Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Uniflu Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Caffeine	30.0 mg
Codeine Phosphate	10.0 mg
Diphenhydramine Hydrochloride	15.0 mg
Paracetamol	500.0 mg
Phenylephrine Hydrochloride	10.0 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White, film coated, oblong tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief from the discomforts associated with influenza and colds *i.e.* nasal and sinus congestion, headache, fever, aching limbs, coughing and runny nose; and for the symptomatic relief of nasal congestion in allergic conditions such as hay fever.

4.2 Posology and method of administration

Adults:

One Uniflu Tablet to be swallowed whole with water, followed by one tablet every six hours until the symptoms disappear.

Not more than four tablets of Uniflu to be taken in 24 hours.

Elderly:

As adult dose.

Paediatric population:

Children aged less than 12 years:
Uniflu Tablets are contraindicated in children below the age of 12 years (see section 4.3).

Children aged 12 years to 18 years:

Uniflu Tablets are not recommended for use in children aged 12 years to 18 years with compromised respiratory function (see section 4.4).

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

One tablet every eight hours until symptoms disappear.

Not more than three tablets of Uniflu to be taken in 24 hours.

For longer term use, the risk benefit should be assessed regularly by the prescriber.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Phenylephrine
Hyperthyroidism, hypertension, cardiovascular disorders coronary heart disease. Patients treated with monoamine oxidase inhibitors (MAOIs) or within fourteen days of stopping such treatment.

Caffeine
Patients with history of peptic ulceration

Codeine
Chronic obstructive airways disease, acute respiratory depression, asthma, alcoholism, head injury, raised intracranial pressure and where there is risk of paralytic ileus.

In children below the age of 12 years due to an increased risk of developing serious and life-threatening adverse reactions.

In women during breast-feeding (see section 4.6).

In patients for whom it is known they are CYP2D6 ultra-rapid metabolisers.

Paediatric patients (refer to section 4.2) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions.

4.4 Special warnings and special precautions for use

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

Paracetamol, should be used with caution in patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Caution is advised in patients who are sensitive to aspirin or NSAIDs, due to the potential for cross-reactivity to paracetamol. Hypersensitivity reactions such as bronchospasm have been reported in these patients.

Prolonged use of high doses of codeine may result in the development of tolerance and dependence.

Post Cholecystectomy – codeine may cause sphincter of oddi dysfunction. Avoid in cholecystectomised patients.

CYP2D6 metabolism

Codeine is metabolised by the liver enzyme CYP2D6 into morphine, its active metabolite. If a patient has a deficiency or is completely lacking this enzyme an adequate therapeutic effect will not be obtained. Estimates indicate that up to 7% of the Caucasian population may have this deficiency. However, if the patient is an extensive or ultra-rapid metaboliser there is an increased risk of developing side effects of opioid toxicity even at commonly prescribed doses. These patients convert codeine into morphine rapidly resulting in higher than expected serum morphine levels.

General symptoms of opioid toxicity include confusion, somnolence, shallow breathing, small pupils, nausea, vomiting, constipation and lack of appetite. In severe cases this may include symptoms of circulatory and respiratory depression, which may be life-threatening and very rarely fatal.

Estimates of prevalence of ultra-rapid metabolisers in different populations are summarized below:

Population	Prevalence %
African/Ethiopian	29%
African American	3.4% to 6.5%
Asian	1.2% to 2%
Caucasian	3.6% to 6.5%
Greek	6.0%
Hungarian	1.9%
Northern European	1%-2%

Children with compromised respiratory function

Codeine is not recommended for use in children in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma or extensive surgical procedures. These factors may worsen symptoms of morphine toxicity.

Antihistamines such as diphenhydramine should be used with caution in conditions such as epilepsy, prostatic hypertrophy, glaucoma, urinary retention, pyloroduodenal obstruction, renal or hepatic impairment, or porphyria.

Patients should be advised not to take other paracetamol-containing products, other products containing antihistamines, other drugs with sedating properties or alcohol concurrently.

