

## เอกสารกำกับยาสำหรับผู้ป่วยฉบับภาษาอังกฤษ

### **Prucalopride**

### **RESOLOR®**

film coated tablets



#### **WHAT IS RESOLOR FOR?**

RESOLOR is used to treat long-term recurring constipation in adults in whom laxatives do not work well enough.



#### **WHEN NOT TO TAKE RESOLOR**

##### **Do not take if you:**

- are allergic (hypersensitive) to prucalopride or any of the other ingredients of RESOLOR,
- have severe kidney disease and are on kidney (renal) dialysis,
- have a torn (perforated) or blocked gut (intestines) or other gut problems such as Crohn's disease, ulcerative colitis or toxic megacolon/megarectum.



#### **WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?**

##### **Take special care with RESOLOR if you:**

- have severe kidney problems,
- have severe liver problems,
- have a serious medical problem such as: lung or heart problems, cancer or AIDS.

Tell your doctor if you have thoughts of harming or killing yourself at any time while taking RESOLOR.

If you have very bad diarrhea and are taking a contraceptive pill, the contraceptive pill may not work properly and you should talk to your doctor about other contraception methods.



#### **Children**

RESOLOR should not be given to children under **18** years.



#### **Pregnancy**

If you are of child bearing age, you should talk to your doctor about contraception during treatment with RESOLOR. RESOLOR is not recommended during pregnancy. If you are, pregnant, or you think you may be pregnant, or if you are planning to become pregnant, talk to your doctor about the risks and benefits of taking RESOLOR.



#### **Breast-feeding**

You are advised not to take RESOLOR if you are breast-feeding, because small amounts of RESOLOR can be passed on to your baby in breast milk. If you are breast-feeding or thinking about breast-feeding, talk to your doctor.



### **Driving or operating machinery**

RESOLOR may cause dizziness and tiredness, especially on the first day of treatment which may make you less alert. Don't drive or use machines unless you are sure you are not affected.



### **Other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.



## **HOW TO TAKE RESOLOR AND HOW MUCH**

RESOLOR comes in the form of **film coated tablets** to be taken by mouth.

You can take RESOLOR with or without food and drinks.

Always take RESOLOR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should take RESOLOR every day for as long as your doctor prescribes it.

Your doctor may check how well RESOLOR is working after the first 4 weeks and regularly after that.

### ***Adults (including people over 65 years)***

The usual dose of RESOLOR for adults is one 2 mg tablet once a day. If you are older than 65 years, the usual starting dose is one 1 mg tablet once a day, which your doctor may increase to 2 mg once a day if needed.

Your doctor may also prescribe a lower dose of one 1 mg tablet daily if you have kidney or liver problems.

RESOLOR is only for adults and should not be taken by children and adolescents up to 18 years.

### **If you take more RESOLOR than you should**

It is important to keep to the dose as prescribed by your doctor. If you have taken more RESOLOR than you should, you may get diarrhea, headache and/or nausea. If you get diarrhea, make sure that you drink more water than usual and ask your doctor or pharmacist for further advice.

### **If you forget to take RESOLOR**

If you forget to take a dose, take it as soon as you remember and then continue treatment as before. Do not take a double dose to make up for a missed dose.

### **If you stop taking RESOLOR**

If you stop taking RESOLOR, your constipation may come back again.

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

### **Important information about some of the ingredients of RESOLOR**

RESOLOR contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.



### **UNDESIRE D EFFECTS**

Like all medicines, RESOLOR can cause side effects, although not everybody gets them. The side effects usually happen when you first start using RESOLOR and usually disappear within a few days.

#### **Very common side effects**

These may affect more than 1 in 10 people

- Headache
- Nausea
- Diarrhea
- Stomach pain

#### **Common side effects**

These may affect up to 1 in 10 people

- Decreased appetite
- Feeling dizzy
- Vomiting
- Indigestion (dyspepsia)
- Passing wind
- Unusual bowel sounds
- Feeling very tired

#### **Uncommon side effects**

These may affect up to 1 in 100 people

- Muscle tremor
- Fever
- Weakness
- Rectal bleeding
- Frequent need to pass urine (pollakiuria)
- Heart beat feels fast or uneven (palpitations) **If you get a fast or uneven heart beat, tell your doctor straight away as you may need medical attention.**
- Migraine
- Spinning sensation (vertigo)

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.



### **HOW TO STORE RESOLOR**

Keep out of the sight and reach of children.

This medicine can be kept for only a limited period. Do not use RESOLOR after the date (month and year) printed after "EXP", even if it has been stored properly.

See storage conditions on the outer pack.

You are advised to return expired medicine to your pharmacist.



## WHAT IS IN RESOLOR?

RESOLOR is a medicine to treat constipation.

The active ingredient is **prucalopride**.

- One film-coated tablet of RESOLOR 1 mg contains 1 mg prucalopride (as prucalopride succinate).
- One film-coated tablet of RESOLOR 2 mg contains 2 mg prucalopride (as prucalopride succinate).

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate,

hypromellose, triacetin, titanium dioxide (E171), macrogol 3000. The 2 mg tablet also contains iron oxide red (E172), iron oxide yellow (E172), FD&C blue no. 2 aluminium lake (E132)

### **Nature and Contents of Container**

Aluminium/aluminium-perforated unit dose blisters containing 7 tablets. Each pack contains 1x7, 2x7, 3x7 and 4x7 film-coated tablets.

Not all pack sizes may be marketed.

Latest update of this package insert: 17 January 2020

### **Manufactured by**

Janssen Cilag S.p.A., Latina, Italy

### **Marketing Authorization numbers**

RESOLOR 1 mg: 1C 61/55 (N)

RESOLOR 2 mg: 1C 62/55 (N)

### **Date of Authorizations**

#### RESOLOR 1mg

Initial Authorization Date: 18 July 2012

SMP Released Approval: 30 December 2015

#### RESOLOR 2mg

Initial Authorization Date: 18 July 2012

SMP Released Approval: 30 December 2015

### **Date of Revision of the text**

10 May 2021 (CPPI v. 17 January 2020)

**Imported by**

Janssen-Cilag Ltd.

106 Moo 4 Lad Krabang Industrial Estate,  
Chalongkrung Rd., Lamplatew, Lad Krabang,  
Bangkok 10520

Tel: +662-792-7200

Fax: +662-792-7222

**Warnings according to Ministry of Public Health announcement**

Do not use when having stomachache or nausea.

Please see full prescribing information at

- <http://www.fda.moph.go.th/sites/oss/Pages/Main.aspx>

- <http://ndi.fda.moph.go.th/>