Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Veganin Plus Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Paracetamol 500 mg, Codeine Phosphate hemihydrate 8 mg and Caffeine 30 mg.

For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
White, capsule-shaped tablet with dimensions of 17.55 mm x 7.5 mm and debossed on one face to read PCC.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Codeine-containing products are indicated in patients older than 12 years of age for the short-term treatment of acute moderate pain which is not relieved by other analgesics such as paracetamol or ibuprofen alone.
Suitable for migraine, headache, rheumatic pain, period pain, toothache and neuralgia.

4.2 Posology and method of administration

Posology

Adults:
2 tablets taken with water every 4-6 hours.
No more than 8 tablets in 24 hours.

Adolescents aged 16 - 18 years of age:
1-2 tablets taken with water every 6 hours when necessary. Not more than 8 tablets in 24 hours.

Paediatric population:
Children aged 12 - 15 years:
1 tablet taken with water every 6 hours when necessary. Not more than 4 tablets in 24 hours.

Children aged less than 12 years:
Codeine should not be used in children below the age of 12 years because of the risk of opioid toxicity due to the variable and unpredictable metabolism of codeine to morphine (see sections 4.3 and 4.4).

Do not exceed the stated dose.
The duration of treatment should be limited to 3 days and if no effective pain relief is achieved the patients/carers should be advised to seek the views of a physician.

Elderly patients
Experience has indicated that normal adult dose of paracetamol is usually appropriate. However in frail, immobile, elderly subjects or in elderly patients with renal or hepatic impairment, a reduction in the amount or frequency of dosing may be appropriate. The maximum daily dose of paracetamol should not exceed 60mg/kg/day (up to a maximum of 2g per day) in the following situations, unless directed by a physician:

- Weight less than 50kg

- Chronic alcoholism
- Dehydration
- Chronic malnutrition

Renal Impairment

It is recommended, when giving paracetamol to patients with renal impairment, to reduce the dose and to increase the minimum interval between each administration to at least 6 hours unless directed otherwise by a physician. See table below:

Glomerular filtration rate	**Dose**
10-50 ml/min	500mg every 6 hours
<10ml/min	500mg every 8 hours

The restrictions related to the use of paracetamol products in patients with renal impairment are primarily a consequence of the paracetamol content of the drug (see section 4.4).

Hepatic Impairment
In patients with hepatic impairment or Gilbert's Syndrome, the dose should be reduced or the dosing interval prolonged. The daily dose of paracetamol should not exceed 2g/day unless directed by a physician. The restrictions related to the use of paracetamol products in patients with hepatic impairment are primarily a consequence of the paracetamol content of the drug (see section 4.4).

Method of administration
For oral administration only.

4.3 Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1;
- Conditions where morphine and opioids are contraindicated, e.g. acute asthma, respiratory depression, risk of paralytic ileus acute alcoholism, head injuries, raised intracranial pressure and following biliary tract surgery (see section 4.4).
- In all paediatric patients (0-18 years of age) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions (see section 4.4);
- In women during breastfeeding (see section 4.6);
- In patients for whom it is known they are CYP2D6 ultra-rapid metabolisers
- In children below the age of 12 years for the symptomatic treatment of cough and/or cold due to an increased risk of developing serious and life-threatening adverse reactions;
- In patients with chronic constipation

4.4 Special warnings and precautions for use

Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking paracetamol or codeine. Underlying liver disease increases the risk of paracetamol-related liver damage.
The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Care should be observed in administering the product to any patients whose condition may be exacerbated by opioids, particularly the elderly, who are especially sensitive to their central and gastro-intestinal effects, those on concurrent CNS depressant drugs and those with prostate hypertrophy.

Patients with a history of cholecystectomy should consult a doctor before using this product as it may cause acute pancreatitis in some patients.

Patients should be advised not to exceed the recommended dose as taking a painkiller for headaches too often or for too long can make them worse.

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product Patients with inflammatory or obstructive bowel disorders or acute abdominal conditions should consult a doctor before using this product.

