

# RESOLOR<sup>®</sup> FILM COATED TABLET

Prucalopride Succinate (1mg, 2mg)

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**What RESOLOR<sup>®</sup> is used for**

RESOLOR<sup>®</sup> is used to treat long-term recurring constipation in women in whom laxatives do not work well enough.

**How RESOLOR<sup>®</sup> works**

RESOLOR<sup>®</sup> belongs to a group of gut motility enhancing medicines (gastrointestinal prokinetics). It acts on the muscle wall of the gut, helping to restore the normal functioning of the bowel.

**Before you use RESOLOR<sup>®</sup>***- When you must not use it*

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

*Pregnancy and lactation**Pregnancy*

If you are of child bearing age, you should talk to your doctor about contraception during treatment with RESOLOR<sup>®</sup>. RESOLOR<sup>®</sup> 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<sup>®</sup>.

*Breastfeeding*

You are advised not to take RESOLOR<sup>®</sup> if you are breastfeeding, because small amounts of RESOLOR<sup>®</sup> can be passed on to your baby in breast milk. If you are breastfeeding or thinking about breastfeeding, talk to your doctor.

*Children*

RESOLOR<sup>®</sup> should not be given to children and adolescents under 18 years.

*- Before you start use it*

- Take special care with RESOLOR<sup>®</sup> if you:
- have severe kidney problems,
  - have severe liver problems,
  - have a serious medical problem such as: lung or heart problems, nerve, mental problems, cancer or acquired immune deficiency syndrome (AIDS).

*Important information about some of the ingredients of RESOLOR<sup>®</sup>*

RESOLOR<sup>®</sup> 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.

*- Taking 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.

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.

**How to use RESOLOR<sup>®</sup>***- How much to use*

RESOLOR<sup>®</sup> comes in the form of film coated tablets to be taken by mouth. You can take RESOLOR<sup>®</sup> with or without food and drinks.

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

The usual dose of RESOLOR<sup>®</sup> 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 severe kidney or liver problems.

RESOLOR<sup>®</sup> is only for female adults.

*- When to use it*

Always take this medicine exactly as your doctor told you. You should check with your doctor or pharmacist if you are not sure.

*- How long to use it*

You should take RESOLOR<sup>®</sup> every day for as long as your doctor prescribes it. Your doctor may check how well RESOLOR<sup>®</sup> is working after the first 4 weeks and regularly after that.

*- If you forget to use it*

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 use too much (overdose)*

It is important to keep to the dose as prescribed by your doctor. If you have taken more RESOLOR<sup>®</sup> 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.

**While you are using it***- Things you must do*

Always take RESOLOR<sup>®</sup> exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

*- Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give RESOLOR<sup>®</sup> to anyone else, even if they have the same symptoms or condition as you.

*- Things to be careful of**Driving and using machines*

RESOLOR<sup>®</sup> 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.

*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.

**Side 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
- Feeling sick (nausea)
- Diarrhea
- Stomach pain

**Common side effects**

These may affect up to 1 in 10 people

- Dizziness
- Vomiting
- Disturbed digestion
- Rectal bleeding
- Windiness (flatulence)
- Unusual bowel sounds
- Need to pass urine more often than usual (in children)
- Tiredness

**Uncommon side effects**

These may affect up to 1 in 100 people

- Loss of appetite
- Shaking
- Fever
- Weakness
- Strong pounding heart. If you get a pounding heart, tell your doctor straight away as you may need medical attention.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [(Public → Reporting Side Effects to

Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of RESOLOR®**

- Storage  
Do not store above 30°C.

Store in original blister package to protect from moisture.

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.

Keep out of sight and reach of children.

- Disposal  
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product description**

- What it looks like  
**RESOLOR® 1 mg film-coated tablets** are white to off-white round shaped biconvex tablets marked "PRU 1" on one side.

**RESOLOR® 2 mg film-coated tablets** are pink round shaped biconvex tablets marked "PRU 2" on one side.

- Ingredients
  - Active ingredient  
The active ingredient is prucalopride succinate.
  - Inactive ingredient  
Lactose monohydrate, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, hypromellose, triacetin, titanium dioxide (E171), macrogol 3000. The 2mg tablet also contains iron oxide red (E172), iron oxide yellow (E172), FD&C blue no. 2 aluminium lake (E132).

- MAL number(s)  
**RESOLOR® 1 mg film-coated**  
MAL12025075AZ

**RESOLOR® 2 mg film-coated**  
MAL12025076AZ

**Manufacturer**

Janssen Cilag SPA  
Via C. Janssen,  
Borgo San Michele,  
04100 Latina, Italy

**Product registration holder**

Johnson & Johnson Sdn Bhd  
Lot 3 & 5, Jalan Tandang  
46050 Petaling Jaya  
Selangor, Malaysia

**Date of revision**

18/07/2018 (MY PI CCDS vNov13)

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