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## PATIENT INFORMATION LEAFLET

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### UNIFLU™ TABLETS

### WITH GREGOVITE 'C'™ (VITAMIN C) TABLETS

**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 has 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.

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

1. What Uniflu with Gregovite 'C' (Vitamin C) tablets are and what they are used for
2. What you need to know before you take Uniflu with Gregovite 'C' (Vitamin C) tablets
3. How to take Uniflu with Gregovite 'C' (Vitamin C) tablets
4. Possible side effects
5. How to store Uniflu with Gregovite 'C' (Vitamin C) tablets
6. Contents of the pack and other information

#### **1. What Uniflu with Gregovite 'C' (Vitamin C) tablets are and what they are used for**

Uniflu with Gregovite 'C' (Vitamin C) tablets should be taken to relieve the symptoms of colds, and flu such as nasal and sinus congestion, headache, fever, aching limbs, coughing and runny nose. Uniflu with Gregovite 'C' (Vitamin C) tablets can also be taken to relieve the symptoms of allergic conditions like hayfever, such as nasal congestion.

This medicine should be taken at the first signs of sneezing, dry throat, aching limbs, coughing, headache and cold shivers.

#### **How Uniflu with Gregovite 'C' (Vitamin C) tablets work**

- **Paracetamol:** an analgesic which acts as a painkiller and reduces fever.
- **Codeine Phosphate:** an antitussive which acts as a cough suppressant.
- **Diphenhydramine Hydrochloride:** an antihistamine which stops a runny nose and reduces irritation of the nasal passages and thus provides relief from sneezing.
- **Phenylephrine Hydrochloride:** a decongestant which reduces inflammation and blockages of the nasal passages.

- **Caffeine:** a mild stimulant to counter the sedative effects of the diphenhydramine hydrochloride.
- **Ascorbic Acid (Vitamin C):** the body's reserves of Vitamin C are reduced during cold and flu infections, thus it is helpful to increase the intake to help the body fight the infection, and speed up recovery.

## **2. What you need to know before you take Uniflu with Gregovite 'C' (Vitamin C) tablets**

### **Do not take Uniflu tablets or Gregovite 'C' (Vitamin C) tablets:**

- if you think you may be allergic to any of the ingredients in these tablets
- if you are under 12 years old
- if you know that you metabolise very rapidly codeine into morphine
- if you are breast-feeding
- if you are an adolescent older than 12 years of age and have had your tonsils or adenoids removed because of obstructive sleep apnoea syndrome
- if you have an overactive thyroid, circulation problems, high blood pressure or heart disease
- if you are taking monoamine oxidase inhibitors (MAOIs) such as phenelzine or isocarboxazid used to treat depression or you have stopped taking these in the last 14 days
- if you have ever had a peptic ulcer (stomach ulcer)
- if you are suffering from chronic obstructive airways disease, asthma or have breathing problems
- if you consume excessive amounts of alcohol on a regular basis
- if you have suffered any type of head injury or you have increased pressure in the brain
- if you have a swollen stomach or stomach pain
- if you are pregnant, or are thinking of becoming pregnant (unless directed by your doctor)
- if you are already taking medicines which contain paracetamol.

### **Adolescents older than 12 years of age**

Uniflu tablets are not recommended in adolescents with compromised respiratory function.

### **Warnings and Precautions**

#### **CONTAINS PARACETAMOL AND CODEINE**

Talk to your doctor or pharmacist before taking Uniflu tablets or Gregovite 'C' (Vitamin C) tablets if:

- you have liver or kidney problems
- you have an enlarged prostate gland or difficulty in passing urine
- you suffer from epilepsy
- you suffer from glaucoma
- you have porphyria
- you have stomach problems
- you have Raynaud's syndrome (poor circulation which makes the toes and fingers numb and pale)
- you know that you are allergic to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs)
- you know that you suffer from a condition called hyperoxaluria; a condition which means you often get kidney stones
- you have had your gallbladder removed

- you are elderly
- you are going to have a skin test for allergy. Treatment with Uniflu tablets will need to be stopped at least two days before your test
- you are going to have any other blood, stool or urine tests

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine. 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 have an effect on their cough symptoms. 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.

Taking codeine regularly over a long time can lead to addiction, which may cause you to feel restless and irritable when you stop the tablets.

Taking a painkiller for headaches regularly, too often or for too long, can make them worse.

Uniflu tablets should not be used to treat persistent or chronic cough such as occurs with smoking, asthma or emphysema or if cough is accompanied by excessive mucus (phlegm), unless directed by the doctor.

### **Other medicines and Uniflu with Gregovite 'C' (Vitamin C) tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- Monoamine oxidase inhibitors (MAOIs) such as phenelzine or isocarboxazid used to treat depression or you have stopped taking these in the last 14 days. Uniflu tablets must not be taken if this applies to you (refer to section 'Do not take Uniflu tablets or Gregovite 'C' (Vitamin C) tablets')
- Other antihistamines (used to treat allergic health conditions) or any other medicines with sedating properties
- Atropine (used to treat stomach problems)
- Antidepressant medicines
- Metoclopramide (used to treat nausea and vomiting and problems with the stomach and foodpipe)
- Domperidone (for stomach problems including nausea and vomiting)
- Cholestyramine (used to treat diarrhoea caused by abnormal absorption of bile acid and high cholesterol levels)
- Chloramphenicol (an antibiotic used to treat bacterial infections)
- Anticoagulants (medicines to thin your blood, such as warfarin)
- Probenecid (used to treat gout)
- Idrocilamide (used to treat muscular pain)
- Imatinib (used to treat cancer)
- Any medicines to treat high levels of iron in your body, for example desferrioxamine

- Other medicines containing paracetamol
- Medicines to lower your blood pressure

### **Uniflu with Gregovite 'C' (Vitamin C) tablets with drinks and alcohol**

You should avoid having alcohol, and caffeine containing drinks such as tea, coffee and some canned drinks while you are taking Uniflu Tablets.

