

## DATA SHEET

# UNIFLU<sup>®</sup> with GREGOVITE 'C'<sup>®</sup> Tablets

### PRESENTATION

UNIFLU is a lilac, oblong, sugar-coated tablet.

GREGOVITE 'C' is a circular, biconvex, lemon-flavoured, chewable, plain yellow tablet.

#### Each UNIFLU tablet contains:

|                                    |     |     |     |     |     |     |        |
|------------------------------------|-----|-----|-----|-----|-----|-----|--------|
| Paracetamol B.P.                   | ... | ... | ... | ... | ... | ... | 500 mg |
| Codeine Phosphate B.P.             | ... | ... | ... | ... | ... | ... | 10 mg  |
| Diphenhydramine Hydrochloride B.P. | ... | ... | ... | ... | ... | ... | 15 mg  |
| Phenylephrine Hydrochloride B.P.   | ... | ... | ... | ... | ... | ... | 10 mg  |
| Caffeine B.P.                      | ... | ... | ... | ... | ... | ... | 30 mg  |

#### Each GREGOVITE 'C' tablet contains:

|                                |     |     |     |     |     |     |        |
|--------------------------------|-----|-----|-----|-----|-----|-----|--------|
| Vitamin C (Ascorbic Acid B.P.) | ... | ... | ... | ... | ... | ... | 300 mg |
|--------------------------------|-----|-----|-----|-----|-----|-----|--------|

### LICENSED CLINICAL INDICATIONS

For the symptomatic relief and speedy recovery from the discomforts associated with influenza, blocked-up nose, sinus congestion, headache, fever, aching limbs, sneezing, coughing, runny nose and nasal congestion in allergic conditions such as hay fever.

UNIFLU together with GREGOVITE 'C' (Vitamin C) should be taken at the **first** signs of sneezing, dry throat, aching head and limbs and cold shivers.

### ROUTE OF ADMINISTRATION

Oral

### DOSAGE

Adults and Elderly: One UNIFLU tablet (lilac colour) swallowed whole with water and one GREGOVITE 'C' (Vitamin C 300 mg) tablet (yellow colour, lemon-flavoured), swallowed, sucked or chewed, followed by **ONE TABLET OF EACH EVERY SIX HOURS** until the symptoms disappear.

**NOT MORE THAN FOUR TABLETS OF UNIFLU TO BE TAKEN IN 24 HOURS.**

Children:

Under 12 years: **NOT** recommended.

Over 12 years: One tablet of each UNIFLU (lilac colour) and GREGOVITE 'C' (yellow colour, lemon-flavoured) every **EIGHT HOURS** until the symptoms disappear.

**NOT MORE THAN THREE TABLETS OF UNIFLU TO BE TAKEN IN 24 HOURS**

**CONTAINS PARACETAMOL**

## CONTRA-INDICATIONS

The Phenylephrine content of **UNIFLU** tablets contra-indicates their use in hyperthyroidism and hypertension, cardiovascular and coronary diseases and should not be given to patients being treated with monoamine oxidase inhibitors or within fourteen (14) days of stopping such treatment. **UNIFLU** tablets are contra-indicated in chronic obstructive airways disease.

## INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

Alcohol and other central nervous system depressants can potentiate the sedative effect of **UNIFLU** tablets. Patients are warned to avoid alcoholic drink whilst using the product. Phenylephrine may antagonise the effects of concurrent antihypertensive therapy.

## EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Drowsiness may be experienced during treatment with **UNIFLU** tablets and patients are advised not to drive or operate machinery, if affected.

## OTHER UNDESIRABLE EFFECTS (FREQUENCY AND SERIOUSNESS)

Headache, dry mouth, blurred vision, gastro-intestinal disturbance, urinary retention and occasional rashes have been reported. Hypertension may occur due to Phenylephrine.

## USE IN PREGNANCY AND LACTATION

The safe use of **UNIFLU** tablets in pregnancy has not been established. They should not, therefore, be used in pregnancy except under close medical supervision. **UNIFLU** tablets should also be avoided in nursing mothers.

## OTHER SPECIAL WARNINGS AND PRECAUTIONS

**UNIFLU** should be administered with care to patients with impaired kidney or liver function. Caution is required in patients with epilepsy, prostatic hypertrophy and glaucoma.

## OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES)

Overdosage may lead to tachycardia, hypertension, nausea, vomiting, delayed onset hepatic failure due to paracetamol and respiratory depression due to codeine. Treatment consists of supportive measures, gastric lavage, as well as correction of any fluid or electrolyte imbalance. Intravenous n-acetylcysteine and naloxone may be needed as antidotes in severe cases. In cases of severe hypertension intravenous phentolamine may be required.

## INCOMPATIBILITIES (MAJOR)

No major incompatibilities have been reported.

## PHARMACEUTICAL PRECAUTIONS

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

## KEEP OUT OF REACH OF CHILDREN.

## DO NOT EXCEED THE STATED DAILY DOSE.

## LEGAL CATEGORY

P: Pharmacy-only medicine.

## PACKAGE QUANTITIES

Packs each of 6 tablets of **UNIFLU** and 6 tablets of **GREGOVITE 'C'** in press-thru blisters.

Packs each of 12 tablets of **UNIFLU** and 12 tablets of **GREGOVITE 'C'** in press-thru blisters.

## UK PRODUCT LICENCE NUMBERS

**UNIFLU** tablets: 0528/5007R

**GREGOVITE 'C'** tablets: 0528/5004R

PRODUCT AUTHORISATION NUMBER IN REPUBLIC OF IRELAND  
PA/142/1/1.

## DATE OF REVIEW OF DATA SHEET

November 1993