Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tevicon 13.7g Powder for Oral Solution, Sachet

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

A white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tevicon is indicated for the treatment of chronic constipation and 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

Adults, adolescents and the elderly: 1 –3 sachets daily in divided doses. Normal dose for most patients is 1-2 sachets per day. Depending on the individual response 3 sachets per day might be needed.

A course of treatment for constipation does not normally exceed 2 weeks, although this can be repeated if required.

For extended use, the lowest effective dose should be used.

Special populations

Paediatric population
Tevicon should not be used in children below 12 years of age. Alternative products are available for children.

Renal impairment
No dosage change is necessary for the treatment of chronic constipation.

Faecal impaction

A course of treatment for faecal impaction with *Tevicon* 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.

Special populations

Paediatric population
Tevicon should not be used in children below 12 years of age. Alternative products are available for children.

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.

Renal impairment
No dosage change is necessary for the treatment of faecal impaction.

Method of administration

Each sachet should be dissolved in 125 ml of 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 *Tevicon* 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.

The cause of constipation should be investigated if daily use of laxatives is necessary. Patients using this preparation should seek medical advice if there is no improvement after two weeks.

Long term use can be necessary in serious chronical or refractory constipation due to i.e. multiple sclerosis (MS) or Parkinson’s disease, or constipation induced by drugs, especially opioides or antimuscarine products.

If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) *Tevicon* 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 gastro-intestinal transitrate induced by *Tevicon* (see section 4.5).

Paediatric population
There is no clinical data on the use *Tevicon* in children, therefore it should not be used in children below 12 years of age.

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 *Tevicon* (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

4.6 Fertility, pregnancy and lactation

Pregnancy
Tevicon can be used during pregnancy. There is no documented experience from the use of *Tevicon* in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal reproductive development, delivery or postnatal development (see section 5.3). As Macrogol has a molecular weight above 3000 da very little if any will be absorbed. Therefore it seems unlikely that the use of this product will cause problems during pregnancy.

Breast-feeding
Tevicon can be used during breast-feeding. There is no documented experience from the use of macrogol during breast-feeding. Macrogol with a molecular weight above 3000 da will not or hardly be resorbed.

Fertility
There are no data on the effects of *Tevicon* 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

Tevicon 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 *Tevicon*. Mild diarrhoea usually responds to dose reduction.

System Organ Class	**Frequency**	**Adverse event**
Gastrointestinal disorders	Common	Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, and anorectal discomfort.
Immune system disorders	Very rare	Allergic reactions, including anaphylactic reactions, dyspnoea and skin reactions. (see below)
Metabolism and nutrition disorders	Not known	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Not known	Headache.
Skin and	Very rare	

subcutaneous tissue disorders		Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
General disorders and administration site conditions	Not known	Peripheral oedema.

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side affects you can help provide more information on the safety of this medicine.

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: A06A D65

Mechanism of action
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 with electrolytes 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 efficacy and safety
Clinical studies in the use of macrogol with electrolytes 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 data do not indicate a special risk for humans. These data are originated from conventional studies in the field of pharmacology, repeated dose toxicity, genotoxicity, carcinogenity and reproductive toxicity.
Results from animal 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

Acesulfame potassium (E950)
Lemon Flavour (contains acacia gum (E414) and flavouring)

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 four layers (inner to outer): low density polyethylene, aluminium, low density polyethylene and paper.

Pack sizes: Boxes of 8, 10, 20, 30, 50 or 100 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

Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA0749/146/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th February 2011

Date of last renewal: 31st January 2014

10 DATE OF REVISION OF THE TEXT

July 2017