Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Dual Action Dry Syrup, Pseudoephedrine 30mg, Dextromethorphan 10mg, Triprolidine 1.25mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of Benylin Dual Action Dry Syrup contains:

Pseudoephedrine hydrochloride 30 mg
Dextromethorphan hydrobromide 10 mg
Triprolidine hydrochloride 1.25 mg

Excipients with known effect:
Each 5 ml of Benylin Dual Action Dry Syrup also contains:
Sorbitol solution (70%) 1000.0mg
Sucrose 2835.0mg

Methylhydroxybenzoate (E218) 5.00mg
Ponceau 4R (E124) 0.8mg
Ethanol (96% v/v) 201.5mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
A clear, bright red, blackberry-flavoured syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

BENYLIN Dual Action Dry Syrup is indicated for the relief of dry cough and upper respiratory tract congestion such as is associated with the common cold and influenza.

4.2 Posology and method of administration

Posology

Adults and Children 12 years and over:
10 ml every 4-6 hours, up to four times a day

Maximum daily dose: 40ml (80mg dextromethorphan, 240mg pseudoephedrine and 10mg triprolidine).

Children under 12 years:
This medicine is contraindicated in children under the age of 12 years. [See section 4.3]

Use in the elderly
There have been no specific studies of Benylin Dual Action Dry Syrup in the elderly. Experience has indicated that normal adult dosage is appropriate.

Hepatic Dysfunction
Caution should be exercised when administering Benylin Dual Action Dry Syrup to patients with hepatic impairment.

Renal Dysfunction
Caution should be exercised when administering Benylin Dual Action Dry Syrup to patients with mild to moderate renal impairment.

Method of administration
For oral use.

4.3 Contraindications

Benylin Dual Action Dry Syrup is contraindicated in individuals with hypersensitivity to dextromethorphan, pseudoephedrine, triprolidine, or to any of the excipients listed in section 6.1.

Benylin Dual Action Dry Syrup is contraindicated in patients who are receiving monoamine oxidase inhibitors (MAOIs) or who have received these within the previous 14 days. There is a risk of serotonin syndrome with the concomitant use of dextromethorphan and MAOIs, and the concomitant use of this product and MAOIs may cause a rise in blood pressure and/or hypertensive crisis (see section 4.5)

This product is contraindicated in patients taking selective serotonin reuptake inhibitors. (SSRIs, see section 4.5).

Benylin Dual Action Dry Syrup is contraindicated in individuals who are concomitantly taking other sympathomimetic decongestants.

Benylin Dual Action Dry Syrup is contraindicated in individuals who have diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease / renal failure.

Benylin Dual Action Dry Syrup is contraindicated in patients with cardiovascular disease, hypertension and in those who are taking beta-blockers (see section 4.5).

Benylin Dual Action Dry Syrup is contraindicated in patients in, or at risk of developing respiratory failure.

Benylin Dual Action Dry Syrup is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Benylin Dual Action Dry Syrup may cause drowsiness. This product should not be used to sedate a child

If any of the following occur, this product should be stopped:

- Hallucinations
- Restlessness
- Sleep disturbances

Severe Skin reactions
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued and appropriate measures taken if needed.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Patients with the following conditions should be advised to consult a physician before using this product:

- Susceptibility to angle-closure
- Urinary retention and/or prostatic enlargement

Although pseudoephedrine has virtually no pressor effects in normotensive patients, Benylin Dual Action Dry Syrup should be used with caution in patients taking tricyclic antidepressants, or other sympathomimetic agents (such as appetite suppressants and amphetamine-like psychostimulants). The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

Pseudoephedrine may act as a cerebral stimulant giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

Triprolidine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives and tranquilisers.

Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.

While taking this product, patients should be advised to avoid alcoholic drinks and consult a healthcare professional prior to taking with central nervous system depressants.

Cases of dextromethorphan abuse and dependence have been reported. Caution is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.

Serotonin Syndrome
Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)) and CYP2D6 inhibitors. Serotonin syndrome may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms.
If serotonin syndrome is suspected, treatment with Benylin Dual Action Dry Syrup should be discontinued.