Antihistamines and opioids should be used with caution in the elderly as they may be more susceptible to adverse effects.

Use of phenylephrine should be avoided in patients with prostatic hyperplasia.

This medicine should be used with caution in patients with occlusive vascular disease including Raynaud's phenomenon.

Treatment with Uniflu Tablets should be stopped for at least two days before skin testing for allergy is undertaken (see section 4.5 Interactions with other medicinal products and other forms of interaction).

The label will state:

Do not exceed the stated dose. Keep out of the sight and reach of children.

If symptoms persist consult your doctor. Patients receiving other regular medication should be warned to consult their physician before using this product.

Longer term use – the risk/benefit should be assessed regularly by the prescriber.

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

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

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

Paracetamol may cause a marginal increase in blood levels of chloramphenicol.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Probenecid reduces the clearance of paracetamol. Studies suggest that probenecid inhibits paracetamol glucuronidation

Restrict or avoid concomitant regular paracetamol use with imatinib.

Phenylephrine
Phenylephrine may antagonise the effect of concurrent antihypertensive therapy. There is increased risk of severe hypertension when phenylephrine is used concurrently with monoamine oxidase inhibitors (MAOIs), including moclobemide or adrenergic neurone blocking agents.

Diphenhydramine
Diphenhydramine may enhance the sedative action of central nervous depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and neuroleptics.

MAOIs may enhance the antimuscarinic effects of antihistamines, Diphenhydramine may have an additive action with other antimuscarinic drugs such as atropine or antidepressants.

Antihistamines such as diphenhydramine may suppress the cutaneous histamine response to allergen extracts. Therefore, treatment with Uniflu Tablets should be stopped at least two days before skin testing for allergy to avoid effects on the test results (see section 4.4 'Special warnings and precautions for use').

Caffeine
The majority of primary caffeine metabolism may be accounted for by cytochrome P450 1A2 (CYP1A2). Therefore, caffeine has the potential to interact with active substances that are substrates for CYP1A2, inhibit CYP1A2, or induce CYP1A2. For example, idrocilamide may markedly reduce the clearance of caffeine, which can lead to caffeine toxicity.

4.6 Pregnancy and lactation

Pregnancy
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. Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

There is inadequate evidence for the safety of diphenhyramine and phenylephrine in human pregnancy. Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion, with subsequent risk of foetal hypoxia.

Breast-feeding
Uniflu tablets are contraindicated in women during breastfeeding (see section 4.3).

At normal therapeutic doses codeine and its active metabolite may be present in breast milk at very low doses and is unlikely to adversely affect the breast fed infant. However, if the patient is an ultra-rapid metaboliser of CYP2D6, higher levels of the active metabolite, morphine, may be present in breast milk and on very rare occasions may result in symptoms of opioid toxicity in the infant, which may be fatal.

Paracetamol is excreted in breast milk but not in a clinically significant amount.

Caffeine and diphenhydramine have been detected in breast milk. Because of the higher risk for infants of development of side effects to antihistamines, diphenhydramine is not recommended in nursing mothers.

Phenylephrine may significantly reduce milk production.

4.7 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.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:
Very common: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from the available data

Paracetamol

Immune system disorders	*Not known:* Hypersensitivity (including skin rash and bronchospasm[1]) Anaphylaxis
Hepatobiliary disorders	*Not known:* Hepatotoxicity[2]
Skin and subcutaneous tissue disorders	*Very rare:* Skin reaction[3] *Not known:* Angioedema Urticaria Pruritis Fixed drug eruption

[1]See section 4.4

[2]There have been reports of severe hepatotoxicity, including fatalities, in chronic alcoholics who have taken paracetamol in amounts within the recommended therapeutic range.

[3]Very rare cases of serious skin reactions have been reported.

There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol.

