

Package Leaflet: Information for the user

Solpa Cold & Flu Multi-Relief Capsules **Paracetamol 500mg, Guaifenesin 100mg, Phenylephrine hydrochloride 6.1 mg**

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 have 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 Solpa Cold & Flu Multi-Relief Capsules is and what it is used for
2. What you need to know before you take Solpa Cold & Flu Multi-Relief Capsules
3. How to take Solpa Cold & Flu Multi-Relief Capsules
4. Possible side effects
5. How to store Solpa Cold & Flu Multi-Relief Capsules
6. Contents of the pack and other information

1) What Solpa Cold & Flu Multi-Relief Capsules is and what it is used for

Solpa Cold & Flu Multi-Relief Capsules contains the following active substances:

- **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- **guaifenesin** which is an expectorant to help loosen phlegm
- **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 and the pain and congestion of sinusitis, including aches and pains, headache, blocked nose and sore throat, chills and feverishness (high temperature). They can also loosen stubborn mucus (phlegm) and provide relief from chesty coughs.

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 Solpa Cold & Flu Multi-Relief Capsules

Do not take this Solpa Cold & Flu Multi-Relief Capsules if you:

- are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have liver problems, (including alcoholic liver disease)
- 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.
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- have porphyria, which is a type of blood disorder that causes skin or nervous system problems
- are taking other decongestant products containing sympathomimetic amines (e.g. phenylephrine, pseudoephedrine).
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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 suffer from alcoholic liver disease or alcohol dependence
- if you have been told by your doctor you have an intolerance to some sugars
- if you have a circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.
- If you have an enzyme deficiency or metabolic disorder (Glucose-6-phosphate dehydrogenase deficiency, glutathione deficiency or familial non-haemolytic jaundice).
- If you are dehydrated.
- if you have an enlarged prostate or have difficulty passing urine
- if you have asthma or chronic cough
- if you have asthma and are sensitive to acetylsalicylic acid
- if you have heart or circulation disease
- if you have frequent or daily headaches.

Check with your doctor before use if you have liver or kidney problems, are underweight (<50 kg), are 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 at the same time as taking other paracetamol-containing products.

During treatment with Perrigo Cold & Flu Powder for Oral Solution, 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).

Children and adolescents

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

Other medicines and Solpa Cold & Flu Multi-Relief Capsules

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 Solpa Cold & Flu Multi-Relief Capsules (see 'Do not take Solpa Cold & Flu Multi-Relief Capsules'):

- 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 pseudoephedrine.
- Medicines used to lower blood pressure such as guanethidine, reserpine and methyl dopa.

If you are taking any of the following medicines, talk to your doctor before taking Solpa Cold & Flu Multi-Relief Capsules:

- Probenecid which is sometimes 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 (called metabolic acidosis) that must have urgent treatment (see section 2).
- phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine)

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

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Other important information:

This medicine with alcohol

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

Pregnancy and breastfeeding

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.

Taking phenylephrine hydrochloride during pregnancy can cause deformities at birth.

This medicine should not be used in pregnancy.

Breastfeeding

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

If you **are taking medication**, or **are under medical care**, consult your doctor before using this medicine. Do not take with other flu, cold or decongestant products.

Long term use of this product is not recommended.

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 2 capsules, that is to say essentially 'sodium-free'.

3) How to take Solpa Cold & Flu Multi-Relief Capsules

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

Adults, the elderly and adolescents aged 16 years and over who weigh more than 50kg:

The recommended dose is two capsules every 4-6 hours when necessary to a maximum of 4 doses in 24 hours. Do not exceed the stated dose. Do not take more than 8 capsules (4 g paracetamol) in any 24-hour period.

Solpa Cold & Flu Multi-Relief Capsules 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 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. 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 this medicine and what to do

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 immediately:

- 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
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 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 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 Solpa Cold & Flu Multi-Relief Capsules

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 foil. The expiry date refers to the last day of that month.

Do not store above 25°C.

6) Contents of the pack and other information

What this medicine contains

The active substances are: Paracetamol 500 mg, guaifenesin 100 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 quinoline yellow (E104), indigo carmine (E132), erythrosine (E127) and titanium dioxide (E171).

What this medicine looks like and contents of the pack

This medicine contains Blue /green capsules, available in pack size of 8 or 16 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,
Ireland

Manufacturer(s)

Omega Pharma International NV
Venecoweg 26
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Perrigo Supply Chain International DAC,
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