

## Macrogol 3350 + electrolytes (optimized taste)

### Sachet

#### **MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE**

Powder for oral solution

For treatment of acute and chronic constipation for adults, adolescents and elderly patients  
With natural orange flavour

1 sachet with 13.955 g of powder for oral solution



Expiry date:



Batch number:



Do not store above 25 °C!



Please follow instructions for use!



**Manufacturer:**

Fairpharm Vertriebs GmbH  
Georg-Kalb-Straße 5  
82049 Pullach i. Isartal  
Germany  
www.fairpharm.com



Distributor: *Company name, address  
website with product information*



0197



Medical Device

#### **Composition:**

1 sachet with 13.955 g of powder contains:

Macrogol 3350                      13.125 g

Other ingredients: sodium chloride, potassium chloride, citric acid, monosodium citrate, orange flavouring (contains sorbitol), silica colloidal anhydrous, sodium cyclamate, saccharin sodium

#### **How to take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*:**

Adults, adolescents aged 12 years and over and elderly patients: 1 sachet makes up one dose.  
Depending on the severity of your constipation you may take 1 sachet one to three times daily.

**Macrogol 3350 + electrolytes (optimized taste)**

Dissolve the contents of one sachet in 125 ml or half a glass of water while stirring. You may take this product at any time and independent from meals and drinks.

The reconstituted solution can be covered and stored in the refrigerator (2°C to 8°C) and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

**Keep out of the sight and reach of children!**

## **Macrogol 3350 + electrolytes (optimized taste)**

### **Carton box**

*MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*

Powder for oral solution

With natural orange flavour

X sachets, each containing 13.955 g of powder for oral solution.

#### **Composition:**

1 sachet with 13.955 g of powder contains:

Macrogol 3350            13.125 g

Other ingredients: sodium chloride, potassium chloride, citric acid, monosodium citrate, orange flavouring (contains sorbitol), silica colloidal anhydrous, sodium cyclamate, saccharin sodium

**For treatment of acute and chronic constipation for adults, adolescents and elderly patients**



batch number:



Expiry date:



**Do not store above 25 ° C!**



**Please follow instructions for use!**

**Keep out of the sight and reach of children!**

## Macrogol 3350 + electrolytes (optimized taste)

**Manufacturer:**

Fairpharm Vertriebs GmbH  
Georg-Kalb-Straße 5  
82049 Pullach i. Isartal  
Germany  
[www.fairpharm.com](http://www.fairpharm.com)



**Distributor:** *company name, address*  
*website with product information*



Medical Device



UDI

### **How to take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*:** **Adults, adolescents aged 12 years and over and elderly patients:**

You may take this product at any time and independent from meals and drinks.

1 sachet makes up one dose.

Depending on the severity of your constipation you may take 1 sachet one to three times daily.

#### How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml or half a glass of water. Stir well until the powder has dissolved completely and the solution is clear or slightly turbid. Then you can drink the solution.

#### Duration of treatment

The course of treatment normally lasts 2 weeks. If the constipation persists, you should contact your doctor. In case your constipation is caused by a sickness such as Parkinson's disease or multiple sclerosis or if you take medication that causes constipation, your doctor may recommend to you to take *MACROGOL 3350 + ELECTROLYTES\_OPT.TASTE, LAXATIVE* for a longer period of time.

Reconstituted *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* solution can be covered and stored in the refrigerator (2°C to 8°C) and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

## Macrogol 3350 + electrolytes (optimized taste)

### **Instructions for use**

#### ***MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE***

13.955 g of powder for oral solution



Please read these instructions for use carefully because they contain important information you have to consider before using this product. This medical device is available without prescription. However, you still need to take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your physician or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 14 days.
- 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.

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

1. What is *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* and what it is used for?
2. What you need to know before you take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*
3. How to take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*
4. Possible side effects
5. How to store *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*
6. Further information

#### **1. What is *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* and what is it used for?**

*MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* is a laxative used for the treatment of acute and chronic constipation for adults, adolescents and elderly patients. It is not recommended for children under 12 years of age. *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* helps you to have a comfortable gastro-intestinal activity, even if you have been suffering from constipation for a longer period of time already.

#### **2. What you need to know before you take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE***

Do not take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* in case of:

- Hypersensitivity to any of the ingredients (please see composition)
- Severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon
- Perforated gut (bowel) wall
- Blockage in the intestine (gut obstruction, ileus)

## **Macrogol 3350 + electrolytes (optimized taste)**

- Painful abdominal syndromes of indeterminate cause

If you are not sure, talk to your doctor or pharmacist before taking *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*.

### **Take special care**

As with all laxatives, an organic disorder should have been ruled out before initiation of treatment. Without investigating the cause of constipation, *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* should not be taken on a continuous daily basis for an extended period of time. You should seek medical advice in case of persistent abdominal pain.

In case of diarrhoea, caution should be exercised in patients who are prone to a disturbance of water or electrolyte balance (e.g. elderly, patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control should be considered.

