

## **Package Leaflet: Information for the user**

### **Paracetamol 500 mg/Guaifenesin 100 mg/Phenylephrine hydrochloride 6.1 mg/Capsule, hard**

**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 symptoms persist for more than 3 days, get worse or other symptoms occur.

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

1. What is Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard and what it is used for
2. What you need to know before you take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard
3. How to take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard
4. Possible side effects
5. How to store Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard
6. Contents of the pack and other information

#### **1. What is Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard and what it is used for**

Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard contains the following active substances:

- Paracetamol which is a pain reliever (analgesic) for pains including headache and sore throat, and also helps reduce your temperature when you have a fever (antipyretic).
- Guaifenesin which is an expectorant to help loosen mucus (phlegm) when you have a chesty cough.
- Phenylephrine hydrochloride which is a decongestant used to reduce swelling in the passages of the nose to help you breathe more easily.

This medicine is used for the short-term relief of the symptoms colds and flu including mild to moderate pain, headache, blocked nose and sore throat, chills and fever, and for relief from chesty coughs. You should only use Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard if you have a combination of cold and flu symptoms such as pain/fever, nasal congestion and chesty cough.

This medicine can be used by adults, the elderly and adolescents aged 16 years and over.

You must talk to a doctor if symptoms persist for more than 3 days, get worse or other symptoms occur.

**2. What you need to know before you take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard**

**Do not take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard if you:**

- are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's) such as moclobemide, phenelzine, isocarboxazid and tranylcypromine, or have taken them within the last 14 days.
- have high blood pressure (hypertension).
- have heart or blood vessel disease (cardiovascular disease).
- have an overactive thyroid (hyperthyroidism).
- have diabetes.
- have a rare adrenal gland tumour (phaeochromocytoma)
- are taking tricyclic antidepressants such as imipramine and amitriptyline.
- are taking beta-blockers or other medicines used to treat high blood pressure.
- have closed angle glaucoma (high pressure inside the eyes).
- have severe hepatic impairment.
- are pregnant.
- are taking other decongestant products containing sympathomimetic amines (e.g. phenylephrine).

**Warnings and precautions**

You should see your doctor if:

- you experience symptoms for more than 3 days.
- your symptoms get worse.
- you develop a high fever or other symptoms.

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

- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.
- are taking medicine which affects liver function.
- have an enzyme deficiency or metabolic disorder (Glucose-6-phosphate dehydrogenase deficiency, glutathione deficiency or familial non-haemolytic jaundice).
- have a disorder which causes red blood cells to be destroyed faster than they are made (haemolytic anaemia)
- are dehydrated.

- have difficulty passing urine or an enlarged prostate.
- have chronic cough, asthma or emphysema.
- have frequent or daily headaches.
- have asthma and are sensitive to acetylsalicylic acid.

Check with your doctor before use if you have liver or kidney problems, are underweight (<50 kg), become malnourished or regularly drink alcohol as this may increase your risk of liver damage. You may need to reduce the amount of paracetamol that you take or avoid using this product altogether.

This product contains paracetamol. Do not use this product concomitantly with other paracetamol-containing products.

### **Children and adolescents**

Do not give this medicine to children and adolescents under 16 years of age.

### **Other medicines and Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard**

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

If you are taking any of the following medicines do not take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard (see 'Do not take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard'):

- Tricyclic antidepressants such as imipramine and amitriptyline.
- Monoamine oxidase inhibitors (MAOI's) such as moclobemide, phenelzine, isocarboxazid and tranylcypromine, used to treat depression.
- Medicines known as beta-blockers, such as metoprolol and atenolol.
- Other products containing sympathomimetic amines such as phenylephrine.
- Medicines used to lower blood pressure such as guanethidine, reserpine and methyldopa.

If you are taking any of the following medicines, talk to your doctor before taking Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard:

- Probenecid which is commonly used to treat gout.
- 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.
- The antibiotic chloramphenicol.
- Medicines to treat heart problems, such as digoxin.
- Medicines to treat migraine such as ergotamine and methylsergide.
- Other cough medicines.
- Other cold and flu medicines.
- If you are taking Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and

which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Talk to your doctor before taking this medicine if you are going to have urine tests because taking this medicine may affect the results.

**Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard with alcohol**

Avoid drinking alcohol when taking this medicine.

**Pregnancy and breast-feeding**

Pregnancy

Do not take this medicine if you are pregnant or think you may be pregnant.

If you are planning to have a baby, talk to your doctor or pharmacist before taking this medicine.

Based on human experience, phenylephrine hydrochloride causes congenital malformation when administered during pregnancy.

