

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Preparation name, form and strength

**Resolor[®] 1 mg,
Film-coated tablets**

**Resolor[®] 2 mg,
Film-coated tablets**

The active ingredient and its quantity:

Prucalopride 1 mg (as prucalopride succinate)

Prucalopride 2 mg (as prucalopride succinate)

Inactive ingredients and allergens in the preparation - see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Resolor belongs to a group of medicines that increase intestinal motility. Resolor acts on the muscle of the wall of the gut, and helps restore the normal functioning of the bowel.

Resolor is intended for symptomatic treatment of chronic constipation in adults in whom previous treatment with laxatives failed.

The medicine is not intended for use in children and adolescents below the age of 18. The medicine was not sufficiently tested in these populations.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient prucalopride or to any of the additional ingredients contained in Resolor. For a list of the additional ingredients, see section 6 "Further Information".
- You are being treated with dialysis.
- You are suffering from perforation of the gut wall or intestinal obstruction, from a severe inflammation of the intestine, such as Crohn's disease, ulcerative colitis (an ulcerative inflammation of the large intestine), widening of the large intestine and the rectum (megacolon or megarectum).

Special warnings regarding use of the medicine:

Before treatment with Resolor, inform the doctor of your condition:

- If you are suffering from a severe kidney disease.
- If you are suffering from a severe liver disease.
- If you are under medical supervision due to a serious medical problem, such as: a lung disease, heart disease, medical problems in the nervous system or mental health problems, cancer, AIDS or a hormonal disorder.
- If you have or have had depression, suicidal thoughts or actions, mood problems.
- If you are suffering from severe diarrhea, oral contraceptives may not work properly and it is therefore recommended to use an additional contraceptive method. Read additional information in the patient leaflet of the oral contraceptives that you are using.

Children and adolescents

Resolor is intended for adults only. Do not give this medicine to children or adolescents under the age of 18.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Taking Resolor and food

Resolor can be taken at any time of the day, with or without food and drink.

Pregnancy and breastfeeding

Pregnancy:

Resolor is not recommended for use during pregnancy.

- Tell your doctor if you are pregnant or planning to become pregnant.
- Use a reliable contraceptive to prevent pregnancy while using Resolor. Consult the doctor.
- Inform the doctor if you become pregnant during treatment with Resolor.

Breastfeeding:

- While breastfeeding, the active ingredient, prucalopride, can pass into the breast milk. It is not recommended to breastfeed during the course of treatment with Resolor. Consult the doctor.

Driving and use of machines

Resolor is not expected to affect the ability to drive or use machines.

However, sometimes Resolor can cause dizziness and fatigue, especially on the first day of treatment, and this may have an effect on the ability to drive and use machines.

Resolor contains lactose monohydrate

If you know you have an intolerance to certain sugars, refer to your doctor before you start taking Resolor.

3. HOW SHOULD THE MEDICINE BE USED?

Always use this preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and the treatment regimen will be determined by the doctor only.

Take Resolor every day for the period of time your doctor has set for treatment.

Your doctor may want to re-evaluate your condition and the improvement resulting from treatment after the first 4 weeks of treatment, and thereafter, at fixed intervals.

The usual dosage of Resolor for most patients is one 2 mg tablet, once a day.

If you are over 65 years of age or are suffering from a severe liver disease, the initial dosage is one 1 mg tablet, once a day, and the doctor may increase the dosage to one 2 mg tablet, once a day, as necessary.

Your doctor may recommend a lower dosage of one 1 mg tablet, once a day, if you have a severe kidney disease.

Taking a higher dosage than recommended will not improve the effect of the medicine.

Do not exceed the recommended dosage

There is no information regarding crushing/halving/chewing.

Resolor is intended for adults only. Do not give this medicine to children or adolescents under the age of 18.

It is important to take the medicine at the dosage determined by the doctor.

- **If you accidentally take a higher dosage** of Resolor than recommended, you may suffer from diarrhea, headache and/or nausea. In case of diarrhea, be sure to drink enough water.
- **If you forget to take Resolor:**
Do not take a double dose of Resolor to compensate for the forgotten tablet. Take the next dose at the regular time.
- Adhere to the treatment regimen as recommended by the doctor.
- Even if there is an improvement in your health, do not discontinue treatment with Resolor without consulting the doctor or pharmacist.
- **If you stop taking the medicine Resolor**, your constipation symptoms may return.
- **Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Resolor may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of

them.

Side effects may primarily occur at the beginning of treatment, and will usually pass within a few days of beginning treatment.

Resolor may cause serious side effects, including unusual changes in mood or behavior, thoughts of hurting yourself, trying to hurt yourself, or suicide. Stop taking Resolor immediately and tell your doctor immediately if your depression gets worse, you feel sad, hopeless or begin to have thoughts of suicide, thoughts of hurting yourself or if you have tried to hurt yourself.

Very common side effects, effects which occur in more than 1 in 10 users

- Headache
- Nausea
- Diarrhea
- Abdominal pain

Common side effects, effects which occur in 1-10 in 100 users

- Decreased appetite
- Dizziness
- Vomiting
- Dyspepsia
- Flatulence
- Abnormal bowel sounds
- Tiredness

Uncommon side effects, effects which occur in 1-10 in 1,000 users

- Tremor
- Palpitations
- Rectal bleeding
- Increased frequency of passing urine (pollakiuria)
- Fever
- Feeling unwell

Inform the doctor if you experience palpitations.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting Side Effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning.

- Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
 - Do not store the medicine at a temperature that exceeds 30° C. Protect from moisture.
 - Keep Resolor tablets in the original blister package to protect the medicine from moisture.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Lactose Monohydrate, Microcrystalline Cellulose, Magnesium Stearate, Colloidal Silicon Dioxide, Hypromellose, Titanium Dioxide (E171), Macrogol 3000, Triacetin.

The 2 mg tablet also contains:

Iron Oxide Red (E172), Iron Oxide Yellow (E172), FD&C blue No. 2 aluminum lake (E132).

Allergenic ingredients: The medicine contains lactose.

Each 1 mg Resolor tablet contains 150 mg lactose monohydrate.

Each 2 mg Resolor tablet contains 165 mg lactose monohydrate.

- What does the medicine look like and what are the contents of the package:
Resolor 1 mg film-coated tablet is white to off-white, biconvex, round, with “PRU 1” written on one side.
Resolor 2 mg film-coated tablet is pink, biconvex, round, with “PRU 2” written on one side.
- The package contains 4 aluminium tray packages/blisters (with calendar marking).
Each blister contains 7 film-coated tablets.
- Package size: The package contains 28 film-coated tablets.

Manufacturer name and Address: Amdipharm limited, Dublin, Ireland.

Registration holder and Address: Biotis ltd., 22 Hamelacha st., Rosh Ha'ayin.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Resolor 1 mg film-coated tablets:

149-82-33682-00

Resolor 2 mg film-coated tablets:

149-83-33683-00

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