Veganin Plus contains codeine whose regular or prolonged use may produce psychological and physical dependence. This product should be used with caution in patients with current or past history of substance abuse or dependence (including drug or alcohol) or mental illness (e.g., major depression). Abuse or misuse may result in overdose and/or death (see Section 4.9).

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of 'medication overuse headache' should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Paracetamol should be administered only with particular caution under the following circumstances:

- Glutathione deficiency
- Chronic alcoholism
- Dehydration
- Chronic malnutrition
- The elderly
- Adults and adolescents weighing less than 50 kg
- Renal impairment (GFR ≤50ml/min)
- Glucose-6-phosphate dehydrogenase deficiency
- Haemolytic anaemia
- Concomitant treatment with medicinal products affecting hepatic function
- Hepatic impairment
- Gilbert's Syndrome (familial non-haemolytic jaundice)

Patients taking, or who have taken, monoamine oxidase inhibitors (MAOIs) within the preceding two weeks (see section 4.5) should not take this product.

Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs:
Concomitant use of Veganin Plus and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant use with these sedative medicines should be under medical supervision and reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Veganin Plus concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5)

Do not take with other paracetamol or codeine containing medicines.
Immediate medical advice should be sought in the event of overdosage even if the patient feels well because the risk of irreversible liver damage (see section 4.9).

Codeine, as with other opioids should be used with caution in patients with hypotension, hypothyroidism, head injury or raised intracranial pressure.

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 analgesic 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 metabolizers 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%

Paediatric population:
Post-operative use in children
There have been reports in the published literature that codeine given post-operatively in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, led to rare, but life-threatening adverse events including death (see also section 4.3). All children received doses of codeine that were within the appropriate dose range; however there was evidence that these children were either ultra-rapid or extensive metabolisers in their ability to metabolise codeine to morphine.

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.

This product should be used only when clearly necessary. Prolonged use without medical supervision may be harmful. Do not take for more than 3 days without consulting a doctor. Do not exceed the stated dose.

In general, medicinal products containing paracetamol should be taken for only a few days without the advice of a physician or dentist and not at high doses.

If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.

Prolonged or frequent use is discouraged. Patients should be advised not to take other paracetamol containing products concurrently. Taking multiple daily doses in one administration can severely damage the liver; in such case medical assistance should be sought immediately.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism), who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

If symptoms persist, consult your doctor.

Keep this medicine out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol
The rate of paracetamol absorption may be increased by metoclopramide or domperidone and may be reduced by cholestyramine. Cholestyramine should not be administered within one hour of taking paracetamol.

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.

The use of drugs which induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptive steroids, may increase the extent of metabolism of paracetamol, resulting in reduced plasma concentration of the drug and a faster elimination rate.

Drugs which induce hepatic microsomal enzymes, such as alcohol and barbiturates, may increase the hepatotoxicity of paracetamol, particularly after overdosage.

There is limited evidence suggesting that paracetamol may affect chloramphenicol pharmacokinetics, but its validity has been criticised and evidence of a clinically relevant interaction appears to be lacking. Although no routine monitoring is needed, it is important to bear in mind this potential interaction when these two medications are concomitantly administered, especially in malnourished patients.

In case of concomitant treatment with probenecid, the dose of paracetamol should be reduced because probenecid reduces the clearance of paracetamol by 50% because it prevents the conjugation of paracetamol with glucuronic acid.

Paracetamol may affect the half-life of chloramphenicol. Evidence of a clinically relevant interaction appears to be lacking. Although no routine monitoring is needed, it is important to bear in mind this potential interaction when these two medications are concomitantly administered, especially in malnourished patients

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4).

Codeine
Opiate analgesics may interact with monoamine oxidase inhibitors (MAOIs) and result in serotonin syndrome. Whilst evidence is limited for the interaction with codeine, it is recommended that the product should not be taken concurrently or within two weeks of stopping treatment with a MAOI. The effect of CNS depressants (including alcohol) may be potentiated by codeine.

Concurrent use of codeine with antidiarrhoeal and antiperistaltic agents may increase the risk of severe constipation. Codeine may antagonise the effects of metoclopramide and domperidone on gastrointestinal motility. Concomitant use of antimuscarinics or medications with antimuscarinic action may result in an increased risk of severe constipation, which may lead to paralytic ileus and or/urinary retention.

