

PATIENT INFORMATION LEAFLET

UNIFLU
WITH VITAMIN C TABLETS
Paracetamol 500mg • Diphenhydramine Hydrochloride 15mg
Phenylephrine Hydrochloride 10mg • Caffeine 30mg
Ascorbic Acid 300mg

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Uniflu with Vitamin C Tablets carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Uniflu with Vitamin C Tablets are and what they are used for
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1. What Uniflu with Vitamin C Tablets are and what they are used for

Uniflu Tablets are for the symptomatic relief from the discomfort associated with influenza and colds i.e. nasal and sinus congestion, headache, fever, aching limbs, coughing and running nose. Vitamin C Tablets are used as a vitamin C supplement during cold and influenza (flu) infections.

2. Before you take Uniflu with Vitamin C Tablets

Do not take Uniflu Tablets

- if you are already taking other paracetamol-containing products
- if you are allergic to paracetamol or any of the other ingredients
- if you have an over-active thyroid, high blood pressure or heart disease
- if you are currently taking monoamine oxidase inhibitors (MAOIs) (a type of antidepressant) or within 14 days of stopping such treatment
- if you are taking other sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma)
- if you are suffering from persistent or chronic cough such as occurs with smoking, asthma or emphysema (serious lung condition causing shortness of breath), or if cough is accompanied by excessive mucus (phlegm).
- if you have glaucoma (high pressure in the eye)
- if you suffer from urinary retention (difficulty passing urine)
- if you have breathing problems

Do not take Vitamin C Tablets:

- If you are allergic to ascorbic acid or any of the other ingredients

Take special care with Uniflu with Vitamin C Tablets

Talk to your doctor before taking Uniflu with Vitamin C Tablets:

- if you have liver problems, such as alcoholic liver disease – you have an increased risk of overdose
- if you have kidney problems
- if you have an enlarged prostate gland causing difficulty in passing urine
- if you suffer from epilepsy
- if you suffer from angina.

During treatment with Uniflu, tell your doctor straight away if:

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).

Taking other medicines

Please tell your doctor or pharmacist before taking Uniflu with Vitamin C Tablets if you are taking or have recently taken any other medicines, including:

- blood thinning tablets (warfarin and other coumarins)
- chloramphenicol (antibiotic)
- cholestyramine (cholesterol lowering medication)
- phenothiazines or antidepressants
- medicines to treat high blood pressure
- medicines to treat nausea and vomiting (such as metoclopramide and domperidone)
- heart medication such as digitalis, beta-adrenergic blockers, guanethidine, reserpine or methyldopa
- a general anaesthetic
- atropine
- medicines obtained without a prescription
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment (see section 2).

Taking Uniflu with Vitamin C Tablets with food and drink

The sedative effect of Uniflu Tablets is increased by alcohol. Therefore, alcoholic drinks should be avoided whilst you are taking Uniflu with Vitamin C Tablets.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Uniflu Tablets may make you feel sleepy. If affected:

- do not drive because Uniflu Tablets could stop you driving safely
- do not use any tools or machines.

Important information about some of the ingredients of Uniflu with Vitamin C Tablets

Uniflu Tablets contain Carmoisine (E122) which may cause allergic reactions.

Vitamin C Tablets contain sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Uniflu with Vitamin C Tablets

Adults and Elderly:	Swallow 1 Uniflu tablet and 1 Vitamin C tablet (swallow, suck or chew) with water every six hours. Do not take more than 4 tablets in 24 hours.
Children aged 12 and over:	Swallow 1 Uniflu tablet and 1 Vitamin C tablet (swallow, suck or chew) with water every eight hours. Do not take more than 3 tablets in 24 hours.
Children under 12 years:	Not recommended.

If you do not feel any better after taking this medicine for 3 days, consult your doctor or pharmacist.

If you take more Uniflu with Vitamin C Tablets 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.

Overdose may lead to increased heart rate, high blood pressure, sickness, liver damage and breathing problems.

If you forget to take Uniflu with Vitamin C Tablets

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

4. Possible side effects

Like all medicines, Uniflu with Vitamin C Tablets can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following mild side effects:

- difficulty passing urine
- headache
- dry mouth
- blurred vision
- stomach upsets (nausea, diarrhoea, abdominal cramps, stomach pains)
- tremors
- rashes
- high blood pressure.
- blood disorders which can lead to a reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia), or reduction in the number of white blood cells which makes infections more likely (agranulocytosis).
- insomnia and nervousness
- very rare cases of serious skin reactions have been reported.

Frequency not known (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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

You can also report side effects directly via:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Uniflu with Vitamin C Tablets

Keep out of the reach and sight of children.

Do not take Uniflu Tablets with Vitamin C after the expiry date which is stated on the packaging.

Do not store above 25°C. Store in the original package to protect from moisture. Do not use if foil strip is damaged.

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. Further information

What Uniflu with Vitamin C Tablets contain:

The active substances per Uniflu Tablet:

Paracetamol500 mg

Diphenhydramine hydrochloride15 mg

Phenylephrine hydrochloride10 mg

Caffeine30 mg

The other ingredients are:

Core: Acacia; Protein S (Byco C) (Hydrolysed Gelatin); Alginic Acid (E400); Magnesium Stearate; Stearic Acid; Sodium Starch Glycollate (Type A)

Coating: Opadry II Pink (includes Polyvinyl Alcohol, Talc (E553b), Titanium Dioxide (E171), Macrogol, Lecithin, Carmoisine Aluminium Lake, FD&C Blue Indigo Carmine Aluminium Lake (E132)).

The active substances per Vitamin C Tablet:

Ascorbic Acid (Vitamin C) 300 mg

(as Ascorbic Acid /Sodium Ascorbate)

The other ingredients are:

Saccharin Sodium; Stearic Acid; Magnesium Stearate; Compressible Sugar; Quinoline Yellow Lake 19248 (E104); Hypromellose; Pectin; Lemon Flavour (E2954) (includes Maltodextrin, Acacia, Lactose).

What Uniflu with Vitamin C Tablets look like and contents of the pack

Uniflu Tablets are pink, oblong, film coated tablets. They are only available in combined blister packs with Vitamin C Tablets.

Vitamin C Tablets are a yellow, biconvex, circular, plain, lemon flavoured, chewable tablet.

There are 6 dose packs (containing 6 Uniflu Tablets and 6 Vitamin C Tablets) or 12 dose packs (containing 12 Uniflu Tablets and 12 Vitamin C Tablets).

Marketing Authorisation Holder

PHOENIX LABS

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