

# NEW ZEALAND DATA SHEET

## 1. PRODUCT NAME

Noumed Cold & Flu Relief

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains the active ingredients:

- Paracetamol 500 mg
- Pseudoephedrine hydrochloride 30 mg

For the full list of excipients, see section 6.1 List of excipients.

## 3. PHARMACEUTICAL FORM

Noumed Cold & Flu Relief are white, round tablets with a break-line on one side. Uncoated tablets.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Noumed Cold & Flu Relief is used for temporary relief from the symptoms of cold and flu: nasal congestion, runny nose, headache, body aches and pains, and fever.

### 4.2 Dose and method of administration

*Adults & Children 12 years and over*

Take 2 tablets every 4 to 6 hours if necessary. Do not halve the tablet.

No more than 4 doses should be taken in a 24-hour period.

This medicine should not be taken with other medicines containing paracetamol unless advised to do so by a doctor or pharmacist

#### Use in Adults

This medicine should not be taken for more than a few days at a time except on medical advice.

#### Use in Children

Do not give to children under 12 years of age. This medicine should not be taken for more than a few days at a time except on medical advice.

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### 4.3 Contraindications

Noumed Cold & Flu Relief is contraindicated for use in patients with the following conditions:

- Known hypersensitivity or idiosyncratic reaction to paracetamol, pseudoephedrine, (or substances of a similar chemical structure) or any of the other ingredients in this medicine.
- Uncontrolled hypertension or severe coronary artery disease.
- Taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days.

Refer also to 'Interactions with other medicines and other forms of interactions' for additional information.

### 4.4 Special warnings and precautions for use

Noumed Cold & Flu Relief should be used with caution in patients with the following conditions:

- Impaired hepatic function
- Impaired renal function
- Hypertension
- Hyperthyroidism
- Diabetes mellitus
- Coronary heart disease
- Ischaemic heart disease
- Glaucoma
- Prostatic hypertrophy

This medicine contains pseudoephedrine which may cause sleeplessness if taken up to several hours before going to bed.

Refer to 'Interactions with other medicines and other forms of interaction' for additional information.

#### *Ischaemic colitis*

Some cases of ischaemic colitis have been reported with pseudoephedrine. Discontinue the product and seek medical advice if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

#### *Serious skin reactions*

Serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported very rarely in

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patients receiving paracetamol. Patients should be informed about the signs of serious skin reactions and use of the product should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

### *Posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS)*

There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. This product should be discontinued immediately, and medical advice sought if signs/symptoms of PRES/RCVS develop.

### *Ischaemic optic neuropathy*

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. The product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

### *Use in elderly*

No data available.

### *Paediatric use*

No data available.

### *Effects on laboratory tests*

No data available.

## 4.5 Interaction with other medicines and other forms of interaction

The following interactions with paracetamol have been noted:

- Anticoagulant drugs (warfarin) – dosage may require reduction if paracetamol and anticoagulants are taken for a prolonged period of time
- Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide
- Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- Paracetamol may increase chloramphenicol concentrations

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- The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- Paracetamol excretion may be affected, and plasma concentrations altered when given with probenecid
- Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.
- High anion gap metabolic acidosis from pyroglutamic acid (5-oxoproline) has been reported with concomitant use of therapeutic doses of paracetamol and flucloxacillin. Patients reported to be most at risk are elderly females with underlying disease such as sepsis, renal function abnormality, and malnutrition.

The following interactions with pseudoephedrine have been noted:

- Antidepressant medication e.g. tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis
- Other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants – may cause an increase in blood pressure and additive effects
- Antihypertensives e.g. methyldopa and beta-blockers – may cause an increase in blood pressure
- Urinary acidifiers enhance elimination of pseudoephedrine
- Urinary alkalinisers decrease elimination of pseudoephedrine

### 4.6 Fertility, pregnancy and lactation

#### *Effects on fertility*

No data available.

#### *Use in Pregnancy*

Category B2: Pseudoephedrine has been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals are inadequate or may be lacking, but available data shows no evidence of an increased occurrence of foetal damage.

Noumed Cold & Flu Relief should not be used in pregnancy unless the potential benefits to the patient are weighed against the possible risk to the foetus.

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## *Use in Lactation*

Paracetamol is excreted in small amounts (< 0.2%) in breast milk. Maternal ingestion of paracetamol in usual analgesic doses does not appear to present a risk to the breastfed infants.

It has been estimated that 0.5% to 0.7% of a single dose of pseudoephedrine ingested by the mother will be excreted in the breast milk over 24 hours.

Therefore, Noumed Cold & Flu Relief is not recommended for breastfeeding mothers (see also Contraindications).

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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

### 4.8 Undesirable effects

Side effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Skin rashes and hypersensitivity reactions occur occasionally. Overdosage with paracetamol if left untreated can result in severe, sometimes fatal liver damage and rarely, acute renal tubular necrosis.

Adverse effects of pseudoephedrine include:

- cardiovascular stimulation – elevated blood pressure, tachycardia or arrhythmias
- central nervous system (CNS) stimulation – restlessness, insomnia, anxiety, tremors and (rarely) hallucinations
- skin rashes and urinary retention

Children and the elderly are more likely to experience adverse effects than other age groups.

Adverse drug reactions identified during post-marketing experience with paracetamol, pseudoephedrine, and the combination appear in the following table. The frequency category was estimated from spontaneous reporting rates.

Adverse events that have been observed during clinical trials and/or post-marketing use are ranked under the following frequency: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  and  $< 1/10$ ), uncommon ( $\geq 1/1000$  and  $< 1/100$ ), rare ( $\geq 1/10,000$  and  $< 1/1,000$ ), very rare ( $< 1/10,000$ ).