Quinidine can inhibit the analgesic effect of codeine.

Codeine may delay the absorption of mexiletine and thus reduce the antiarrhythmic effect of the latter. Cimetidine inhibits the metabolism of opioid analgesics resulting in increased plasma concentrations.

Sedative medicines such as benzodiazepines or related drugs
The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

Caffeine
Caffeine, a CNS stimulant, has an antagonistic effect towards the action of sedatives and tranquilizers. Caffeine may enhance the tachycardia effect of some decongestants.

4.6 Fertility, pregnancy and lactation

Pregnancy
Use during pregnancy should be avoided, unless advised by a physician. This includes maternal use during labour because of the potential for respiratory depression in the neonate. Regular use of codeine during pregnancy may cause physical dependence in the foetus leading to withdrawal symptoms in the neonate.

The safety of paracetamol-caffeine-codeine during pregnancy has not been established relative to the possible adverse effects on foetal development and should be avoided. In pregnancy a total daily consumption above 200 mg caffeine per day could possibly increase the risk of spontaneous abortion and low birth weight

Breast-feeding

This medicine is 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 and caffeine are excreted in breast milk but not in a clinically significant amount. Although significant caffeine toxicity has not been observed in breastfed infants, caffeine may have a stimulating effect on the infant.

Fertility

There are no data available regarding the influence of paracetamol, codeine, and caffeine on fertility.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by drowsiness.

4.8 Undesirable effects

Adverse reactions reported from extensive post-marketing experience are tabulated below by System Organ Class and frequency. The following convention has been utilized for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥ 1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

Paracetamol:

System Organ Class	Frequency	Undesirable Effect
Blood and lymphatic system disorders	Very rare	Thrombocytopenia Agranulocytosis
Immune system disorder	Very rare	Anaphylaxis
	Very rare	Allergies (not including angioedema)
Metabolism and nutrition disorders	Not known	High anion gap metabolic acidosis
Respiratory, thoracic and mediastinal disorders	Very rare	Bronchospasm in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Very rare	Hepatic dysfunction
Skin and subcutaneous tissue disorders	Very rare	Cutaneous hypersensitivity reactions including skin rashes, pruritus, sweating, purpura, urticaria and angioedema.
	Very rare	Very rare cases of serious skin reactions have been reported: toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens-Johnson syndrome (SJS) acute generalized exanthematous. pustulosis (AGEP)
Renal and urinary disorders	Very rare	Sterile pyuria (cloudy urine)

Description of selected adverse reactions

High anion gap metabolic acidosis – Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Caffeine

System Organ Class	Frequency	Undesirable Effect
Nervous system disorders	Not known	Dizziness, headache, tremor
Psychiatric disorders	Not known	Nervousness, irritability

When the recommended paracetamol-caffeine-codeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Codeine
Adverse reactions identified during post-marketing use are listed below by organ system class.

System Organ Class	Frequency	Undesirable Effect
Psychiatric disorders	Not known	Drug dependency can occur after prolonged use of codeine at high doses
Rare		Hallucinations, nightmares and restlessness
Nervous system disorders	Not known	Dizziness, worsening of headache with prolonged use, drowsiness
Eye disorders	Not known	Blurred or double vision
Cardiac disorders	Not known	Palpitations
Vascular disorders	Not known	Facial flushing, postural hypotension
Gastrointestinal disorders	Not known	Constipation, nausea, vomiting, dyspepsia, dry mouth, acute pancreatitis in patients with a history of cholecystectomy
Rare		Stomach cramps
Skin and subcutaneous tissue disorder	Not known	Pruritus, sweating
	Not known	Allergic reactions (itch, skin rash, facial oedema)
Renal and urinary disorders	Not known	Difficulty with micturition (dysuria, increased frequency, decrease in amount)

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 HPRA Pharmacovigilance Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Paracetamol
Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors:
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 overdosage 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, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

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 or 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) but results should not delay initiation of treatment beyond 8 hours after ingestion, as the effectiveness of the antidote declines sharply after this time. Activated charcoal should not be used if it is anticipated that oral methionine will be given to the patient. 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.

