

Package Leaflet: Information for the patient



Paracetamol 120mg/5ml Diphenhydramine Hydrochloride 12.5mg/5ml

Read all of this leaflet carefully before you start taking this medicine, or giving it to a child, because it contains important information for you.

Always give this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if your child does not feel better or feels worse.

What is in this leaflet:

1. What Dozol is and what it is used for
2. What you need to know before you give Dozol to your child
3. How to give Dozol
4. Possible side effects
5. How to store Dozol
6. Contents of the pack and other information.

1. What Dozol is and what it is used for

Dozol is a caramel flavoured sugar free oral solution. This medicine contains two different active ingredients - paracetamol and diphenhydramine. Like all medicines these ingredients may cause harm in overdose. Do not give this medicine to your child without the advice of a healthcare professional.

Paracetamol is a pain killer and provides effective relief of teething pains, irritability after an immunisation, aches or pains. It also lowers high temperatures.

Diphenhydramine hydrochloride is an antihistamine, which provides relief of sleeplessness as a result of the conditions listed above.

It is suitable for children aged from 2 years.

2. What you need to know before you give Dozol to your child

Do not give Dozol to your child if:

- Your child is allergic to paracetamol or diphenhydramine hydrochloride or to any of the other ingredients of this medicine (listed in section 6)
- Your child is under 2 years of age
- Your child has epilepsy (large doses of antihistamines may bring on epileptic fits)
- Your child is taking any other paracetamol containing products
- Your child is taking other antihistamine/ diphenhydramine products
- Your child has a rare sugar intolerance called hereditary fructose intolerance
- Your child is taking or has recently taken (in the last 14 days) antidepressants called monoamineoxidase inhibitors (MAOIs)
- Your child has porphyria.

You must not give Dozol if any of the above applies. If you are unsure about whether you can give this medicine speak to your doctor or pharmacist .

Warnings and precautions

- Talk to your doctor or pharmacist before giving Dozol to your child.
- Dozol may cause drowsiness. Children receiving this medicine should be kept under supervision
- Dozol should be given with caution to children with known liver or renal impairment.
- During treatment with Teedex, tell your doctor straight away if: If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

If adults take this medicine:

The following warnings also apply if you are an adult taking this medicine:

- If you drink large amounts of alcohol, you may be more prone to the side effects of paracetamol, and the dangerous effects of a paracetamol overdose
- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, think you might be pregnant or are breast feeding
- May cause drowsiness, if affected do not drive or operate machinery.

Other medicines and Dozol:

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This means medicines you have bought yourself as well as those you have on prescription from your doctor. Dozol should not be taken if your child is taking any other medicines, without the advice of a doctor / pharmacist.

Please inform your doctor or pharmacist if your child is taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment (see section 2)

Important information about some of the ingredients

- Contains propylene glycol which may cause alcohol-like effects
- Contains sorbitol (E420) and maltitol (E965). If your child has an intolerance to some sugars, contact your doctor before giving this medicinal product
- Sorbitol content 1.5g/5mL, sorbitol may have a mild laxative effect; the calorific content of sorbitol is 2.6Kcal/g
- Contains the preservatives ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218), colouring agent ponceau 4R (E124), all of which may cause allergic reactions (possibly delayed)

3. How to give Dozol

Always give this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Check the table below to see how much of the medicine to use:

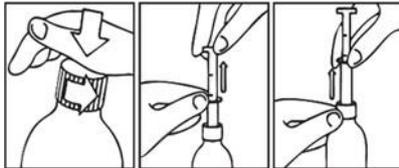
- **Do not** give Dozol to children under 2 years of age
- Dozol Oral solution should be taken by mouth only
- It is important to ensure that your child receives the correct dose. The dose needs to be accurately measured using the oral syringe provided.

Instructions for use:

- Open bottle cap by twisting it and pushing downwards. Place syringe into bottle.
- Pull the plunger towards you until the 2.5ml or the 5ml marking is level with the outer clear plastic rim.

continued, please turn over.

- Press the plunger gently, into the child’s mouth, to release a trickle. Do not squirt it out quickly. The child should be allowed time to swallow the medicine.
- The syringe should be washed, by hand, and air-dried after use.



The recommended dose is as follows:

Age	Dose	How Often (in 24 hours)
2 to 4 years	5mL	3 times
4 to 6 years	7.5mL	3 times
6 to 8 years	10mL	3 times
8 to 10 years	15mL	3 times
10 to 12 years	20mL	3 times
<ul style="list-style-type: none"> • There needs to be sufficient time between doses - the interval between doses should be six hours • Do not give more than 3 doses in any 24 hours • For short term use only • Not recommended for routine use • Never exceed the dose recommended on the package leaflet • It is essential that this medicine is not administered with other medicines which contain paracetamol. If you 		

are not sure if a medicine contains paracetamol, check with your pharmacist and carefully read the package leaflet

- **Do not administer with any other medicine without checking with your healthcare professional.**

If anyone has taken or given more Dozol than they should:

Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible, liver damage.

Take your medicine or the pack with you so that the doctor knows what you have taken.

If you forget to take or give a dose of Dozol:

If you have missed a dose, don't worry; give the next dose when needed provided that the last dose was given at least 6 hours ago.

Do not give a double dose to make up for a forgotten dose.

If your child's symptoms do not go away, or, get worse or if you are not sure how to give this medicine and would like further information, then please contact your doctor as soon as possible.

4. Possible side effects

Like all medicines, Dozol can cause side effects, although not everybody gets them.

Stop giving Dozol and seek immediate medical help if you notice the following rare but serious symptoms:

- Allergic (hypersensitivity) reactions including skin rash. Very rare cases of serious skin reactions have been reported
- Unexpected bruising or bleeding, sore throat,

infections or fever, pale skin and weakness or breathlessness. These can be a sign of severe blood disorders (thrombocytopenia and agranulocytosis)

- Problems with movement and co-ordination or tremor
- Liver problems which can cause yellowing of the skin or whites of the eyes (jaundice).

Other side effects may include:

Commonly: Drowsiness, headache, dry mouth, nose and throat, blurred vision, upset stomach, difficulty in passing urine, phlegm on the chest.

Rarely: Low blood pressure, dizziness, confusion, increased awareness of the heartbeat (palpitations), depression, problems with sleeping, fits (convulsions), excitability in children.

Not known (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Reporting of side effects

If you or your child 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

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 Dozol

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 label and carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Do not refrigerate or freeze. Keep bottle in the outer carton. 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 Dozol contains:

The active ingredients (per 5ml) are paracetamol 120mg and diphenhydramine hydrochloride 12.5mg.

The other ingredients are macrogol 4000, glycerol, propylene glycol, sorbitol liquid (E420), maltitol liquid (E965), neohesperidin dihydrochalcone, saccharin sodium, ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), butterscotch yellow (E160), caramel flavour, ponceau 4R (E124), purified water.

What Dozol looks like and contents of the pack

Dozol is a clear amber coloured liquid.

This medicine is available in pack sizes of 100ml and 30ml.

Not all pack sizes may be available.

Marketing Authorisation Holder

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