SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dozol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Paracetamol Ph.Eur.120mg and Diphenhydramine HCl Ph.Eur. 12.5mg

3 PHARMACEUTICAL FORM

Clear amber liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Children of 6 – 12 years of age: for the treatment of mild to moderate pain, including headache, sore throat, aches and pain. Relief of influenza, feverishness and feverish colds and associated symptoms of runny nose and sneezing.

4.2 Posology and method of administration

Child's Age	How Much	How often (in 24 hours)
6 – 8 years	**Two 5mL**	**3 times**
8-10 years	**Three 5mL**	**3 times**
10-12 years	**Four 5mL**	**3 times**
• **Do not give more than 3 doses in any 24 hour period** • **Leave at least 4 hours between doses**		

- **Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist**
- **Parents or carers should seek medical attention if the child's condition deteriorates during treatment**
- **Do not exceed the stated dose**

4.3 Contraindications

Large doses of antihistamines may precipitate fits in epileptics.

Hypersensitivity to the active substances or to any of the excipients.

Not to be used in children under the age of six years.

Monoamine inhibitors (MAOIs) or within 14 days of stopping treatment.

4.4 Special warnings and precautions for use

1. Contains paracetamol
2. Do not exceed the stated dose.
3. Leave at least 4 hours between doses.
4. Do not give more than 3 doses in any 24 hour period.
5. Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.
6. The product should be administered with caution to patients with known liver or renal impairment. The hazards of overdose are greater in those with alcoholic liver disease.
7. Keep out of the reach and sight of children.
8. This product may cause drowsiness. Children receiving this medication should be kept under supervision. This product should not be used to sedate a child.
9. Do not give with any other paracetamol-containing products.
10. Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.
11. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
12. Sorbitol may have a mild laxative effect. The calorific value of sorbitol is 2.6 Kcal/g.
13. May cause alcohol like symptoms.
14. May cause allergic reactions (possibly delayed).
15. Do not take with any other cough and cold medicines.
16. As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this

product.

17. Use with caution in prostatic hypertrophy, urinary retention, susceptibility to angle-closure, hepatic disease.
18. For oral use only.
19. Never give more medicine than shown in the table.
20. Always use the syringe supplied with the pack.
21. Do not store above 25ºC. Store in the original package.
22. Keep out of the reach and sight of children.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.
Effects of alcohol and other sedatives may be potentiated.

Diphenhydramine hydrochloride may enhance the sedative effects of CNS depressants including barbituates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol. It may also have an additive muscarinic action with other drugs such as atropine and some antidepressants.
Diphenhydramine hydrochloride should not be used in patients taking monoamine inhibitors (MAOIs) or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are no adequate and well controlled studies on the use of diphenhydramine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Use of sedating antihistamines during the third trimester may result in adverse reactions in premature infants and neonates.

This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus. The lowest effective dose and the shortest duration of treatment should be considered.

Lactation

Diphenhydramine has been detected in breast milk, but levels have not been reported and the effects are unknown. However, because of the potential risk of antihistamines to nursing infants, Dozol Oral Solution is not recommended for use in nursing mothers.

Fertility

There is no information on the effect of Dozol Oral Solution on fertility.

4.7 Effects on ability to drive and use machines

May cause drowsiness. If affected do not drive or operate machinery.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. Very rare cases of serious skin reactions have been reported. There have been a few reports of blood dyscrasias including thrombocytopoenia and agranulocytosis but these were not necessarily causally related to paracetamol.

Common side-effects:

CNS effects: Drowsiness (usually diminishes within a few days), paradoxical stimulation, headache, psychomotor impairment.

Antimuscarinic effects: Urinary retention, dry mouth, blurred vision, gastrointestinal disturbances, thickened respiratory tract secretions.

Rare side-effects: Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

SOC: Metabolism and nutrition disorders
"High anion gap metabolic acidosis'' with frequency ''Not known'' (cannot be estimated from the available data)
Description of selected adverse reactions
High anion gap metabolic acidosis
Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors

If the patient:

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

b) Regularly consumes ethanol in excess of recommended amounts.

Or

c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

Mild cases of overdose with antihistamines are mainly characterised by prominent anticholinergic effects including dry mouth, headache, nausea, tachycardia and urinary retention. Larger overdoses will have additional antihistamine effects which may depress or stimulate the CNS. In small children, the stimulatory effects predominate and clinical features include hallucinations, ataxia and convulsions. The child may be hot, flushed and have dilated pupils. Cardiorespiratory depression and coma can subsequently develop followed by rapid death. Overdosing diphenhydramine in adults usually results in drowsiness followed by convulsions and coma. Fever and flushing are uncommon. Overdosed patients are best treated by gastric lavage and supportive measures. Administration of activated charcoal may be useful. Convulsions can be controlled with diazepam. Peripheral anticholinergic effects can be controlled with subcutaneous neostigmine

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is an antipyretic and analgesic. Diphenhydramine HCl is an antihistamine with anticholinergic, anti-emetic, anti-allergic and sedative effects.

5.2 Pharmacokinetic properties

Paracetamol and Diphenhydramine HCl are both readily absorbed from the gastro-intestinal tract. Both are widely distributed throughout the body. Both are metabolised in the liver and excreted in the urine. As Dozol is a solution, absorption of the actives is rapid following oral ingestion.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 4000
Glycerol
Propylene glycol
Liquid Sorbitol 70% (non-crystallising)
Liquid Maltitol
Neohesperidin Dihydrochalcone
Saccharin Sodium
Nipasept containing: Ethyl Parahydroxybenzoate (E214)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Annatto extract (E160)
Caramel Flavour CD65424
Ponceau 4R (E124)
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Do not refrigerate

Do not store above 25ºC

Protect from light

6.5 Nature and contents of container

Amber glass bottles with Child Resistant Tamper Evident Cap. A syringe composed of a low density polyethylene pipette and a polystyrene plunger with measures at 2.5mL and 5mL will be provided.

100ml and 30ml

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Phoenix Healthcare Limited

Suite 12, Bunkilla Plaza

Bracetown Business Park

Clonee, County Meath

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 42727/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/01/1977 / 10/01/2007

10 DATE OF REVISION OF THE TEXT

15/04/2025