

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Ilvico® Cold and Flu film-coated tablets**

Paracetamol 325mg, Caffeine 30mg, Brompheniramine maleate 3mg

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

This medicine is available without prescription. However, you still need to use Ilvico carefully to get the best results from it. Ilvico Cold and Flu film-coated tablets will be referred to as Ilvico throughout the leaflet.

- 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.

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

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

#### **1. WHAT ILVICO IS AND WHAT IT IS USED FOR**

Ilvico Cold and Flu film-coated tablets contain paracetamol, caffeine and brompheniramine. Ilvico Cold and Flu film-coated tablets are used for the relief of symptoms associated with the common cold, influenza, and upper respiratory tract infections.

You must talk to a doctor if you do not feel better or if you feel worse.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ILVICO TABLETS**

##### **Do not take Ilvico if:**

- You are allergic (hypersensitive) to paracetamol, caffeine or brompheniramine, or any of the other ingredients of Ilvico.
- You suffer from severe liver diseases (with or without liver insufficiency), viral hepatitis (increases the risk of liver toxicity).
- You suffer from peptic ulcers.
- You suffer from severe kidney impairment.
- You suffer from haemophilia (a disorder that affects blood clotting).
- You are less than 12 years old.
- You are pregnant or are breast-feeding.
- You have tachyarrhythmia (fast heart rate).
- You suffer from narrow-angle glaucoma.
- You suffer from brain damage or epilepsy.

- You have an enlarged prostate or urinary retention, you have a bladder problem called vesical neck obstruction. Your symptoms may get worse when taking these tablets.

### **Warnings and precautions**

#### **Take special care with Ilvico if:**

- You suffer from anaemia or you have heart, lung, liver, or kidney problems. Do not take Ilvico for long periods of time.
- You regularly drink alcohol. Ilvico may cause liver damage.
- You are an alcoholic. You need to be careful how much paracetamol you take - talk to your doctor or pharmacist.
- You are undergoing diagnostic tests involving blood and/or urine, as Ilvico may interfere with these tests.
- As brompheniramine may interfere with allergenic tests on the skin, you should suspend treatment with Ilvico at least 3 days before taking such tests.
- You have asthma. This may get worse when taking these tablets.
- You have a genetic disorder known as glucose-6-phosphate dehydrogenase deficiency.
- You have a tumour of the adrenal glands (phaeochromocytoma).
- You have an overactive thyroid.

Precaution is advised in children as brompheniramine may cause paradoxical excitation (increased talkativeness, excitement, excessive movement).

### **Other medicines and Ilvico Tablets**

#### **This product CONTAINS PARACETAMOL. DO NOT TAKE ANY OTHER PARACETAMOL CONTAINING PRODUCTS.**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, specifically the following:

- Anticoagulants (to prevent blood clotting e.g. warfarin or acenocoumarol).
- Medicines containing alcohol (including some cold remedies).
- Anti-convulsants (to prevent seizures and epilepsy e.g. phenytoin, phenobarbital, methyl phenobarbital, primidone, lamotrigine).
- Medicines containing oestrogen such as oral contraceptives ('the pill') and hormone replacement therapy (HRT).
- Antibiotics such as rifampicin, chloramphenicol and isoniazid.
- Anticholinergic drugs such as glycopyrrolate and propantheline.
- Antiretroviral drugs for treatment of HIV infection such as zidovudine (ATZ).
- Antidepressants such as Monoamine Oxidase Inhibitors (MAOIs) e.g. phenelzine and isocarboxazid.
- Other antidepressants such as tricyclic anti-depressants e.g. imipramine, lofepramine, doxepin, citalopram, fluoxetine, sertraline.
- St. John's wort.
- Antimigraine drugs.
- Antifungal drugs.
- Barbiturates e.g. phenobarbital.
- Other paracetamol containing medicines, or other analgesic drugs (painkillers).
- Antimuscarinic drugs such as propantheline bromide used to treat cramps or spasms of the stomach or excessive sweating.

- Antiemetic (prevention of feeling sick) drugs such as metoclopramide.
- Calcium channel blockers.
- Sympathomimetic drugs.
- Tranquilizers such as benzodiazepines.
- Clozapine used to treat schizophrenia.
- 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.

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as those you have on prescription from your doctor, such as probenecid (a medicine for gout), propranolol (a medicine for our heart or treatment of blood pressure), loop diuretics (water tablets), cholestyramine (a medicine for high cholesterol levels or itching caused by excess bile) or drugs prescribed for insomnia (difficulty sleeping).

