and IV) and liver diseases or in patients with severe dehydration as the safety of use in these patient groups has not been adequately demonstrated.

Careful monitoring of the electrolyte and water balance is necessary in relevant patients at risk e.g. the elderly or debilitated.

If patients develop any symptoms indicating shifts of fluid/ electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) Endofalk should be stopped immediately, electrolytes measured and any abnormality treated appropriately.

***Ischaemic colitis***

Post-marketing cases of ischaemic colitis, including serious, have been reported in patients treated with macrogol for bowel preparation. Macrogol should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate). Patients presenting with sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis should be evaluated promptly.

***Note for use***

No other solution or additives (especially sugar or flavouring substances incompatible with Endofalk solution) should be added to the Endofalk drinking solution as this can lead to a change in osmolarity or the electrolyte composition or to the development of explosive gas mixtures in the intestines on breakdown of the added substances by the intestinal bacterial flora.

This medicinal product contains 32.5 mmol (or 747 mg) sodium per sachet, equivalent to 37.4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicinal product contains 2.5 mmol (or 97.5 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

**4.5 Interaction with other medicinal products and other forms of interactions**

Intestinal absorption of other medicinal products may be reduced transiently with the concomitant use of Endofalk. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products (e.g. 'anti-epileptics'). If the administration of a medicinal product is absolutely necessary for a vital indication shortly before or during the ingestion of Endofalk, oral administration should be avoided, where possible, and alternatives used.

In diagnostic investigations of the discharged intestinal liquid using enzymatic test procedures (e.g. ELISA), there may be interactions between macrogol 3350 and the enzymatic tests.

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

For Endofalk no clinical data on exposed pregnancies are available.

Animal studies have not shown teratogenic effects. Therefore, considering the absence of absorption of macrogol 3350, administration of Endofalk to pregnant women may be considered after careful risk/benefit assessment.

##### Breast-feeding

There are no human data on the excretion of macrogol 3350 in human milk. However macrogol 3350 is poorly absorbed. The prescription of Endofalk to breast feeding women can be considered if necessary.

#### 4.7 Effects on ability to drive and use machines

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

#### 4.8 Undesirable effects

The most frequently observed undesirable effects with Endofalk during a clinical trial were abdominal distension and nausea (very common).

These effects are largely attributable to the drinking of relatively large volumes of liquid within a short period. If gastro-intestinal symptoms, in particular nausea and vomiting develop, the administration of Endofalk should be temporarily slowed or stopped until the symptoms disappear.

The undesirable effects, which have been reported with the use of Endofalk and comparable macrogol containing bowel cleansing preparations spontaneously and in the context of clinical trials, are summarised in the following table, grouped by system organ class and frequency.

System Organ Class	Frequency according to MedDRA convention		
	Very common ( $\geq 1/10$ )	Common ( $\geq 1/100$ to $< 1/10$ )	Not known (cannot be estimated from the available data)
Immune System Disorders			Anaphylactic shock
Metabolism and nutrition disorders			Dehydration, electrolytes disorders (hypocalcaemia, hypokalaemia, hyponatraemia)
Psychiatric disorders			Insomnia
Nervous System Disorders			Neurological effects ranging from mild disorientation up to generalised seizures as a consequence of altered serum levels of electrolytes (see metabolism and nutrition disorders)
Cardiac Disorders			Cardiac arrhythmias, tachycardia
Gastrointestinal Disorders	Nausea, feeling of fullness, flatulence	Vomiting, gastric colics, irritation of the anus	Mallory-Weiss-Syndrome
Respiratory, thoracic and			Lung edema, rhinorrhoea, presumable of allergic origin

mediastinal disorders		
Skin and subcutaneous tissue disorders		Urticaria, dermatitis, presumably of allergic origin
General Disorders		General malaise

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

#### **4.9 Overdose**

On overdose, severe diarrhoea will occur. Only in severe overdose, derangement of the electrolyte and water balance and or the acid and base balance may be expected. Adequate replacement of fluids and monitoring of the serum electrolytes and pH should be carried out. If there is derangement of the electrolyte and water balance or of the acid-base balance, the electrolytes should also be replaced and the acid-base balance should be adjusted.

In the case of aspiration, toxic lung oedema may develop, which requires immediate intensive care, including positive pressure respiration.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Osmotically acting laxatives; macrogol combinations

ATC code: A 06 AD 65

Endofalk is a mixture of various salts with macrogol 3350 for the production of an isotonic bowel-cleansing solution.

The pharmacodynamic action consists of the initiation of diarrhoea. The intestines are emptied and cleansed. In the finished solution the electrolytes are present in a balanced form so that the absorption and secretion of water and electrolytes in the gastro-intestinal tract are largely neutral and the net flow is almost zero. The addition of high molecular macrogol 3350 gives rise to an iso-osmolar concentration which has a comparable particle concentration to plasma. This prevents any notable shift in fluids between the gastro-intestinal lumen and the vascular space. There is practically no influence on the body's electrolyte and water balance because of this equilibration and osmolarity.

#### **5.2 Pharmacokinetic properties**

Macrogol 3350 itself is an inert compound which is only minimally absorbed during the gastro-intestinal transit and it is not metabolised. A minimal amount of macrogol 3350, <1% of the applied dose, is excreted in the urine.

#### **5.3 Preclinical safety data**

Preclinical studies have shown that Macrogol 3350 does not have any significant systemic toxic potential.

Two teratogenicity studies were performed, one in rats and one in rabbits. Macrogol 3350 was administered orally at doses up to 2000 mg/kg bodyweight/day between day 6 and day 17 of gestation in rats and between day 6 and day 18 of gestation in rabbits. Results of both studies did not show any evidence of maternotoxic or teratogenic effects up to 2000 mg/kg bodyweight/day.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Saccharin sodium  
Orange- and passionfruit flavour  
Silica, colloidal anhydrous

## **6.2 Incompatibilities**

The solution should not be mixed with other solutions or additives. (see section 4.4.)

## **6.3 Shelf life**

Sachets: 5 years

Reconstituted solution: 3 hours at room temperature (<25°C), 48 hours at 2 °C – 8 °C (in a refrigerator).

## **6.4 Special precautions for storage**

Sachets: This medicinal product does not require any special storage conditions.

Reconstituted solution:

Do not store above 25°C

or

Store at 2 °C – 8 °C (in a refrigerator).

## **6.5 Nature and contents of container**

Sachets:  
covering material paper/Alu/PE.

Pack sizes of 6 sachets and 72 sachets

Not all pack sizes may be marketed

## **6.6 Special precautions for disposal and other handling**

No special requirements

## **7 MARKETING AUTHORISATION HOLDER**

Dr. Falk Pharma GmbH  
Leinenweberstrasse 5  
79108 Freiburg  
Germany

## **8 MARKETING AUTHORISATION NUMBER**

PA0573/006/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 25 March 2004

Date of last renewal: 20 October 2008

## **10 DATE OF REVISION OF THE TEXT**

May 2021