

PACKAGE LEAFLET: INFORMATION FOR THE USER

UNIFLU PLUS
WITH VITAMIN C TABLETS
Paracetamol 500mg • Codeine Phosphate Hemihydrate 10mg
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 Plus with Vitamin C Tablets carefully to get the best results from it.

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

Uniflu Plus 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 Plus with Vitamin C Tablets

Do not take Uniflu Plus Tablets

- If you are under 12 years of age
- 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 know that you metabolise very rapidly codeine into morphine
- 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)
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- 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
- if you are planning a pregnancy or are pregnant or breast feeding.

Do not take Vitamin C Tablets:

- if you are allergic to ascorbic acid or any of the ingredients.

Take special care with Uniflu Plus with Vitamin C Tablets

Talk to your doctor before taking Uniflu Plus 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 Plus 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 methyl dopa
- 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 Plus with Vitamin C Tablets with food and drink

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

Children and adolescents

Use in children and adolescents after surgery:

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Use in children with breathing problems:

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Use in adolescents older than 12 years of age:

Codeine is not recommended in adolescents with compromised respiratory function for the treatment of influenza and colds.

Pregnancy and breast-feeding

Do NOT take Uniflu plus tablets if you are planning a pregnancy or are pregnant or breast feeding. Codeine and morphine passes into breast milk.

Driving and using machines

Uniflu Plus Tablets may make you feel sleepy. If affected:

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

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

Uniflu Plus Tablets contain codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cough. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief or relieve their cough. Other people are more likely to get serious side effects because a very high amount of morphine is produced.

If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

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 medicinal product.

3. How to take Uniflu Plus with Vitamin C Tablets

Adults and Elderly:	Swallow 1 Uniflu Plus 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 Plus 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:	Uniflu Plus should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

If you take more Uniflu Plus 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 Plus 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 Plus 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)
- hypersensitivity (allergic reactions) e.g. skin rashes
- high blood pressure
- tremors
- 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.

Reporting of 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. You can also report side effects directly via HPRA Pharm.acovigilance, 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 Plus with Vitamin C Tablets

Keep out of the reach and sight of children.

Do not take Uniflu Plus with Vitamin C Tablets 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 Plus with Vitamin C Tablets contain

The active substances per Uniflu Plus Tablet:

Paracetamol500 mg

Codeine phosphate hemihydrate.....10 mg
Diphenhydramine hydrochloride15 mg
Phenylephrine hydrochloride10 mg
Caffeine 30 mg

The other ingredients are:

Core: Acacia; Protein S (Byco C) (Hydrolysed Gelatin); Alginic Acid (E400); Magnesium Stearate; Stearic Acid; Sodium Starch Glycolate (Type A);
Coating: Opadry II White (includes Polyvinyl Alcohol, Titanium Dioxide (E171); Macrogol; Talc (E553b)).

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 Plus with Vitamin C Tablets look like and contents of the pack

Uniflu Plus Tablets are white, 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.

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

Marketing Authorisation Holder

PHOENIX LABS
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OR

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Date of review of Patient Information Leaflet

January 2025

Legal Status

[P] Pharmacy-Only-Medicine

Marketing Authorisation Number

Ireland: PA 1113/6/1

**Please note, only the site responsible for batch release will be named on the PIL*