

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
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1. WHAT ILVICO IS AND WHAT IT IS USED FOR

Ilvico contains paracetamol, caffeine and brompheniramine.

It is 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

Do not take Ilvico if:

- You are allergic (hypersensitive) to paracetamol, caffeine or brompheniramine, or any of the other ingredients of Ilvico.
- You are less than 12 years old.
- 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 have an enlarged prostate, urinary retention, or you have a bladder problem called vesical neck obstruction. Your symptoms may get worse when taking Ilvico.
- You suffer from haemophilia (a disorder that affects blood clotting).
- You have tachyarrhythmia (fast heart rate).
- You suffer from narrow-angle glaucoma.
- You suffer from brain damage or epilepsy.
- You are taking or have been taking during the last 14 days MAOIs (Monoamine Oxidase Inhibitors), used to treat anxiety, depression, or Parkinson's disease.

Warnings and precautions

During treatment with Ilvico, 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).

Talk to your doctor or pharmacist before taking Ilvico if:

- You suffer from anaemia, weight less than 50kg or suffer from dehydration or malnutrition.
- You have heart, lung, liver, or kidney disease. Do not take Ilvico for long periods of time.
- You have alcoholic liver disease or regularly drink alcohol. Regular consumption of alcohol adversely affects liver function and may increase the risk of liver toxicity from products containing paracetamol.
- You have asthma. This may get worse when taking these tablets.
- You have Gilbert's Syndrome (familial jaundice).
- You suffer from glutathione deficiency in your body.
- 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.
- 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.

Precaution is also advised:

- in children, as brompheniramine may cause paradoxical excitation (increased talkativeness, excitement, excessive movement),
- in the elderly: talk to your doctor or pharmacist before you take Ilvico, as you may be more likely to get side effects including confusion, and you may need to take a lower daily dose.

Other medicines and Ilvico

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:

- Medicines containing alcohol (including some cold remedies).
- Anticoagulants (to prevent blood clotting e.g., warfarin or acenocoumarol).
- Anticonvulsants (to prevent seizures and epilepsy e.g., phenytoin, phenobarbital, methyl phenobarbital, primidone, lamotrigine).
- 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).
- Antimuscarinic drugs, such as propantheline bromide, used to treat cramps or spasms of the stomach or excessive sweating.
- Antidepressants such as tricyclic anti-depressants e.g., imipramine, lofepramine, doxepin, citalopram, fluoxetine, sertraline.
- St. John's wort.
- Antimigraine drugs.
- Antifungal drugs.
- Barbiturates, such as phenobarbital.
- Clozapine, used to treat schizophrenia.

- Probenecid, used for gout.
- Other analgesic drugs (painkillers).
- Antiemetics (for prevention of feeling sick), such as metoclopramide and domperidone.
- Loop diuretics (water tablets).
- Drugs prescribed for insomnia, sedating products, hypnotics, or tranquilizers, such as benzodiazepines.
- Calcium channel blockers, and other medicines to treat blood pressure, such as propranolol.
- Other drugs with anticholinergic effects (e.g., antipsychotics, antispasmodics, drugs for Parkinson diseases, atropine, drugs for the treatment of overactive bladder or lung diseases, or drugs for asthma).
- Sympathomimetic drugs, like phenylpropanolamine.
- Cholestyramine (a medicine for high cholesterol levels or itching caused by excess bile).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see section 2).

Always tell your doctor or pharmacist about all the medicines you are taking. This means products you have bought yourself, as well as medicines you have been prescribed, as many other drugs can affect liver function and may increase the risk of liver toxicity.

Ilvico with food and drink

Avoid drinking alcohol when taking Ilvico. The tablets should be swallowed with a drink of water preferably after a meal. You should limit the intake of caffeine-containing medicines, food, and drinks while taking Ilvico. Concomitant use of alcohol should be avoided.

Pregnancy and breast-feeding

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.

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, dizzy or have blurred vision. 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.

Do not take Ilvico 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 a day.

Long term use without medical supervision may be harmful.

If you are an elderly person, have liver or kidney impairment, weigh less than 50kg, regularly drink alcohol, have malnutrition or are dehydrated, you might need a lower dose. Talk with your pharmacist or doctor.

You should stop taking this medicine once your symptoms have disappeared unless you have any problems. In that case, stop taking Ilvico and 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 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.

Stop taking the product and contact your doctor immediately if you notice:

- allergic reactions e.g., skin rashes, itching, swelling of lips, tongue or throat, or difficulty in breathing,

- an increase in the number of nose bleeds or notice that you bruise or bleed more easily.

Rarely, a severe reduction in blood cells which makes infections more likely.

Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters, or rash. If a skin reaction occurs, stop use and seek medical help right away.

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.

Common side effects reported:

- Drowsiness.
- Restlessness, insomnia.
- Dry mouth.
- Lack of muscular coordination, numbness, and tingling.
- High blood pressure (hypertension).

Rare side effects reported:

- Hypersensitivity.
- Skin rash and urticaria (nettle rash).
- Potentially life-threatening allergic reactions (anaphylaxis).
- Temporary vasodepression (dilation of blood vessels).

Very rare side effects reported:

- Anaemia.
- Blood disorders such as low red/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).
- Skin disorders, such as blisters or non-specific skin reactions and sweating.

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

- Headache.
- Allergic dermatitis.
- Euphoria, irritability, agitation, nervousness.
- Fatigue, dizziness.
- Somnolence, sedation.
- Lack of cognition or consciousness.
- Tremors or convulsions.
- Constipation.
- Feeling sick (nausea), being sick (vomiting).
- Indigestion, abdominal pain and/or discomfort.
- Low blood pressure (hypotension).
- Palpitations (caused by fluttering heartbeat), or irregular heartbeat including fast heart rate (tachycardia).
- Visual disturbances (as dilation of the pupil, blurred vision, dry eyes).
- Difficulty passing water (including retention, pain, burning, itching) - in particular those with an enlarged prostate.
- Erectile dysfunction.
- Liver disorders (e.g., jaundice, increase in liver enzymes).
- 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 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. 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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