#### **Ilvico with food and drink**

Avoid drinking alcohol when taking Ilvico Tablets. The tablets should be swallowed with a drink of water preferably after a meal.

#### **Pregnancy and breast-feeding**

Do not take Ilvico tablets when pregnant or breast-feeding unless advised by a doctor.

#### **Driving and using machines**

Ilvico Tablets may make you feel drowsy. If you are affected, you should not drive or operate machinery.

#### **Important Information about some of the ingredients of Ilvico**

Suitable for people with coeliac disease.

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

### **3. HOW TO TAKE ILVICO**

The product should only be used when clearly necessary. You should check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose.

**You should not take Ilvico Cold and Flu Film-Coated Tablets with other paracetamol containing products.**

**IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE EVEN IF YOU FEEL WELL BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE.**

The recommended dose is:

### **Adults and children older than 12 years**

One or two tablets taken orally with water three times daily.  
Long term use without medical supervision may be harmful.

You should stop taking this medicine once your symptoms have disappeared unless you have any problems. In that case, check with your doctor. If symptoms persist or worsen you should consult your doctor.

### **If you take more Ilvico than you should**

Contact your doctor or go to your nearest hospital casualty department immediately, even if you feel well, because of the risk of delayed, serious liver damage.

Take your tablets or the pack with you so that the doctor knows what you have taken.

### **If you forget to take Ilvico**

If you have missed a dose, take it as soon as you remember and then take your next dose after 8 hours. Do not take a double dose to make up for a forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ilvico Cold and Flu Film-Coated Tablets can cause side effects, although not everybody gets them.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This product contains an antihistamine, which has been known to cause, in children and occasionally in adults, insomnia (difficulty in sleeping), nervousness, high fever, tremors and fits.

Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, dizziness, difficulty in breathing, wheezing or shortness of breath, swollen, face throat, lips, hands or fingers - these have been reported very rarely (less than 1 in 10,000 of users).

Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters, or rash.

The following side effects have been reported frequently (between 1 in 10 and 1 in 100 users):

- Drowsiness.
- Other undesirable effects include dizziness, lack of muscular coordination, numbness and tingling, headache and restlessness.
- A dry mouth.
- High blood pressure (hypertension).

The following side effects have been reported rarely (between 1 in 1,000 and 1 in 10,000 of users):

- Feeling sick (nausea).
- Excitation.

- Low blood pressure (hypotension).

The following side effects have been reported very rarely (less than 1 in 10,000 of users):

- Blood disorders such as low red and/or white blood cells and/or platelet levels.  
Symptoms include tiredness, fatigue, bruising of skin, nose bleeds, bleeding gums, infections, fever, throat pain, ulcers in the throat and mouth.
- Bronchospasm (difficulty in breathing) or dyspnoea (shortness of breath)
- Insomnia (unable to sleep)
- Nervousness, hyperpyrexia (high fever)
- Tremors or convulsions
- Skin disorders such as blisters or non-specific skin reactions and sweating.

Not Known (frequency cannot be estimated from the variable data):

- Palpitations (caused by fluttering heartbeat) or irregular heartbeat
- Visual disturbances (dilation of the pupil, blurred vision or dry eyes)
- Fatigue
- Difficulty passing water
- Liver disorders (e.g. jaundice, increase in liver enzymes).

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effect directly via HPRA Pharmacovigilance website [www.hpra.ie](http://www.hpra.ie).

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

## **5. HOW TO STORE ILVICO**

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

Do not store above 25°C. Do not use the tablets after the expiry date which is stated on the carton and blister strip after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Ilvico contains**

- The active substance(s) are paracetamol 325mg, caffeine 30mg and brompheniramine maleate 3mg.
- The other ingredient(s) are microcrystalline cellulose, sodium starch glycolate Type A, crospovidone, hypromellose, cellulose powder, magnesium stearate, titanium dioxide E171, glycerol, macrogol 4000, macrogol 6000, talc, colloidal anhydrous silica.

### **What Ilvico looks like and contents of the pack**

The tablets are almost white, round film-coated tablets. They are supplied in blister packs containing 20 tablets.

**Marketing Authorisation Holder**

P&G Health Germany GmbH, Sulzbacher Strasse 40, 65824 Schwalbach am Taunus, Germany.

**Manufacturer**

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**Product Authorisation Number**

PA 22703/001/001

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