

Package leaflet: Information for the user

<Please insert Registered Product Name here>

Paracetamol, Phenylephrine, Caffeine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take 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 you do not feel better or if you feel worse after 3 days.

#### **What is in this leaflet**

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

#### **1. What this medicine is and what it is used for**

##### **This medicine contains:**

- **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- **phenylephrine** which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

##### **The Day capsules also contain:**

- caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

The Day capsules are used for the relief of the symptoms of sinus pain and congestion, including relief of aches and pains, headache, fatigue (tiredness) and drowsiness, nasal congestion (blocked nose) and feverishness (high temperature).

The Night capsules are used for the relief of the symptoms of colds and flu, including aches and pains, sore throat, headache, nasal congestion (blocked nose) and feverishness (high temperature).

#### **2. What you need to know before you take this medicine**

##### **Do not take this medicine if you:**

are **allergic** to paracetamol, caffeine, phenylephrine or any of the other ingredients

- have a serious heart condition or cardiovascular disorder(s)
- have high blood pressure (hypertension)
- have a history of stomach ulcers
- have an overactive thyroid
- have an enlarged prostate

- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's), or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid.

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking this medicine if you:**

- are pregnant or breast-feeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have diabetes
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.

#### **During treatment with this medicine, tell your doctor straight away 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).

#### **Other medicines and this medicine**

- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins – you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitone
- tricyclic antidepressants such as imipramine, amitriptyline
- medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (e.g atenolol) or vasodilators (e.g hydralazine)
- other decongestant drugs such as ephedrine or xylometazoline
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

#### **Contains paracetamol.**

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

#### **This medicine with food, drink and alcohol**

Do not drink alcohol (beer, wine, spirits etc) while taking this product.

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Information about some of the ingredients in this medicine:**

This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'.

### **3. How to take this medicine**

Swallow the capsules whole with water. Do not chew.

#### **Adults, the elderly and children aged 16 years and over:**

**2 Day capsules** every 4 to 6 hours during the daytime, as required, **followed by 2 Night capsules** at bedtime. Leave at least 4 to 6 hours between doses. **Do not take more** than 8 capsules (4 doses) in any 24 hour period.

**Do not give to children under 16 years.**

If the symptoms of your cold or flu persist for more than three days, or worsen, consult your pharmacist or doctor.

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

**This medicine does not contain a sleep aid.**

**If you take more of this medicine than you should**

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. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

#### **4. Possible side effects**

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

**Rare side effects are:**

- allergic reactions such as skin rash
- tingling and coolness of the skin
- a faster or slower heartbeat
- a rise in blood pressure with headache, vomiting (being sick) and irregular heartbeat (palpitations)
- nausea (feeling sick) (*Day Capsule only*)
- difficulty sleeping (insomnia) (*Day Capsule only*)
- Problems or pain passing urine.

**More rarely, the following side effects can happen:**

- you may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

Very rare cases of serious skin reactions have been reported.

Frequency “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 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store this medicine**

**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date printed on the pack. Do not store above 25°C.

## **6. Contents of the pack and other information**

### **What this medicine contains**

Day Capsules: Each Day capsule contains the active ingredients: paracetamol 500 mg, caffeine 25 mg and phenylephrine hydrochloride 6.1 mg.

The other ingredients in the Day capsules are: maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc. The capsule shell is made of gelatin and contains the colours: quinoline yellow (E104), titanium dioxide (E171), patent blue V (E131), erythrosine (E127) and indigo carmine (E132).

**Night Capsules:** Each Night capsule contains the active ingredients: paracetamol 500 mg and phenylephrine hydrochloride 6.1 mg.

The other ingredients in the Night capsules are: maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc. The capsule shell is made of gelatin and contains the colours titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).

### **What this medicine looks like and contents of the pack**

The pack contains 12 red and blue coloured day capsules and 4 light blue and dark blue coloured night capsules.

### **Marketing Authorization Holder & Manufacturer:**

Wrafton Laboratories Limited, Braunton, Devon EX33 2DL, UK.

This leaflet was last revised in January 2025.

PL 12063/0074