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Package leaflet: Information for the user
Co-Danthramer 75 mg/1000 mg per 5 ml Oral Suspension
75 mg Dantron and 1000 mg Poloxamer 188/5 ml

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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, see section 4.

What is in this leaflet:

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1. What Co-Danthramer is and what it is used for
Co-Danthramer 75 mg/1000 mg per 5 ml Oral Suspension ("Co-Danthramer") belongs to a group of laxatives called stimulant laxatives. It works by encouraging normal bowel movements between 6 and 12 hours after taking it. Co-Danthramer is used for the prevention and treatment of constipation in seriously ill patients.

2. What you need to know before you take Co-Danthramer
Do not take Co-Danthramer if you:
- are allergic to dantron, poloxamer 188 or any of the other ingredients of Co-Danthramer *(see Section 6 and end of Section 2).*
- are pregnant or are breast-feeding.
- suffer from intestinal obstruction - bowel blockage.
- have signs of appendicitis or inflamed bowel (severe pain in your side).

Co-Danthramer is not suitable for children under 12.

Take special care with Co-Danthramer
Before you take Co-Danthramer, tell your doctor if you:
- suffer from incontinence as prolonged contact with the skin can cause irritation and peeling of the skin, or staining.
- have hereditary fructose intolerance.
- suffer from liver disease, alcoholism or epilepsy.
- have ever had kidney-related problems.

Taking other medicines
You must tell your doctor if you are taking or have recently taken any other medicines, including other laxatives and medicines obtained without a prescription. Co-Danthramer may modify or increase the effects of other medicines.

Pregnancy and breast-feeding
Do not take Co-Danthramer if you are, or are likely to become pregnant, or are breast-feeding *(see end of Section 2).*

Driving and using machines
Co-Danthramer may cause unusual tiredness or weakness and, if affected, you should not drive or operate machinery *(see end of Section 2).*

Important information about some of the ingredients of Co-Danthramer:

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The product contains:
- **Sorbitol (E420):** this medicine contains 1300 mg of sorbitol per 5 ml which is equivalent to 260 mg per ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **Ethanol:** this medicine contains 250 mg of alcohol (ethanol) in each 5 ml which is equivalent to 50 mg per ml. The amount in 5 ml of this medicine is equivalent to 5.9 ml beer, 2.5 ml wine per dose.
  The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.
  The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.
  If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.
  If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- **Propylene glycol (E1520):** this medicine contains 260 mg propylene glycol in each 5 ml which is equivalent to 52 mg/ml.
- **Sodium:** this medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.
- **Ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218):** may cause allergic reactions, which may be delayed.

3. How to take Co-Danthramer
Always take Co-Danthramer exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Shake the bottle well before taking Co-Danthramer, but avoid contact with skin to prevent staining.

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The effects of Co-Danthramer are usually seen 6 to 12 hours after you have taken it.

The usual dose is:

Adults and children over 12 years:	One 5 ml spoonful at bedtime.
Children under 12 years:	Not recommended for use.

Your doctor may advise you to take your medicine in a different way, so you must always follow your doctor's advice about when and how to take Co-Danthramer. Check with your doctor if you are unsure.

If you take more Co-Danthramer than you should:
Co-Danthramer can cause diarrhoea if you take too much at once. If it is used for long periods of time, you may get diarrhoea which may lower the salt levels in the blood, causing weakness, dehydration, faintness and tiredness. If this occurs, eat a balanced diet containing foods rich in potassium and drink plenty of water. If you are unsure contact your doctor or pharmacist who will recommend what action you should take.

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If you forget to take Co-Danthramer:
If you forget to take a dose, then miss that dose and take it at the next convenient time.
If you have any questions on the use of this product, ask your doctor or pharmacist for advice.

4. Possible side effects
Like all medicines, Co-Danthramer can cause side effects, although not everybody gets them.

Possible side effects are:
- abdominal cramps
- rash
- urine may be coloured red
- stomach upset
- irritation and peeling or staining of the skin e.g. in incontinence
- unusual tiredness or weakness

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With prolonged use, the following may occur:
- discolouration of the lining of your stomach
- kidney stones - failure
- bowels may stop working normally - stopping salt and nutrients being absorbed into the blood

In animals, dantron can cause growths in the bowel and liver. There may be a possible, but very small risk of this happening in humans.

Reporting of side effects
If you get any side effects, talk to your doctor. 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; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-Danthramer
Keep this medicine out of the sight and reach of children. Do not use Co-Danthramer after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Do not store above 25˚C, and store in the original container.

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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. Contents of the pack and other information
What Co-Danthramer contains
Each 5 ml of Co-Danthramer contains:
- **Active ingredients:** 75 mg Dantron and 1000 mg Poloxamer 188.
- **Other ingredients:** aluminium magnesium silicate, xanthan gum, glycerol (E422), sorbitol (E420), saccharin sodium, propylene glycol (E1520), ethanol, methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), citric acid monohydrate, sodium citrate, purified water and peach flavour liquid (contains propylene glycol).

What Co-Danthramer looks like and contents of the pack:
Co-Danthramer is a yellow/orange, peach-flavoured oral suspension, and is available in 100 ml, 150 ml, 200 ml, 300 ml, 500 ml and 1 litre amber glass bottles. Not all pack sizes may be marketed.

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Marketing Authorisation Holder and Manufacturer
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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Each 5 ml contains:
75 mg Dantron, 1000 mg Poloxamer 188. It also contains sorbitol (E420), ethanol, propylene glycol (E1520), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214) and propyl parahydroxybenzoate (E216). This product contains 6.2% v/v of ethanol, see leaflet.
Suspension for oral administration.
Keep out of the sight and reach of children.
Dosage: As directed by physician.
Shake the bottle well before use.
Do not store above 25˚C. Store in the original container. Read the package leaflet before use.
MA Holder and Manufacturer:
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
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