Codeine
The effects in codeine overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Codeine overdose associated with central nervous 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-pint in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely. Symptoms of codeine overdosage also include cold clammy skin, confusion, convulsions, dizziness, drowsiness, nervousness or restlessness, miosis, bradycardia, dyspnoea, unconsciousness and weakness.

Management of codeine overdose 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 350mg or a child more than 5mg/kg. Give naloxone if coma or respiratory depression is present. Naloxone is competitive antagonist and has a short half-life so large and repeated doses may be required in a seriously poisoned patient. A dose of 0.4-2mg is given intravenously or intramuscularly to adults, this is repeated at intervals of 2-3 minutes if necessary up to 10mg naloxone may be given. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken. Codeine is not dialyzable.

Caffeine
Caffeine overdose may cause diuresis, tachycardia, irritability, nervousness, restlessness, gastrointestinal disturbance and CNS stimulation such as agitation, excitement, insomnia and tremors. Lethal doses of caffeine tend to be between 5-10g. The management of caffeine toxicity is generally symptomatic and supportive (e.g. hydration). For acute ingestion, emesis or gastric lavage is advised.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Opioids in combination with non-opioid analgesics, codeine and paracetamol.
ATC code: N02A J06

Paracetamol has analgesic, antipyretic and mild anti-inflammatory properties. It inhibits prostaglandin synthesis, especially in the Central Nervous System. Paracetamol does not inhibit chronic inflammatory reactions.

Caffeine acts on the Central Nervous System, on muscle, including the cardiac muscle and on the kidneys. Caffeine is a potent stimulator of the CNS. Its action on the CNS is mainly on the higher centres and produces a condition of wakefulness and increased mental activity.

Codeine is a centrally acting weak analgesic. Codeine exerts its effect through μ opioid receptors, although codeine has low affinity for these receptors, and its analgesic effect is due to its conversion to morphine. Codeine, particularly in combination with other analgesics such as paracetamol, has been shown to be effective in acute nociceptive pain.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the upper gastro-intestinal tract. It is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Peak blood levels of 15-20 micrograms per ml

after normal 1g doses of paracetamol occur within 30-60 minutes depending on dosage form. It is rapidly distributed throughout the body and is primarily metabolised in the liver with exertion via the kidney. Elimination half –life is about 2 hours after reaching a peak following a 1g oral dose.Excretion is almost completely renal, in the form of conjugated metabolites.

Caffeine is absorbed readily after oral administration; maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours. 65-80% of administered caffeine is excreted in the urine as l-methyluric acid l-methylxanthine. Caffeine passes readily into the Central Nervous System and into saliva; concentrations have also been detected in breast milk. Caffeine is metabolised almost completely and is excreted via the kidney. Caffeine has a plasma half-life of approximately 3.5 hours and peak plasma concentrations may occur some 50-75 minutes after oral administration.

Codeine Phosphate is well absorbed after oral administration and is widely distributed. About 86% is excreted in the urine in 24 hours; 40-70% is free or conjugated codeine, 5-15% is free or conjugated morphine and 10-20% is free or conjugated norcodeine.

5.3 Preclinical safety data

Codeine and caffeine, individually and in combination, have a well-established safety profile. There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available for paracetamol.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Methylcellulose
Povidone
Water, Purified
Talc
Calcium stearate

Film Coating
Hypromellose (5)
Hypromellose (15)
Polyethylene glycol 3350

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.Store in the original package.

6.5 Nature and contents of container

250 micron opaque white UPVC/20 micron aluminium foil blister inside a carton.

OR

30 micron pyramidally embossed hard temper aluminium (with 250 micron PVC blisters) inside a carton.

OR

35/9 paper/foil with PVC blister inside a carton.

8 tablets per blister, either 1, 2, 3 or 4 strips per carton.

OR

10 tablets per blister, either 1, 2 or 3 strips per carton.

OR

12 tablets per blister strip, either 1 or 2 strips per carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

None

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27September 2002
Date of last renewal: 19 July 2006

10 DATE OF REVISION OF THE TEXT

February 2025