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

Do not take Uniflu with Gregovite 'C' (Vitamin C) tablets if you are pregnant, think you may be pregnant or are planning to have a baby, unless directed to do so by your doctor.

Do not take Uniflu Tablets while you are breast-feeding. Codeine and morphine passes into breast milk.

### **Driving and using machines**

Drowsiness may be experienced whilst taking Uniflu tablets. If you are affected, **DO NOT** drive or operate machinery.

### **Gregovite C (Vitamin C) tablets contain lactose and sucrose**

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 with Gregovite C (Vitamin C) tablets**

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

**Do not exceed the stated daily dose. If symptoms persist or worsen, consult your doctor or pharmacist.**

### **Adults and Elderly:**

One Uniflu tablet (white colour) swallowed whole with water and one Gregovite 'C' (Vitamin C) tablet (yellow colour, lemon-flavoured) swallowed, sucked or chewed. Dosage may be repeated every six (6) hours until the symptoms disappear.

**Do not take more than four (4) Uniflu tablets in 24 hours.**

### **Children under 12 years of age:**

Do not give to children under 12 years of age.

### **Adolescents older than 12 years of age:**

Uniflu tablets are not recommended in adolescents with compromised respiratory function.

For adolescents aged 12 to 18 years who do not have compromised respiratory function the following is recommended:

One Uniflu tablet (white colour) swallowed whole with water and one Gregovite 'C' (Vitamin C) tablet (yellow colour, lemon-flavoured) swallowed, sucked or chewed.

Dosage may be repeated every eight (8) hours until the symptoms disappear.

**Do not take more than three (3) Uniflu Tablets in 24 hours.**

For long term use of the product, the risks and benefits should be assessed regularly by your doctor.

**If you take more Uniflu with Gregovite 'C' (Vitamin C) tablets than you should**

If you take too many tablets, contact your doctor or nearest accident and emergency department **immediately**, even if you feel well, because of the risk of serious delayed liver damage. Show any left-over medicines or the empty packet to the doctor.

**If you forget to take Uniflu with Gregovite 'C' (Vitamin C) tablets**

If you forget to take a dose of the tablets at the correct time, do not worry. Do not take a double dose. Take the tablets as normal when it is time to do so and then carry on taking them as before.

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| <b>4. Possible side effects</b> |
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Like all medicines this medicine can cause side effects, although not everyone gets them.

Some side effects have been reported associated with some of the active ingredients as in Uniflu. These possible side effects are listed below.

**Serious side effects**

If you experience any of the following side effects, contact your doctor or pharmacist **IMMEDIATELY**:

- allergic reactions including swelling of the face, lips, tongue or throat, difficulty breathing, nettle rash, itching, rash
- serious liver problems in alcoholics, signs include jaundice (yellowing of the skin and eyes)
- inflammation of the pancreas, which causes severe pain in the abdomen and back

**Other side effects**

- blood disorders
- reduction in blood platelets which increases the risk of bruising or bleeding
- severe reduction in the number of white blood cells which makes infections more likely
- constipation
- feeling or being sick
- dizziness
- drowsiness
- headache
- dry mouth, nose and throat
- blurred vision
- stomach upsets
- difficulty passing water
- abdominal pain
- fever
- chills

- diarrhoea
- increased mucus
- difficulty sleeping
- high blood pressure.
- uncontrolled movements
- changes to your heartbeat. It may become faster, slower or irregular.

### **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 also report side effects directly via ADR Reporting, Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

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

## **5. How to store Uniflu with Gregovite 'C' (Vitamin C) tablets**

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

Store in a cool, dry, place, temperature not exceeding 25°C (77°F).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Uniflu with Gregovite 'C' (Vitamin C) tablets contains**

The active substances in Uniflu tablets are Paracetamol 500mg, Codeine Phosphate 10 mg, Diphenhydramine Hydrochloride 15mg, Phenylephrine Hydrochloride 10mg, Caffeine 30mg.

The other ingredients are Acacia, Alginic Acid (E400), Coating (Polyvinyl Alcohol, Titanium Dioxide (E171), Polyethylene Glycol 3350, Talc), Hydrolysed Gelatin, Magnesium Stearate, Sodium Starch Glycollate (Type A), Stearic Acid.

The active substance in Gregovite 'C' is Vitamin C (Ascorbic Acid) 300mg. The other ingredients are Sodium Saccharin, Stearic Acid, Magnesium Stearate, Sucrose, Lemon Flavour (includes Maltodextrin, Acacia, Lactose), Quinoline Yellow (E104).

### **What Uniflu with Gregovite 'C' (Vitamin C) tablets look like and contents of the pack**

Uniflu is a white, film-coated, oblong tablet and Gregovite 'C' (Vitamin C) is a circular, lemon-flavoured, chewable, plain yellow tablet.

UnifluTablets with Gregovite 'C' (Vitamin C) tablets are available in a 24 tablet pack, containing 12 Uniflu and 12 Gregovite 'C' (Vitamin C) tablets in two press-through blisters.

#### **LEGAL CATEGORY**

**P** Pharmacy-Only-Medicine.

#### **Marketing Authorisation Holder and Manufacturer**

The product licence holder is:

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland.

Manufacturer: G R Lane Health Products Limited, Sisson Road, Gloucester. GL2 0GR, United Kingdom.

**This leaflet was last revised in:** July 2020

For further information please contact Phoenix Labs, at the address above.