<b>System Organ Class</b>	
Frequency Category	Adverse Event Preferred Term
<b>Blood and Lymphatic System Disorders</b>	
Unknown	Thrombocytopenia
Unknown	Agranulocytosis

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### **Immune System Disorder**

Very rare Anaphylactic reaction  
Very rare Hypersensitivity

### **Psychiatric Disorder**

Very rare Anxiety  
Very rare Euphoric mood  
Very rare Restlessness  
Very rare Insomnia  
Very rare Hallucinations  
Very rare Hallucination, visual

### **Nervous System Disorder**

Very rare Cerebrovascular accident\*  
Very rare Headache  
Very rare Paraesthesia  
Very rare Psychomotor hyperactivity (in the paediatric population)  
Very rare Tremor  
Very rare Posterior Reversible Encephalopathy Syndrome  
Very rare Reversible Cerebral Vasoconstriction Syndrome

### **Eye Disorders**

Unknown Ischaemic optic neuropathy

### **Cardiac Disorders**

Very rare Arrhythmia  
Very rare Myocardial infarction\*  
Very rare Palpitations  
Very rare Tachycardia

### **Gastrointestinal Disorders**

Very rare Abdominal discomfort  
Very rare Colitis ischaemic  
Very rare Diarrhoea  
Very rare Vomiting

### **Skin and Subcutaneous Tissue Disorders**

Very rare Pruritus  
Very rare Acute generalised exanthematous pustulosis  
Very rare Angioedema  
Very rare Pruritic rash  
Very rare Rash  
Very rare Urticaria  
Very rare Fixed eruption

### **Renal and Urinary Disorders**

Very rare Dysuria  
Very rare Urinary retention

### **General Disorders and Administration Site Conditions**

Very rare Feeling jittery  
Very rare Anxiety

### **Investigations**

Very rare Blood pressure increased  
Very rare Transaminases increased

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\* These events have been reported very rarely in post-marketing safety. A recent postauthorisation safety study (PASS) did not provide any evidence of increased risk of myocardial infarction or cerebrovascular accident associated with the use of vasoconstrictors for nasal decongestion, including pseudoephedrine.

### *Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://pophealth.my.site.com/carmreportnz/s/>

#### 4.9 Overdose

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

##### *Mechanism of action*

Paracetamol is a p-aminophenol derivative that exhibits analgesic and antipyretic activity. It does not possess anti-inflammatory activity. Paracetamol is thought to produce analgesia through a central inhibition of prostaglandin synthesis.

Pseudoephedrine has direct- and indirect- sympathomimetic activity and is an effective decongestant in the upper respiratory tract. It is a stereoisomer of ephedrine and has a similar action, but has been found to have less pressor activity and fewer central nervous system (CNS) effects. Sympathomimetic agents are used as nasal decongestants to provide symptomatic relief. They act by causing vasoconstriction resulting in redistribution of local blood flow to reduce oedema of the nasal mucosa, thus improving ventilation, drainage and nasal stuffiness.

##### *Clinical trials*

No data available.

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### 5.2 Pharmacokinetic properties

#### *Absorption*

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration.

Pseudoephedrine is readily absorbed from the gastrointestinal tract.

#### *Distribution*

Paracetamol is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses but increases with increasing doses.

Small amounts of pseudoephedrine are distributed into breast milk.

#### *Metabolism*

Paracetamol is metabolised extensively in the liver. The metabolites of paracetamol include a minor hydroxylated intermediate which has hepatotoxic activity. This intermediate metabolite is detoxified by conjugation with glutathione, however, it can accumulate following paracetamol overdose (more than 150 mg/kg or 10 g total paracetamol ingested) and if left untreated can cause irreversible liver damage.

Paracetamol is metabolised differently by premature infants, newborns, infants and young children compared to adults, the sulfate conjugate being predominant.

Pseudoephedrine is incompletely metabolised (less than 1 %) in the liver to an inactive metabolite by N-demethylation.

#### *Excretion*

Paracetamol is excreted in the urine mainly as inactive glucuronide and sulfate conjugates. Less than 5 % is excreted unchanged. The elimination half-life varies from about 1 to 3 hours.

Pseudoephedrine is largely excreted unchanged in the urine, together with small amounts of its hepatic metabolite. It has a half-life of about 5–8 hours; elimination is enhanced, and half-life reduced accordingly in acid urine.



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## 5.3 Preclinical safety data

### *Genotoxicity*

No data available.

### *Carcinogenicity*

No data available.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Crospovidone
- Magnesium stearate
- Microcrystalline cellulose
- Povidone
- Pregelatinised maize starch
- Stearic acid
- Purified water

### 6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store below 30 °C. Keep out of reach of children.

### 6.5 Nature and contents of container

The tablets are presented in PVC/PVDC/Aluminium blister packs which are enclosed in a carton. Each blister pack contains 12 tablets.

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The pack sizes are:

- 24 tablets (2 x 12 tablet blister packs in a carton)
- 12 tablets (1 x 12 tablet blister pack in a carton)

## 6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements by taking to your local pharmacy.

## 7. MEDICINE SCHEDULE Controlled

Drug C3.

## 8. SPONSOR

Noumed Pharmaceuticals Limited

Auckland, New Zealand

Freephone 0800 527 545

## 9. DATE OF FIRST APPROVAL

TBC

## 10. DATE OF REVISION OF THE TEXT

26 March 2024

## SUMMARY TABLE OF CHANGES

Section changes	Summary of new information
All	New