Codeine

Immune system disorders	*Not known:* Anaphylaxis
Psychiatric disorders	*Not known:* Addiction[1]
Nervous system disorders	*Not known:* Dizziness Drowsiness
Gastrointestinal disorders	*Not known:* Constipation Nausea

	Pancreatitis Sphincter of oddi dysfunction
Skin and subcutaneous tissue disorders	*Not known:* Angioedema Urticaria Pruritis Fixed drug eruption
Investigations	*Not known:* Blood cortisol decreased

[1]Regular prolonged use of codeine is known to lead to addiction and symptoms of restlessness and irritability may result when treatment is then stopped.

Prolonged use of a painkiller for headaches can make them worse.

Caffeine

Psychiatric disorders	*Not known:* Insomnia
Gastrointestinal disorders	*Not known:* Nausea

Diphenhydramine

Nervous system disorders	*Not known:* Dizziness Drowsiness Headache Extrapyramidal disorder
Eye disorders	*Not known:* Blurred vision
Respiratory, thoracic and mediastinal disorders	*Not known:* Dry nose Dry throat Increased viscosity of nasal secretion
Gastrointestinal disorders	*Not known:* Gastrointestinal disturbance Dry mouth
Renal and urinary disorders	*Not known:* Urination difficulty

Phenylephrine

Nervous system disorders	*Not known:* Headache

Cardiac disorders	*Not known:* Tachycardia Reflex bradycardia Palpitations
Vascular disorders	*Not known:* Hypertension
Gastrointestinal disorders	*Not known:* Nausea Vomiting

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via ADR Reporting. Website: www.medicinesauthority.gov.mt/adrportal.

4.9 Overdose

Overdose may lead to tachycardia, hypertension, nausea, vomiting, delayed onset hepatic failure due to paracetamol and respiratory depression due to codeine.

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.

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.

Paracetamol Overdose

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors are as follows if the patient:

Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

Regularly consumes ethanol in excess of recommended amounts

Or

Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema

and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported

Haemolytic crisis has been reported in patients with glucose-6-phosphate dehydrogenase deficiency.

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention.

Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with *N*-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous *N*-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the National Poisons Information Service or a liver unit.

Codeine Overdose

The effects of codeine overdose will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Central nervous system depression, including respiratory depression may develop but is unlikely to be severe unless other sedative agents have been co-ingested, including alcohol, or the overdose is very large. The pupils may be pin-point in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely. Nightmares, anxiety, agitation, euphoria, dysphoria, depression, paranoia and hallucinations may occur.

Management should include general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Consider activated charcoal if an adult presents within one hour of ingestion of more than 350 mg or a child more than 5 mg/kg.

Give naloxone if coma or respiratory depression is present. Naloxone is a competitive antagonist and has a short half-life so large and repeated doses may be required in a seriously poisoned patient. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken.

Caffeine Overdose

Central nervous system features include agitation, confusion, insomnia, altered consciousness, ataxia, delirium, hallucinations, tremors, hyperreflexia and convulsions. Cerebral haemorrhage has been associated with overdose of certain sympathomimetics.

Cardiovascular features include hypertension with a sinus tachycardia and hypertension-induced reflex bradycardia. In severe cases a hypertensive crisis may develop. Tachycardia, supraventricular and ventricular arrhythmias, myocardial ischaemia and infarction may also occur.

Other features include
vomiting, abdominal pain, dilated pupils, increased body temperature, hypokalaemia, hyperglycaemia, leucocytosis, and rigidity. There have been reports of raised creatine phosphokinase activity, rhabdomyolysis and disseminated intravascular coagulation.

Doses above 5 g may be fatal, due to effects on the cardiovascular system. Treatment should be supportive.

Phenylephrine Overdose

Fatal dose is not known.

Systemic effects of overdose include pallor, systemic hypertension, excitement, restlessness, rapid speech, dilated pupils, convulsions, tachycardia and hallucinations. Muscle tone and limb reflexes are increased. With more severe poisoning, ectopic beats and supraventricular and ventricular tachycardias may develop. Hypokalaemia, due shift of potassium from plasma into cells, may rarely be severe. Hyperglycaemia has been reported occasionally.