Breastfeeding

This medicine should not be taken during breast-feeding without medical advice.

**Driving and using machines**

This product may cause dizziness. Do not drive or operate machinery if you feel dizzy after taking this medicine.

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

**3. How to take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults and adolescents aged 16 years and over who weigh more than 50kg**

The recommended dose is 2 capsules every 4 to 6 hours as required to a maximum of 3 doses in 24 hours. Do not exceed the stated dose. Do not take more than 6 capsules (3g paracetamol) in any 24-hour period.

Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard should not be used in adults, the elderly and adolescents aged 16 years and over, who weigh less than 50kg.

Do not take more than 4 capsules a day in the following situations, unless directed by

your doctor:

- Chronic alcoholism
- Dehydration
- Malnutrition

### **Use in elderly patients and those with liver or kidney disease**

Speak to your doctor or pharmacist before taking this medicine if you are elderly or have kidney or liver disease because you may need a lower or less frequent dose.

### **Use in children and adolescents**

Do not give to children and adolescents under 16 years of age.

For oral use.

Swallow the capsules whole with water. Do not chew.

You must talk to a doctor if symptoms persist for more than 3 days, get worse or other symptoms occur.

### **If you take more Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard 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, irreversible liver damage. Initial symptoms of overdose may include pale skin, nausea, vomiting and abdominal pain. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

### **If you forget to take Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard**

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

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.

- Serious skin reactions
- Allergic reactions which may be severe such as skin rash, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face
- Changes in your blood which may make you more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers

- Problems or pain passing urine
- Increased pressure inside the eye (acute angle glaucoma)
- Dilated pupils
- Breathing problems, which are more likely if you have experienced them before when taking other painkillers such as acetylsalicylic acid or ibuprofen.
- Raised blood pressure
- A faster, slower or irregular resting heartbeat
- Liver problems

The above side effects are rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people). The frequency of pain and problems passing urine is unknown.

Other side effects for this medicine are presented below according to how frequently they are reported to occur.

The frequency of the following side effects is unknown:

- Difficulty sleeping (insomnia)
- Nervousness
- Headache
- Dizziness
- Tingling or cool skin

The frequency of the following side effects is rare (may affect up to 1 in 1,000 people):

- Stomach pain or discomfort
- Diarrhoea (upset stomach)
- Nausea (feeling sick)
- Vomiting (being sick)

The frequency of the following side effects is very rare (may affect up to 1 in 10,000 people):

- Cloudy urine (due to increased white blood cells in urine)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the HPRA Pharmacovigilance, Website: <http://www.hpra.ie>;

By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard**

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

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard contains**

Each capsule contains the active ingredients: Paracetamol (500 mg), Guaifenesin (100 mg) and Phenylephrine hydrochloride (6.1 mg, corresponding to 5 mg phenylephrine base)

The other ingredients are:

Maize starch

Croscarmellose sodium

Sodium lauryl sulfate

Magnesium stearate

Talc

#### Gelatin capsule:

Gelatin

Sodium lauryl sulfate

Quinoline yellow (E104)

Indigo carmine (E132)

Erythrosine (E127)

Titanium dioxide (E171)

Purified water

### **What Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard looks like and contents of the pack**

This medicine is presented as dark blue and green hard gelatin capsules containing an off-white powder. The capsules are provided in a plastic blister pack with a paper/ aluminium foil lid.

This medicine is available in pack sizes of 8, 16, 24 and 32 capsules.  
Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Chefaro Ireland DAC,

The Sharp Building,

Hogan Place,

Dublin 2.

**Manufacturer(s)**

Wrafton Laboratories Limited  
Wrafton  
Braunton  
Devon  
EX33 2DL  
United Kingdom

Omega Pharma International NV  
Venecoweg 26  
Nazareth  
Oost-Vlaanderen  
9810, Belgium

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Bulgaria	<{ name of the medicinal product }>
Croatia	<{ name of the medicinal product }>
Cyprus	<{ name of the medicinal product }>
Czech Republic	<{ name of the medicinal product }>
Estonia	<{ name of the medicinal product }>
Greece	<{ name of the medicinal product }>
Hungary	<{ name of the medicinal product }>
Ireland	<{ name of the medicinal product }>
Latvia	<{ name of the medicinal product }>
Lithuania	<{ name of the medicinal product }>
Poland	<{ name of the medicinal product }>
Portugal	<{ name of the medicinal product }>
Romania	<{ name of the medicinal product }>
Slovakia	<{ name of the medicinal product }>
Slovenia	<{ name of the medicinal product }>

**This leaflet was last revised in October 2022.**