

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Paracetamol, Ascorbic acid, Phenylephrine Hydrochloride 750mg/60mg/10mg  
Powder for Oral solution

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5.0 g sachet of powder for oral solution contains:

### **Active constituents:**

Paracetamol 750.0 mg

Ascorbic Acid 60.0 mg

Phenylephrine Hydrochloride 10.0 mg

### **Excipients with known effect:**

Sucrose 2906 mg

Sodium 49.047mg

For the full list of excipients, see section 6.1

## **3 PHARMACEUTICAL FORM**

Powder for oral solution.

Pale yellow coloured powder.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Short term symptomatic relief of influenza, feverishness, chills and colds including headache, sore throat pain, aches and pains, nasal congestion, sinusitis and its associated pain and acute nasal catarrh.

## 4.2 Posology and method of administration

### Posology

Adults (including elderly) and children aged 12 years and over:

One sachet in a tumbler full of hot water to be taken every four to six hours up to four times a day.

### Children:

Not recommended for children under 12 years of age.

Do not take continuously for more than 5 days without medical advice.

### Method of administration

For oral administration, dissolved in hot water.

## 4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

Concomitant use of other sympathomimetic decongestants.

Pheochromocytoma Closed angle glaucoma.

Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease. Patients taking tricyclic antidepressants, or beta-blocking drugs and those patients who are taking or have taken, within the last two weeks, monoamine oxidase inhibitors (see section 4.5).

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

## 4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Medical advice should be sought before taking this product in patients with these conditions:

- An enlargement of the prostate gland
- Occlusive Vascular disease (e.g. Raynaud's Phenomenon)
- Cardiovascular disease

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.

This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 49.047mg sodium (main component of cooking/table salt) in each dosage unit. This is equivalent to 2.452 % of the recommended maximum daily dietary intake of sodium for an adult.

Concomitant use of other flu, cold or decongestant medicines, or other paracetamol-containing medicines should be avoided.

Consult your doctor if you are taking warfarin.

Do not exceed the stated dose.

If symptoms persist consult your doctor.

Keep out of the sight and reach of children.

Pack Label:

Do not take anything else containing paracetamol while taking this medicine.

Talk to a doctor at once if you take too much of this medicine, even if you feel well.

Do not take anything else containing paracetamol while taking this medicine.

Patient Information Leaflet

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

## **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 colestyramine. 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.

Phenylephrine should be used with caution in combination with the following drugs as interactions have been reported:

Monoamine oxidase inhibitors (including moclobemide)	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see contraindications).
Sympathomimetic amines	Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.
Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyl dopa)	Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
Tricyclic antidepressants (e.g. amitriptyline)	May increase the risk of cardiovascular side effects with phenylephrine.
Ergot alkaloids (ergotamine and methysergide)	Increased risk of ergotism
Digoxin and cardiac glycosides	Increase the risk of irregular heartbeat or heart attack

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 risk factors (see section 4.4).

#### **4.6 Fertility, Pregnancy and lactation**

This product should not be used in pregnancy or whilst breast-feeding without medical advice. Phenylephrine may be excreted in breast milk.

#### **4.7 Effects on ability to drive and use machines**

Patients should be advised not to drive or operate machinery if affected by dizziness.

## 4.8 Undesirable effects

### Paracetamol

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

<b>Body System</b>	<b>Undesirable effect</b>
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis  These are not necessarily causally related to paracetamol
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm *
Hepatobiliary disorders	Hepatic dysfunction
Metabolic and nutrition disorders	High anion gap metabolic acidosis**

#### Description of selected adverse reactions

\* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

\*\* 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.

### Phenylephrine

The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events.

<b>Body System</b>	<b>Undesirable effect</b>
Psychiatric disorders	Nervousness, irritability, restlessness, and excitability
Nervous system disorders	Headache, dizziness, insomnia
Cardiac disorders	Increased blood pressure
Gastrointestinal disorders	Nausea, Vomiting, diarrhoea

Adverse reactions identified during post-marketing use are listed below. The frequency of these reactions is unknown but likely to be rare.

Eye disorders	Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma
Cardiac disorders	Tachycardia, palpitations
Skin and subcutaneous disorders	Allergic reactions (e.g. rash, urticaria, allergic dermatitis). Hypersensitivity reactions including cross-sensitivity with other sympathomimetics may occur
Renal and urinary disorders	Dysuria, urinary retention. This is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.

#### 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](http://www.mhra.gov.uk/yellowcard).

## **4.9 Overdose**

### Paracetamol

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

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

Or

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 overdose 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.

#### Phenylephrine

##### Symptoms and signs

Phenylephrine overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include hypertension and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than required to cause paracetamol-related toxicity.

##### Treatment

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with an alpha blocking drug such as phentolamine.

#### Ascorbic acid

##### Symptoms and signs

High doses of ascorbic acid (>3000 mg) may cause transient osmotic diarrhoea and gastrointestinal effects such as nausea and abdominal discomfort. Effects of overdose of ascorbic acid would be subsumed by severe liver toxicity caused by paracetamol overdose.

## **5.1 Pharmacodynamic properties**

ATC Code: N02BE51

Paracetamol - an analgesic and antipyretic.

Phenylephrine hydrochloride - a sympathomimetic agent with mainly direct effects on adrenergic receptors predominately alpha-adrenergic activity producing nasal decongestion.

Ascorbic acid, vitamin C - is an essential vitamin included to compensate for vitamin C losses which may occur in the initial stages of acute viral infections.

The active ingredients are not known to cause sedation.

## **5.2 Pharmacokinetic properties**

No relevant pharmacokinetic particulars are available on this formulation.

## **5.3 Preclinical safety data**

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Sucrose

Citric acid

Saccharin sodium

Sodium Citrate

Quinoline yellow (E104)

Lemon tetarome flavour

Lemon Juice flavour

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

36 months.

## **6.4 Special precautions for storage**

Do not store above 25°C.

## **6.5 Nature and contents of container**

Each sachet contains 5 g of powder for oral solution. Five or ten sachets are packed into a cardboard carton.

## **6.6 Special precautions for disposal**

None.

## **7 MARKETING AUTHORISATION HOLDER**

Thornton & Ross Ltd.  
Linthwaite,  
Huddersfield,  
HD7 5QH, UK

**8     MARKETING AUTHORISATION NUMBER(S)**

PL 00240/0562

**9     DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
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17/07/2025

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