The benefit of gastric decontamination is uncertain. Consider activated charcoal only if the patient presents within one hour of ingestion of a potentially toxic amount. Monitor pulse, blood pressure and cardiac rhythm. Correct hypokalaemia cautiously. If agitated, sedate with oral diazepam, or in adults, oral or parenteral haloperidol. Tachycardia with adequate cardiac output is best left untreated. Beta-blockers such as metoprolol or esmolol should be used in extreme cases. Ventricular arrhythmias occurring in a patient who is having convulsions are best treated with amiodarone or disopyramide rather than lidocaine or mexiletine since the latter may exacerbate convulsions. Control convulsions with intravenous diazepam or lorazepam. Correct acid, base and metabolic disturbances. If the systolic blood pressure is >220 and diastolic >140 mmHg in the absence of long-standing hypertension give diazepam. Repeat doses may be necessary. Persistent hypertension may respond to a beta-blocker.

Diphenhydramine Overdose

Serious symptoms would not be expected in adults who have ingested less than 1 g diphenhydramine. Young children may be more sensitive to the effects of overdose. Doses greater than 10 mg/kg have been reported to produce severe toxicity.
Common features include nausea, vomiting, flushing, dilated pupils, dry mouth and tongue, hot dry skin, fever, sinus tachycardia, hypertension, ataxia, nystagmus, drowsiness, delirium, agitation, psychosis and visual hallucinations. Uncommon systemic symptoms include myoclonic jerking, rhabdomyolysis, coma and convulsions, cardiac conduction abnormalities and dysrhythmias, cardiovascular collapse, paralytic ileus, urinary retention. Patients who have been unconscious may be hypothermic.

Consider activated charcoal only if the patient presents within 1 hour of ingestion of a potentially toxic amount. Observe for six hours after ingestion. In seriously poisoned patients, ensure a clear airway, and perform blood gas analysis in patients who are deeply unconscious. Assisted ventilation may be required if hypercapnia is present. Correct hypoxia. Correct hypotension by raising the foot of the bed or in severe cases by expanding the intravascular

volume. Dopamine may be necessary in addition in the most severe cases. Control convulsions with oral diazepam. Resist the temptation to treat dysrhythmias with antiarrhythmic drugs. Correct hypoxia and even in the absence of acidosis give intravenous sodium bicarbonate. Forced diuresis, haemodialysis and haemoperfusion are of no value.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Caffeine

Caffeine, like other xanthines, stimulates the central nervous system, increases respiration, affects smooth muscle and exerts a diuretic effect. These effects are all thought to be mediated by the inhibition of phosphodiesterase resulting in a raised cyclic AMP concentration. Of the xanthines, caffeine is the most active in stimulating the central nervous system and is principally used for this purpose and has the least diuretic effect. Its action on the central nervous system is mainly on the higher centres producing a condition of wakefulness and increased mental activity. Caffeine may stimulate the respiratory centre and increase the rate and depth of respiration.

Codeine Phosphate

Codeine phosphate has analgesic, antidiarrhoeal and antitussive actions. Codeine is the antitussive agent against which all other antitussives are evaluated. It acts by depressing the central pathways of the cough reflex in the medulla. The dosage of codeine phosphate employed in Uniflu tablets is that which is necessary to produce antitussive action.

Diphenhydramine Hydrochloride

Diphenhydramine hydrochloride is an ethanolamine derivative with the properties and use of antihistamine. It is less potent than promethazine hydrochloride but has a shorter duration of action. It has sedative, anti-emetic, anticholinergic and local anaesthetic properties.

Diphenhydramine hydrochloride is a histamine H_1-receptor antagonist. It has action on the contraction of smooth muscle and the dilatation and increased permeability of the capillaries. It also has anticholinergic activity.

