

## Package Leaflet: Information for the user

### **Codalax<sup>®</sup> 200 mg/25mg capsules and Codalax<sup>®</sup> Forte 500mg/37.5mg capsules** Poloxamer 188 and Dantron

**Read all of this leaflet carefully before you start taking this medicine.**

- 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

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2. Before you take *Codalax* capsules or *Codalax Forte* capsules
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#### **1. What *Codalax* capsules and *Codalax Forte* capsules are and what they are used for**

These capsules have been prescribed for you to prevent or treat constipation caused by taking painkillers.

Constipation may cause pain, tenderness, bloating (around the stomach), wind and vomiting. Increasing the amount of fibre (fruit, vegetables, wholemeal bread, pasta, brown rice) and fluids you eat and drink may help reduce the problem.

These capsules are only suitable for certain patients and should only be taken by the person for whom they have been prescribed.

*Codalax* and *Codalax Forte* capsules contain the active ingredients poloxamer 188 and dantron. Poloxamer 188 belongs to a group of medicines called faecal softeners and dantron to a group called laxatives. The other ingredients are listed in section 6 of this leaflet.

#### **2. Before you take *Codalax* capsules or *Codalax Forte* capsules**

**Do not take *Codalax* capsules or *Codalax Forte* capsules if:**

- you are allergic (hypersensitive) to poloxamer 188 or dantron;
- you are allergic to any of the other ingredients of the capsules (see section 6 ‘Further Information’);
- your constipation is caused by a blockage of the bowel (intestine).

*Codalax Forte* capsules should not be given to children under 12 years of age.

**Take special care with *Codalax* capsules and *Codalax Forte* capsules**

Talk to your doctor before taking this medicine if you suffer from loss of bladder or bowel control (incontinence).

Children who still wear nappies should not be given *Codalax* capsules.

**Taking other medicines**

Your doctor may have prescribed your capsules at the same time as some other medicines. This may be to prevent you from getting constipation.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and breastfeeding**

Do not take these capsules if you are pregnant, likely to become pregnant or are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

**3. How to take *Codalax* capsules and *Codalax Forte* capsules**

Two different strengths of capsule are available. Your doctor will decide whether *Codalax* or *Codalax Forte* capsules suit you best.

Always take these capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often. You should check with your doctor or pharmacist if you are not sure.

Take your capsules just before you go to bed and always swallow them with a glass of water.

**Adults**

The usual dose is one or two *Codalax* or *Codalax Forte* capsules.

**Children**

Children may take the *Codalax* capsules only. The usual dose for children is one capsule.

**Children under 12 years of age should not be given *Codalax Forte* capsules.**

**If you take more capsules than you should**

Drink plenty of water and call your doctor or hospital straight away. When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

**If you forget to take your capsules**

If you miss a dose you should take it as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten capsule.

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

## 4. Possible side effects

Like all medicines, *Codalax* and *Codalax Forte* capsules can cause side effects, although not everybody gets them.

You may find the skin around your bottom turns pink or red when you take these capsules. Your urine may also turn pink or red. Don't worry, this is quite normal and is harmless.

### **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

HPRA Pharmacovigilance,

Earlsfort Terrace,

IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie);

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

## 5. How to store *Codalax* capsules and *Codalax Forte* capsules

Keep out of the reach and sight of children.

Do not use any capsules after the expiry date stated on the outer carton and blister pack. EXP 08 2010 means that you should not take the capsules after the last day of that month i.e. August 2010.

Do not store your capsules above 30°C.

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.

## 6. Further Information

### **What *Codalax* capsules and *Codalax Forte* capsules contain**

The active ingredients are poloxamer 188 and dantron. Each *Codalax* capsule contains 200 mg of poloxamer 188 and 25 mg of dantron. Each *Codalax Forte* capsule contains 500 mg of poloxamer 188 and 37.5 mg of dantron.

The other ingredients are:

- Butylhydroxytoluene (E321)
- Gelatin
- Iron oxide (E172)
- Sodium laurilsulfate
- Indigo carmine (E132)
- Erythrosine (E127)
- Titanium dioxide (E171)
- Shellac
- Propylene Glycol (E1520)

- Simeticone

**What *Codalax* and *Codalax Forte* capsules look like and the contents of the pack**

*Codalax* capsules are light brown and orange in colour and are marked CX and NAPP.

*Codalax Forte* capsules are light brown and green in colour and are marked CXF and NAPP.

In each box there are 60 capsules.

**Marketing Authorisation Holder and Manufacturer**

The capsules are made by Bard Pharmaceuticals Limited at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

The Marketing Authorisation Holder is Mundipharma Pharmaceuticals Limited Millbank House, Arkle Road, Sandyford, Dublin 18.

**This leaflet was last revised in May 2015**

*Codalax*<sup>®</sup> capsules and *Codalax*<sup>®</sup> *Forte* capsules are protected by Irish Patent No. EP(IE) 0642786.

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