

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Abdomin Citrus powder for oral solution in sachets

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following active ingredients:

|                           |          |
|---------------------------|----------|
| Macrogol 3350             | 13.125 g |
| Sodium chloride           | 350.7 mg |
| Sodium hydrogen carbonate | 178.5 mg |
| Potassium chloride        | 46.6 mg  |

The content of electrolyte ions per sachet when made up to 125 ml of solution is as follows:

|                    |            |
|--------------------|------------|
| Sodium             | 65 mmol/l  |
| Chloride           | 53 mmol/l  |
| Hydrogen carbonate | 17 mmol/l  |
| Potassium          | 5.4 mmol/l |

#### Excipient with known effect:

|                 |         |
|-----------------|---------|
| Sorbitol (E420) | 0.76 mg |
|-----------------|---------|

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Powder for oral solution in sachet.

White, crystalline powder.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For the treatment of chronic constipation.

[Invented name] is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.

#### 4.2 Posology and method of administration

##### Posology

##### **Chronic Constipation**

A course of treatment for constipation with [Invented name] does not normally exceed two weeks, although this can be repeated if required.

As for all laxatives, prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medication, in particular opioids and antimuscarinics.

*Adults, adolescents and the elderly:* 1-3 sachets daily in divided doses, according to individual response.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily.

*Children (below 12 years old):* Not recommended. Alternative products are available for children.

### **Faecal impaction**

A course of treatment for faecal impaction with [Invented name] does not normally exceed 3 days.

*Adults, adolescents and the elderly:* 8 sachets daily, all of which should be consumed within a 6 hour period.

*Children (below 12 years old):* Not recommended. Alternative products are available for children.

*Patients with impaired cardiovascular function:* For the treatment of faecal impaction the dose should be divided so that no more than 2 sachets are taken in any one hour.

*Patients with renal insufficiency:* No dosage change is necessary for the treatment of either constipation or faecal impaction.

### **Method of administration**

Each sachet should be dissolved in 125 ml water. For use in faecal impaction 8 sachets may be dissolved in 1 litre of water.

## **4.3 Contraindications**

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

## **4.4 Special warnings and precautions for use**

The fluid content of [Invented name] when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Diagnosis of impaction/faecal loading of the rectum should be confirmed by physical or radiological examination of the abdomen and rectum.

Mild adverse drug reactions are possible as indicated in section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) [Invented name] should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

The absorption of other medicinal products could transiently be reduced due to an increase in gastrointestinal transit rate induced by [Invented name] (see section 4.5).

In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, see section 4.5.

This medicine contains 24.4 mg potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicinal product contains a maximum of 193 mg sodium per dose, equivalent to 9.7% of the WHO recommended maximum daily intake for sodium. When used long term for constipation, the maximum daily dose of this product is equivalent to 29% of the WHO recommended maximum daily

intake for sodium. [Invented name] is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

This medicine contains 0.76 mg sorbitol in each sachet.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with [Invented name] (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics. Therefore, other medicines should not be taken orally for one hour before, during and for one hour after taking [Invented name].

[Invented name] may result in a potential interactive effect if used with starch-based food thickeners. The macrogol ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

There are limited amount of data from the use of macrogol 3350 in pregnant women. Studies in animals have shown indirect reproductive toxicity (see section 5.3). Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible.

[Invented name] can be used during pregnancy.

##### Breast-feeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 3350 is negligible.

[Invented name] can be used during breast-feeding.

##### Fertility

There are no data on the effects of macrogol 3350 on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

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

[Invented name] has no influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Reactions related to the gastrointestinal tract occur most commonly.

These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of [Invented name]. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse effects is not known as it cannot be estimated from the available data.

| System Organ Class | Adverse Event |
|--------------------|---------------|
|--------------------|---------------|

|                                                             |                                                                                                                                                  |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Immune system disorders</b>                              | Allergic reactions, including anaphylactic reaction, dyspnoea, and skin reactions (see below “ <i>Skin and subcutaneous tissue disorders</i> ”). |
| <b>Metabolism and nutrition disorders</b>                   | Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.                                                                           |
| <b>Nervous system disorders</b>                             | Headache.                                                                                                                                        |
| <b>Gastrointestinal disorders</b>                           | Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal discomfort.                   |
| <b>Skin and subcutaneous tissue disorders</b>               | Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.                                                               |
| <b>General disorders and administration site conditions</b> | Peripheral oedema.                                                                                                                               |

### 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 [the national reporting system listed in Appendix V](#).

## 4.9 Overdose

Severe abdominal pain or distension can be treated by nasogastric aspiration. 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: A06AD65

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defaecation. Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

For the indication of faecal impaction controlled comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 27 adult patients, macrogol 3350 cleared the faecal impaction in 12/27 (44%) after 1 day's treatment; 23/27 (85%) after 2 days' treatment and 24/27 (89%) at the end of 3 days.

Clinical studies in the use of macrogol 3350 in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets a day, but this dose should be adjusted depending on individual response.

### 5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

### 5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity and genotoxicity.

There were no direct embryotoxic or teratogenic effects in rats even at maternally toxic levels that are a multiple of 66 x the maximum recommended dose in humans for chronic constipation and 25 x for faecal impaction. Indirect embryofetal effects, including reduction in fetal and placental weights, reduced fetal viability, increased limb and paw hyperflexion and abortions, were noted in the rabbit at a maternally toxic dose that was 3.3 x the maximum recommended dose in humans for treatment of chronic constipation and 1.3 x for faecal impaction. Rabbits are a sensitive animal test species to the effects of GI-acting substances and the studies were conducted under exaggerated conditions with high dose volumes administered, which are not clinically relevant. The findings may have been a consequence of an indirect effect of macrogol 3350 related to poor maternal condition as the result of an exaggerated pharmacodynamic response in the rabbit. There was no indication of a teratogenic effect.

There are long-term animal toxicity and carcinogenicity studies involving macrogol 3350. Results from these and other toxicity studies using high levels of orally administered high molecular weight macrogols provide evidence of safety at the recommended therapeutic dose.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lemon-lime flavour (maltodextrin; mannitol; gluconolactone; sorbitol (E420); acacia; silica, colloidal anhydrous; natural flavours)

Orange flavour (maltodextrin; acacia;  $\alpha$ -Tocopherol; natural flavours)

Saccharin sodium

Silica, colloidal anhydrous

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

Reconstituted solution: 24 hours.

Store in a refrigerator (2°C – 8°C).

### **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

For storage conditions after reconstitution of the medicinal product, see section 6.3.

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

Sachet: laminate consisting of three layers: paper, polyethylene, aluminium and surlyn.

Pack sizes: Boxes of 2, 6, 8, 10, 20, 30, 50, 60, 100 or 100 (2x50) sachets.

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

Any unused solution should be discarded within 24 hours.

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

**7. MARKETING AUTHORISATION HOLDER**

[To be completed nationally]

**8. MARKETING AUTHORISATION NUMBER(S)**

[To be completed nationally]

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

[To be completed nationally]

**10. DATE OF REVISION OF THE TEXT <MM/YYYY>**

[To be completed nationally]

2026-04-30