# Package leaflet: Information for the user

# Wecol 6.9 g, powder for oral solution

Macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride

# Read all of this leaflet carefully before you take this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice 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 Wecol is and what it is used for
- 2. What you need to know before you use Wecol
- 3. How to take Wecol
- 4. Possible side effects
- 5. How to store Wecol
- 6. Contents of the pack and other information

#### 1. What Wecol is and what it is used for

Wecol is a laxative.

This medicine is used in adults, adolescents and elderly to treat:

- chronic constipation.
- impaction. Impaction is persistent constipation, where a large volume of stools cause a blockage of the rectum and / or colon.

It is not recommended for children below 12 years of age.

# 2. What you need to know before you use Wecol

# Do not take Wecol if you:

- are allergic to Macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or any of the other ingredients in this medicine (listed in section 6).
- have a blockage in your intestine.
- have a perforated gut wall.
- have a severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

# Warnings and precautions

Talk to your doctor or pharmacist before taking Wecol if you have heart or kidney problems, an impaired gag reflex, difficulty swallowing or suffer from heartburn.

When taking Wecol you should continue to take plenty of fluids. The fluid content of Wecol should not replace your regular liquid intake.

#### **Heart conditions**

Follow the special instructions in section 3 if you are taking Wecol for faecal impaction.

## Other medicines and Wecol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, such as medicines for epilepsy, may be less effective during use of Wecol.

You should not take any other medicines by mouth together with Wecol and for one hour before and for one hour after taking Wecol.

If you need to thicken fluids in order to swallow them safely, Wecol may counteract the effect of the thickener.

# Taking Wecol with food and drink

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

## Pregnancy and breast-feeding

We col can be used during pregnancy and breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

# **Driving and using machines**

We col does not affect your ability to drive or use machines.

# Wecol contains potassium

This medicine contains 0.31 mmol (12.22 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

#### Wecol contains sodium

This medicine contains 93.86 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 4.69% of the recommended maximum daily dietary intake of sodium for an adult.

#### Wecol contains sorbitol (E420)

This medicine contains 0.38 mg sorbitol (E420) in each sachet.

# 3. How to take Wecol

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.

#### **Chronic Constipation:**

The recommended dose is 2 to 6 sachets daily, taken in divided doses. You should not normally need to take this medicine for more than 3 days.

# **Faecal impaction:**

Before you take Wecol for faecal impaction, your doctor must check to confirm that you have this condition. The recommended dose is 16 sachets daily, all of which should be consumed within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 4 sachets in any 1 hour.

To prevent further problems from faecal impaction, your doctor may advise that you continue taking this medicine. You should use the dose for treating chronic constipation.

#### How to mix

- Tear open the sachet and pour the contents into a glass.
- Add about 62.5 ml or a quarter of a glass of water to the glass.

- Stir well until all the powder has dissolved and the solution is clear or slightly hazy, before drinking.

# **Duration of treatment**

## **Chronic constipation:**

Treatment usually lasts about 2 weeks. If you need to take Wecol for longer, please see your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation, your doctor may recommend that you take this medicine for longer than 2 weeks. If you need to take Wecol for longer, please see your doctor.

Usually for long-term treatment the dose can be lowered to either 2 or 4 sachets daily.

## **Faecal impaction:**

Treatment can be for up to 3 days.

# If you take more Wecol than you should

You may develop excessive diarrhoea. If this occurs, stop taking Wecol and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

# If you forget to take Wecol

Take the dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

#### 4. Possible side effects

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

# Stop taking Wecol and tell your doctor immediately if you have:

- a serious allergic reaction which causes difficulty in breathing, breathlessness or swelling of the face, lips, tongue or throat.
- signs of a change in your body's fluid or electrolyte levels (salts levels such as high and low levels of potassium in the blood) such as swelling (mainly in the ankles), shortness of breath, feeling weak, increasingly tired or increased thirst with headache.

#### Other side effects include:

- Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash swollen hands, feet or ankles, headaches.
- Sometimes you may have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and mild diarrhoea.

If you are being treated for **chronic constipation**, diarrhoea will usually improve when the dose is reduced.

# **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

# 5. How to store Wecol

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 sachet and carton. The expiry date refers to the last day of the month.

Do not store your Wecol above 25°C.

Once you have made up Wecol in water, if you cannot drink it straight away, keep it covered and in the fridge  $(2-8^{\circ}C)$ . Throw away any solution not used within 6 hours.

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 Wecol contains

One sachet of Wecol contains the following active ingredients:

Macrogol 3350,
 Sodium chloride
 6.563 g
 0.1754 g

- Sodium hydrogen carbonate 0.0893 g

- Potassium chloride 0.0233 g

When the sachet contents are dissolved in a quarter of a glass (62.5 ml) of water, each sachet gives the equivalent of:

- Sodium 65 millimoles/litre
- Chloride 53 millimoles/litre
- Hydrogen carbonate 17 millimoles/litre
- Potassium 5.0 millimoles/litre

The other ingredients are colloidal anhydrous silica, saccharin sodium, orange flavour and lemon lime flavour. The flavourings contain sorbitol (E420) and alpha-tocopherol (E307).

This medicinal product contains potassium, sodium and sorbitol (E420). See section 2 'Wecol contains potassium/sodium/sorbitol (E420)'.

# What Wecol looks like and contents of the pack

We col is a white powder which comes in a sachet. We col is available in boxes of 30, 40, 50, 60 or 100 sachets. Not all pack sizes may be marketed.

# **Marketing Authorisation Holder**

Stirling Anglian Pharmaceuticals Ireland Ltd 3 Burlington Road Dublin 4 D04RD68 Ireland

#### Manufacturer

Klocke Pharma-Service GmbH Strassburger Strasse 77 77767 Appenweier Germany For any information about this medicine, please contact the Marketing Authorisation Holder.

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

IrelandWecolIcelandCosmoColMaltaCosmoCol Half

This leaflet was last revised in April 2023