**If you notice any of the above signs or symptoms, you should stop taking *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* and consult a doctor immediately.**

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

*MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* can be taken during pregnancy or breast-feeding since absorption of macrogol 3350 is negligible and for that reason no effects are anticipated. However, if you are pregnant, planning to become pregnant or breast-feeding, ask your doctor before taking *Macrogol 3350+electrolytes\_opt.taste, laxative*.

### **Driving and using machinery**

*MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* has no effect on the ability to drive or use machinery.

### **Renal insufficiency**

There is no need to adapt the dose for patients with renal insufficiency.

## **Macrogol 3350 + electrolytes (optimized taste)**

### **Use in diabetics**

*MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* is suitable for diabetics. The powder does not contain sugar.

### **Taking *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* with medicines**

Some medicines, for example antiepileptics, may not work as effectively during use with *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE*. Please tell your doctor or pharmacist if you are taking, or have recently taken, any medicines, including medicines obtained without a prescription.

If you need to thicken fluids in order to swallow them safely, *MACROGOL 3350 + ELECTROLYTES\_OPT.TASTE, LAXATIVE* may counteract the effect of the thickener.

### **Important information about ingredients of *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE***

The orange flavour contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medical device.

## **3. How to take MACROGOL 3350 LAXATIVE**

### **Adults, adolescents aged 12 years and over and elderly patients:**

You may take this product at any time and independent from meals and drinks.

1 sachet makes up one dose.

Depending on the severity of your constipation you may take 1 sachet one to three times daily.

### How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml or half a glass of water. Stir well until the powder has dissolved completely and the solution is clear or slightly turbid. Then you can drink the solution.

### Duration of treatment

The course of treatment normally lasts 2 weeks. If the constipation persists, you should contact your doctor. In case your constipation is caused by a sickness such as Parkinson's disease or multiple sclerosis or if you take medication that causes constipation, your doctor may recommend to you to take *MACROGOL 3350 + ELECTROLYTES\_OPT.TASTE, LAXATIVE* for a longer period of time.

Reconstituted *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* solution can be covered and stored in the refrigerator (2°C to 8°C) and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

## **Macrogol 3350 + electrolytes (optimized taste)**

### **If you take more than the recommended dose**

Excessive doses of *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* are likely to cause diarrhoea, abdominal pain, bloating, rumbling, abdominal distension and vomiting which resolves when treatment is interrupted or the dose is reduced.

Large fluid losses due to diarrhoea or vomiting may require correction of electrolyte imbalance. You should contact a doctor in these circumstances.

### **If you forget to take *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE***

If you forget to take a dose, take it as soon as you remember and then continue on as before. Do not take a double dose to make up the forgotten dose.

## **4. Possible side effects**

*MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* may have side effects, but these may not occur for every user.

If you experience any of the following side effects, stop taking *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE* and see your doctor immediately.

- Signs of an allergy, such as rash, itching, swelling of the face, lips, tongue or in the neck or throat area, shortness of breath or difficulty breathing
- Signs of a change in your body's fluid or electrolyte levels (salts levels) such as swelling (mainly in the ankles), feeling weak, increasingly tired or increased thirst with headache

The following side effects are also possible:

- Abdominal (stomach) pain
- Mild diarrhoea (this usually stops when you reduce the number of sachets you take)
- Nausea (feeling sick)
- Vomiting
- Swelling in your abdomen (feeling bloated)
- Stomach rumbling
- Flatulence (wind)
- Soreness of the anus (bottom)

If any side effects bother you or if they last for more than a few days, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You should report any serious incident that has occurred in relation to this product to the manufacturer and to *contact details of the competent authority in the country where the product is distributed*.

## **5. How to store *MACROGOL 3350+ELECTROLYTES\_OPT.TASTE, LAXATIVE***

Keep this medical device out of the reach and sight of children.



## Macrogol 3350 + electrolytes (optimized taste)



Do not use *MACROGOL 3350+ELECTROLYTES OPT.TASTE, LAXATIVE* after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.



Do not store *MACROGOL 3350+ELECTROLYTES OPT.TASTE, LAXATIVE* above 25°C.

As soon as you have *MACROGOL 3350+ELECTROLYTES OPT.TASTE, LAXATIVE* dissolved in water and you cannot drink it completely, you can cover and store it in the refrigerator (2°C to 8°C). After 24 hours, any unused solution should be discarded.

### 6. Further information

1 sachet with 13.955 g of powder contains:

Macrogol 3350            13.125 g

Other ingredients: sodium chloride, potassium chloride, citric acid, monosodium citrate, orange flavouring (contains sorbitol), silica colloidal anhydrous, sodium cyclamate, saccharin sodium



Medical Device



Fairpharm Vertriebs GmbH  
Georg-Kalb-Straße 5  
82049 Pullach i. Isartal  
Germany  
[www.fairpharm.com](http://www.fairpharm.com)



Distributor: *company name, address*  
*website with product information*

Date of information: May 2025