

<Insert Registered Product Name here>

Paracetamol, Phenylephrine

## PATIENT INFORMATION LEAFLET

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

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 information
6. Contents of the pack and other information

### **1) What is this medicine and what is it 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.

These 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 use in children under 16 years of age.**

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

- are **allergic** to paracetamol, phenylephrine or any of the other ingredients
- have a serious heart condition or cardiovascular disorder(s)
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- have high blood pressure (hypertension)
- have an overactive thyroid
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's) or have taken them within the last 14 days – these are medicines such as moclobemide, phenelzine and isocarboxacid
- are taking other decongestants such as ephedrine or xylometazoline.
- have an enlarged prostate or prostate problems
- have a condition called phaeochromocytoma (rare tumor of the adrenal gland tissue)

### **Warnings and precautions**

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

- are pregnant or breastfeeding
- suffer from kidney or liver problems, including alcoholic liver disease
- You have non-cirrhotic liver disease (liver disease that is not associated with changes in the structure of the liver)

- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.
- have diabetes mellitus
- have closed angle glaucoma

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

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.**

- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as cholestyramine
- 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)
- some drugs may affect the way in which phenylephrine hydrochloride works (digoxin and cardiac glycosides).  
are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's) or have taken them within the last 14 days – these are medicines such as moclobemide, phenelzine and isocarboxacid
- other decongestant drugs such as ephedrine or xylometazoline.

**Contains paracetamol.**

**Do not take with any other paracetamol-containing products.**

**Other important information:**

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

**Pregnancy and breast-feeding:**

If you are pregnant or 'breast-feeding', think you may be pregnant or are planning to have a baby, you should not use this product.

This product should not be used in women with a history of pre-eclampsia (high blood pressure during pregnancy which can lead to seizures).

Always Ask your doctor or pharmacist for advice before taking this medicine.

**This medicine contains 129.0 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6.45% of the recommended maximum daily dietary intake of sodium for an adult.**

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

Swallow the capsules whole with water. Do not chew.

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

2 capsules every 4-6 hours as required. Do not take more than 8 capsules in any 24 hour period.

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

**Do not exceed the stated dose.** If your symptoms persist or worsen, you must see a doctor or pharmacist.

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

**Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. You may experience symptoms of dizziness, palpitations (irregular or forceful heartbeat), stomach pain or high blood pressure with headache if you take too much of this medicine.**

**If you forget to take this medicine:**

If you forget to take this medicine Do not take a double dose to make up for a forgotten dose. If you forget a dose, take it as soon as you remember it and then take the next dose at least 4 hours later.

#### **4) Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. 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:

- Serious skin reactions
- Allergic reactions (such as skin rashes)

Other side effects:

Not known (frequency cannot be estimated from the available data):

- Blood disorders, such as thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily), pancytopenia (reduction in white and red blood cells), agranulocytosis, leucopenia or neutropenia (reduction in white blood cells which makes infections more likely)
- Stomach and gut disorder, such as vomiting, nausea or abdominal discomfort
- Difficulty in passing urine (especially in males)

#### **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 [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 your 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:**

Each dark blue / light blue capsule contains the active ingredients: paracetamol 500 mg and phenylephrine hydrochloride 6.1 mg.

The other ingredients 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).

This product is available in packs of 8, 10 and 16 capsules, not all pack sizes may be marketed.

**The Marketing Authorisation holder and manufacturer**

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

Text revised: April 2020

PL 12063/0072