Paracetamol

Paracetamol has both antipyretic and analgesic activities but no useful anti-inflammatory properties. Its mechanism of analgesic effect is not yet defined. Prostaglandin synthetase from the central nervous system is sensitive to paracetamol, explaining its antipyretic effect. It does not, however, have an anti-inflammatory effect as the peripheral tissue prostaglandin synthetase is not affected.

Phenylephrine Hydrochloride

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly α-adrenergic activity and is without stimulator effects on the central nervous system. It is used for its bronchodilator effects and to elicit sympathetic responses (vasoconstriction) where there is congestion and inflammation of the

nasal mucosa.

5.2 Pharmacokinetic properties

Caffeine

Caffeine is absorbed erratically from the gastro-intestinal tract and does not appear to accumulate in any particular tissue. It passes readily into the central nervous system and saliva.

Caffeine is almost completely metabolised and is excreted in the urine as 1-methyluric acid, 1-methylxanthine and other metabolites. Only about 1% remains unchanged.

Codeine Phosphate

Codeine phosphate is absorbed from the gastro-intestinal tract with peak plasma codeine concentrations produced in about one hour. Codeine is metabolised by O and N-demethylation in the liver to morphine and norcodeine. About 10% of an oral dose is demethylated to morphine. The plasma half life of Codeine in healthy volunteers has been found to be about 3.5 hours. Codeine and its metabolites are excreted almost entirely by the kidneys, mainly as conjugates with glucuronic acid.

Diphenhydramine Hydrochloride

Diphenhydramine hydrochloride is absorbed from the gastro-intestinal tract, metabolised by the liver and excreted mainly as metabolites in the urine. Any unchanged diphenhydramine is eliminated more rapidly than its metabolites. It has been reported to be 98% bound to plasma proteins with a normal half-life of 4 to 7 hours.

Paracetamol

Paracetamol is a weak acid which is readily absorbed from the gastro-intestinal tract with peak plasma concentration occurring about 30 minutes to 2 hours after ingestion. Following absorption it is mainly biotransformed by conjugation to the sulphate and glucuronide. Plasma-protein binding is negligible at the usual therapeutic concentrations.

The elimination of paracetamol does not appear to follow saturation kinetics. The half-life of paracetamol ranges from 2-4 hours in healthy adults. In adults, the sulphate and glucuronide account for about 90% of the urinary recovery of paracetamol, each metabolite contributing to half this amount. Less than 5% is excreted as unchanged paracetamol.

In the overdose situation (10g paracetamol or above), the defence mechanisms of the liver which lead to non-toxic glucuronide and sulphate formation are overwhelmed. Normally minor metabolic pathways therefore participate actively in the overall biotransformation of the drug and these produce hepatotoxic metabolites.

Phenylephrine Hydrochloride

The bioavailability of phenylephrine is reduced due to first pass metabolism by monoamine oxidase in the gut and liver.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Acacia
Protein S (Byco C) (hydrolysed gelatin)
Alginic Acid (E400)
Magnesium Stearate
Stearic Acid
Sodium Starch Glycollate (Type A)

Coating
Opadry II White (Polyvinyl Alcohol part hydrolysed, Titanium Dioxide (E171), Polyethylene Glycol 3350, Talc)
Purified Water

6.2 Incompatibilities

No major incompatibilities have been reported.

6.3 Shelf life

36 months, as packaged for sale.

6.4 Special precautions for storage

Uniflu Tablets should be stored in cool, dry place not exceeding 25°C.

6.5 Nature and contents of container

The product is presented in press through blisters containing six Uniflu tablets with six Gregovite 'C' tablets. The blister pack is made from PVC/PVDC with a printed aluminium foil lidding. The foil is printed (red on gold) with the name and PL number of both products, together with the company name.

The product is available in two pack sizes:

i. 12 tablet box containing 1 blister strip
ii. 24 tablet box containing 2 blister strips

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

MA133300401 Uniflu tablets

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd March 2007/ 18th October 2012

10. DATE OF REVISION OF THE TEXT

August 2020