

## **Package leaflet: Information for the user**

### **Tevicon 13.7 g, Powder for Oral Solution, Sachet**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What *Tevicon* is and what it is used for
2. What you need to know before you take *Tevicon*
3. How to take *Tevicon*
4. Possible side effects
5. How to store *Tevicon*
6. Contents of the pack and other Information

#### **1. What *Tevicon* is and what it is used for**

The name of this medicine is *Tevicon* 13.7g Sachet, Powder for Oral Solution.

It is a laxative for the treatment of chronic constipation in adults, children (aged 12 years and above) and the elderly.

It helps you to have a comfortable bowel movement even if you have been constipated for a long time. It also works in very bad constipation called faecal impaction (complete severe constipation).

#### **2. What you need to know before you take *Tevicon***

##### **Do not take *Tevicon***

- if you are allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or any of the other ingredients listed in section 6.
- if you have a perforated gut wall.
- if you have a blockage in your intestine (gut obstruction, ileus) for example by paralysis of the intestine.
- if you have severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

If any of these apply to you, please talk to your doctor or pharmacist for further advice.

##### **Warnings and precautions**

If you develop side effects such as swelling, shortness of breath, feeling tired, dehydration (symptoms include increasing thirst, dry mouth and weakness) or heart problems you should stop taking *Tevicon* and contact your doctor immediately.

Do not take Tevicon for longer periods of time unless you have been instructed to do so by your doctor; for example if you take drugs that can cause constipation or if you have a disease which cause constipation for example Parkinson's disease or multiple sclerosis (MS).

#### **Other medicines and Tevicon**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is no documented experience from the use of macrogol in pregnant women or during breast-feeding. However no effects during pregnancy or on the breastfed newborn/infant are anticipated, since systemic exposure to macrogol is negligible. Therefore Tevicon can be used during pregnancy or while breast-feeding if necessary.

#### **Driving and using machines**

*Tevicon* has no effect on the ability to drive or use machines.

### **3. How to take *Tevicon***

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine can be taken at any time with or without food or drink.

#### **Chronic Constipation (constipation for a long time)**

##### **Dosage – adults, adolescents and older people**

The recommended dose is 1 sachet one to three times daily. The normal dose for most patients is 1-2 sachets per day. Depending on the individual response 3 sachets per day might be needed. The dose depends on the severity of your constipation. The dose can be adjusted down to the lowest effective dose after a couple of days. The time of the treatment is normally 2 weeks. If the symptoms persist after 2 weeks of treatment contact your doctor.

##### **Use in children**

This medicine is not recommended for children below 12 years of age.

##### **Patients with renal insufficiency**

No dosage change is necessary for treatment of chronic constipation.

##### **Patients with a heart condition**

Do not take more than 2 sachets in one hour.

#### **Faecal Impaction (complete severe constipation)**

Before you take this medicine for faecal impaction, it should be confirmed that you have this condition.

##### **Dosage – adults, adolescents and older people**

The recommended dose for faecal impaction (complete severe constipation) is 8 sachets daily. The 8 sachets should be taken within a 6 hour period each day for up to 3 days if required.

**Use in children**

This medicine is not recommended for children below 12 years of age.

**Patients with renal insufficiency**

No dosage change is necessary for treatment of faecal impaction

**Patients with a heart condition**

Do not take more than 2 sachets in one hour.

**Method of Administration**

Dissolve the contents of 1 sachet in a glass of water (125ml or ¼ pint), stir well and drink. If you are being treated for faecal impaction it may be easier to dissolve all 8 sachets in 1 litre of water.

**If you take more *Tevicon* than you should**

You may develop diarrhoea. Stop taking *Tevicon* until it clears, then start again at a lower dose. If you are worried contact your doctor or pharmacist.

**If you forget to take *Tevicon***

Take the dose as soon as you remember and then continue on as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking *Tevicon* and see your doctor immediately:

- a serious allergic reaction which causes difficulty in breathing or dizziness, or swelling of the face, lips, tongue or throat.
- signs of an allergy, such as a rash, itching or shortness of breath.

The following side effects have also been reported:

- *Common (may affect up to 1 in 10 people):* stomach rumbling, swollen stomach or stomach pain, suffering from wind, vomiting, feeling sick, indigestion or a sore anus (bottom). If you experience mild diarrhoea when you start to take *Tevicon* your condition will generally get better if you reduce the amount of *Tevicon* you take.
- *Very rare (may affect up to 1 in 10,000 people):* hives, reddening of the skin or a nettle rash, swelling of the hands, feet or ankles.
- *Not known (frequency cannot be estimated from the available data):* headaches, high and low levels of potassium in the blood.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of side effects**

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland  
FREEPOST  
Pharmacovigilance Section  
Irish Medicines Board  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6767517  
Website: [www.imb.ie](http://www.imb.ie)  
e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

## **5. How to store *Tevicon***

**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.

Unopened sachet: No special storage conditions.

Once you have made up *Tevicon* in water, if you cannot drink it straight away keep it covered and store in a refrigerator (2°C – 8°C). Throw away any solution not used within a 24 hour period.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What *Tevicon* contains**

The active substances are macrogol 3350 (13.125g), sodium chloride (350.7mg), sodium hydrogen carbonate (178.5mg) and potassium chloride (46.6mg).

The other ingredients are lemon flavour and acesulfame potassium (E950) as a sweetener. The lemon flavour contains the following ingredients: acacia gum (E414) and flavouring.

### **What *Tevicon* looks like and contents of the pack**

*Tevicon* is a white powder packed in sachets. It is available in boxes of 8, 10, 20, 30, 50 or 100 sachets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer** Teva Pharma B.V. ,

Swensweg 5,  
2031GA Haarlem, the Netherlands.

**Manufacturer:**  
Chanelle Medical  
Loughrea

Co. Galway  
Ireland.

TEVA NEDERLAND B.V.

Swensweg 5,  
2031 GA Haarlem  
The Netherlands

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Macrogol + Electrolytes Teva
Germany	Macrogol Teva 13.7g Pulver zur Herstellung einer Lösung zum Einnehmen
Hungary	Anagol por belsőleges oldathoz tasakban
Ireland	Tevicon
Luxembourg	Curapeg poudre pour solution buvable
Netherlands	Macrogol en electrolyten 13,7 g Teva, poeder voor drank
Spain	Gotusal 13,7 g polvo para solución oral
United Kingdom	Compound Macrogol 13.7g powder for Oral Solution

**This leaflet was last revised in June 2015.**