Dextromethorphan is metabolised by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10% of the general population are poor metabolisers of CYP2D6. Poor metabolisers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and/or prolonged effects of dextromethorphan. Caution should therefore be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors (see also section 4.5).

Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions.
Patients who are taking other medication including cough and cold medicines and/or who are under the care of a physician, should consult their doctor /pharmacist before taking this product.

Use with caution in mild to moderate renal impairment or in hepatic impairment.

Use with caution in occlusive vascular disease.

Patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician.
This product should be used with caution in atopic children due to histamine release.

This medicine contains 5% v/v ethanol (alcohol), which is up to 190 mg per ml, equal to 5ml beer or 2ml wine per 5 ml. This can be harmful for those suffering from alcoholism. The ethanol content should be taken into account in pregnant or breastfeeding women, children and high-risk groups such as patients with liver disease and epilepsy.

Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed)

The colouring in this medicine may cause allergic reactions.

Each 5ml of this medicine contains 5.6 g of sucrose per 10ml dose. This should be taken into account in patients with diabetes mellitus.

This medicine contains 415 mg of alcohol (ethanol) in each 10 ml dose. The amount in each 10ml dose of this medicine is equivalent to 10 ml beer or 5 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

This medicine contains 8.4mg benzoate salt in each 10ml dose.

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free'.

This medicine contains 2 g sorbitol in each 10 ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Do not take with any other cough and cold medicines.

4.5 Interaction with other medicinal products and other forms of interaction

CNS depressants: Triprolidine may enhance the sedative effects of alcohol and other central nervous system depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Dextromethorphan might exhibit additive CNS depressant effects when co-administered with alcohol, antihistamines, psychotropics, and other CNS depressant drugs.

Appetite suppressants and amphetamine-like psychostimulants: Concomitant use with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants, may cause a rise in blood pressure.

MAOIs (see section 4.3) and/or RIMAs: Pseudoephedrine exerts its vasoconstricting properties by stimulating α-adrenergic receptors and displacing noradrenaline from neuronal storage sites. Since monoamine oxidase inhibitors (MAOIs) impede the metabolism of sympathomimetic amines and increase the store of releasable noradrenaline in adrenergic nerve endings, MAOIs may potentiate the pressor effect of pseudoephedrine.

Benylin Dual Action Dry Syrup should not be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of hypertensive crisis and serotonin syndrome (pyrexia, hypertension, arrhythmias).

Moclobemide: risk of hypertensive crisis.

Antihypertensives: Because of its pseudoephedrine content, this product may partially reverse the hypotensive action of antihypertensive drugs which interfere with sympathetic activity including bretylium, betanidine, guanethidine, debrisoquine, methyldopa, adrenergic neurone blockers and beta-blockers.

Oxytocin: risk of hypertension.

Cardiac glycosides: increased risk of dysrhythmias.

Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism.

Anticholinergic drugs: enhances effects of anticholinergic drugs (such as tricyclic antidepressants and atropine).

Anaesthetic agents: Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias.

CYP2D6 inhibitors
Dextromethorphan is metabolized by CYP2D6 and has an extensive first-pass metabolism. Concomitant use of potent CYP2D6 enzyme inhibitors can increase the dextromethorphan concentrations in the body to levels multifold higher than normal. This increases the patient's risk for toxic effects of dextromethorphan (agitation, confusion, tremor, insomnia, diarrhoea and respiratory depression) and development of serotonin syndrome. Potent CYP2D6 enzyme inhibitors include SSRIs such as fluoxetine and paroxetine, quinidine and terbinafine. In concomitant use with quinidine, plasma concentrations of dextromethorphan have increased up to 20-fold, which has increased the CNS adverse effects of the agent. Amiodarone, flecainide and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol, perphenazine and thioridazine also have similar effects on the metabolism of dextromethorphan. If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dextromethorphan dose may need to be reduced.

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or nursing infant.

Fertility
There is no experience of the effect of Benylin Dual Action Dry Syrup on human fertility.

Pregnancy
There are no adequate and well controlled studies available on the effects of administration of this product in pregnant women.

Breastfeeding
Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast-fed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60 mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. Data from a study of lactating mothers taking 60 mg pseudoephedrine every 6 hours suggests that from 2.2 to 6.7% of the maximum daily dose (240 mg) may be available to the infant from a breastfeeding mother.

