**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Prucalopride STADA 1 mg film-coated tablets**
**Prucalopride STADA 2 mg film-coated tablets**
prucalopride

**Read all of this leaflet carefully before you start taking 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get 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 Prucalopride STADA is and what it is used for
This medicine contains the active substance prucalopride.
Prucalopride 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. It is used for the treatment of chronic constipation in adults in whom laxatives do not work well enough.

Not for use in children and adolescents younger than 18 years.

## 2. What you need to know before you take Prucalopride STADA
**Do not take Prucalopride STADA:**
- if you are allergic to prucalopride or any of the other ingredients of this medicine (listed in section 6).
- if you are on renal dialysis.
- if you suffer from perforation or obstruction of the gut wall, severe inflammation of the intestinal tract, such as Crohn's disease, ulcerative colitis or toxic megacolon/megarectum.

**Warnings and precautions**
Talk to your doctor before taking this medicine.

Take special care with this medicine and tell your doctor if you:
- suffer from severe kidney disease.
- suffer from severe liver disease.
- are currently under supervision by a doctor for a serious medical problem such as lung or heart disease, nervous system or mental health problems, cancer, AIDS or a hormonal disorder.

If you have very bad diarrhoea, the contraceptive pill may not work properly and the use of an extra method of contraception is recommended. See the instructions in the patient leaflet of the contraceptive pill you are taking.

**Other medicines and Prucalopride STADA**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Prucalopride STADA with food and drink**
Prucalopride can be taken with or without food and drinks, at any time of the day.

**Pregnancy and breastfeeding**
Prucalopride is not recommended for use during pregnancy.
- Tell your doctor if you are pregnant or planning to become pregnant.
- Use a reliable method of contraception while you are taking pruclaopride, to prevent pregnancy.
- If you do become pregnant during treatment with prucalopride, tell your doctor.

When breast-feeding, prucalopride can pass into breast milk. Breast-feeding is not recommended during treatment with this medicine. Talk to your doctor about this.

Ask your doctor for advice before taking any medicine.

**Driving and using machines**
Prucalopride is unlikely to affect your ability to drive or use machines. However, sometimes prucalopride may cause dizziness and tiredness, especially on the first day of treatment, and this may have an effect on driving and use of machines.

**Prucalopride STADA contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. How to take Prucalopride STADA
Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Take this medicine every day for as long as your doctor prescribes it.

The doctor may want to reassess your condition and the benefit of continued treatment after the first 4 weeks and thereafter at regular intervals

The usual dose for most patients is one 2 mg tablet once a day.

If you are older than 65 years or have severe liver disease, the 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 recommend a lower dose of one 1 mg tablet daily if you have severe kidney disease.

Taking a higher dose than recommended will not make the product work better.

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

**If you take more Prucalopride STADA than you should**
It is important to keep to the dose as prescribed by your doctor. If you have taken more prucalopride than you should, it is possible that you will get diarrhoea, headache and/or nausea. In case of diarrhoea, make sure that you drink enough water.

**If you forget to take Prucalopride STADA**
Do not take a double dose to make up for a forgotten tablet. Just take your next dose at the usual time.

**If you stop taking Prucalopride STADA**
If you stop taking prucalopride, your constipation symptoms may come back again.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The side effects mostly occur at the start of treatment and usually disappear within a few days with continued treatment.

The following side effects have been reported very commonly (may affect more than 1 in 10 people): headache, feeling sick, diarrhoea and abdominal pain.

The following side effects have been reported commonly (may affect up to 1 in 10 people): decreased appetite, dizziness, vomiting, disturbed digestion (dyspepsia), windiness, abnormal bowel sounds, tiredness.

The following uncommon side effects have also been seen (may affect up to 1 in 100 people): tremors, pounding heart, rectal bleeding, increase in frequency of passing urine (pollakiuria), fever and feeling unwell. If pounding heart occurs, please tell your doctor.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
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 Prucalopride STADA

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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

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 Prucalopride STADA contains**
The active substance is prucalopride.
One film-coated tablet of Prucalopride STADA 1 mg contains 1 mg of prucalopride (as succinate).
One film-coated tablet of Prucalopride STADA 2 mg contains 2 mg of prucalopride (as succinate)

The other ingredients are:
Lactose monohydrate (see section 2), cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, hypromellose, polysorbate 80, macrogol 400 and titanium dioxide (E171). The 2 mg tablet also contains iron oxide red (E172).

**What Prucalopride STADA looks like and contents of the pack**
Prucalopride STADA 1 mg film-coated tablets are white to off white, circular, film-coated tablets with “C” debossed on one side and “11” on the other side.

Prucalopride STADA 2 mg film-coated tablets are pink, circular, film-coated tablets with “C” debossed on one side and “12” on the other side.

This medicine is available in blister packs. Each pack contains 7, 14, 28, 30 or 84 film-coated tablet in blisters or 7 x 1, 14 x 1, 28 x 1, 30 x 1 or 84 x 1 film-coated tablet in unit dose blisters.

**Marketing Authorisation Holder**
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

**Manufacturer**
Chanelle Medical, Loughrea, Co. Galway, Ireland
STADA Arzneimittel AG, Stadastrasse 2-18, Dortelweil, Bad Vilbel, Hesse 61118, Germany

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

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| IE: | Prucalopride STADA 1 mg film-coated tablets<br>Prucalopride STADA 2 mg film-coated tablets |
| DE: | Prucaloprid AL 1 mg Filmtabletten<br>Prucaloprid AL 2 mg Filmtabletten |
| DK: | Prucalopride STADA |
| FI: | Prucalopride STADA 1 mg kalvopäällysteinen tabletti<br>Prucalopride STADA 2 mg kalvopäällysteinen tabletti |
| IS: | Prucalopride STADA |
| SE: | Prucalopride STADA 1 mg filmdragerad tablett<br>Prucalopride STADA 2 mg filmdragerad tablett |

**This leaflet was last revised in May 2020.**