Triprolidine is excreted in breast milk, it has been estimated that approximately 0.06 to 0.2% of a single 2.5 mg dose of triprolidine ingested by a nursing mother will be excreted in the breast-milk over 24 hours.

It is not known whether dextromethorphan or its metabolites are excreted in breast milk.

4.7 Effects on ability to drive and use machines

The product may act as a cerebral stimulant in children, and occasionally in adults. Central nervous system depression or excitation may occur, with symptoms such as dizziness, drowsiness, sleep disturbance and more rarely, hallucinations. Patients receiving it should not drive or operate machinery unless it has been shown that their physical and mental ability remains unaffected.

4.8 Undesirable effects

Placebo controlled studies with sufficient adverse event data are not available for the combination of dextromethorphan, pseudoephedrine and triprolidine.

Adverse drug reactions identified during clinical trials and post-marketing experience with dextromethorphan, pseudoephedrine or the combination of pseudoephedrine and triprolidine or the combination of dextromethorphan and pseudoephedrine are listed below by System Organ Class (SOC).

The frequencies are defined according to the following convention:

Very common ≥1/10
Common ≥1/100 and < 1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥1/10,000 and <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data)

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency is listed as 'Not known'.

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Blood and Lymphatic System Disorders	Rare	Blood disorder
Immune System Disorders	Rare	Hypersensitivity – cross-sensitivity may occur with other sympathomimetics
Metabolism and Nutrition Disorders	Not known	Appetite decreased
Psychiatric Disorders	Common Common Rare Rare Rare Rare Not known Not known Not Known Not known Not known Not known Not known	Insomnia Nervousness Confusional state Depression Hallucination Sleep disorder Agitation Anxiety Delusion Euphoric mood Hallucination, visual Irritability Restlessness
Nervous System Disorders	Very Common Common Common Common Common Rare Rare Rare Not known Not known Not known	Headache Dizziness Paradoxical drug reaction Psychomotor hyperactivity Somnolence Extrapyramidal disorder Seizure Tremor Cerebrovascular accident Paraesthesia Posterior reversible encephalopathy syndrome (PRES) (see section 4.4) / Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)
Eye Disorders	Common	Vision blurred
Cardiac Disorders	Rare Rare Not known Not known	Arrhythmia Palpitations Myocardial infarction / Myocardial ischaemia Tachycardia
Vascular Disorders	Rare Not known	Hypotension Hypertension
Respiratory, Thoracic and Mediastinal Disorders	Common Not known Not known Not known Not known	Increased viscosity of bronchial secretion Bronchospasm Dry Throat Dyspnoea Epistaxis Nasal dryness

	Not known Not known	Respiratory Depression
Gastrointestinal Disorders	Common Common Common Not Known Not Known Not Known Not Known	Dry mouth Gastrointestinal disorder Nausea Abdominal pain Diarrhoea Ischaemic colitis Vomiting
Hepatobiliary Disorders	Rare	Liver disorder
Skin and Subcutaneous Tissue Disorders	Not Known Not Known Not Known Not Known Not Known Not known Not Known	Pustulosis Angioedema Pruritus Rash Rash erythematous Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP) Urticaria
Renal and Urinary Disorders	Common Not Known	Urinary retention (in male patients in whom prostatic enlargement could have been an important predisposing factor) Dysuria
General Disorders and Administration Site Conditions	Not Known	Fatigue

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, Website: www.hpra.ie.

4.9 Overdose

Symptoms and Signs:

The effects of acute toxicity from Benylin Dual Action Dry Syrup may include drowsiness, lethargy, dizziness, ataxia, nystagmus, weakness, hypotonicity, respiratory depression, dryness of the skin and mucous membranes, tachycardia, hypertension, hyperpyrexia, hyperactivity, irritability, convulsions, difficulty with micturition, nausea and vomiting.

Dextromethorphan
It is thought to be of low toxicity, but the effects in overdose will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms and signs:
Dextromethorphan overdose may be associated with nausea, vomiting, dystonia, agitation, confusion, somnolence, stupor, nystagmus, cardiotoxicity (tachycardia, abnormal ECG including QTc prolongation), ataxia, toxic psychosis with visual hallucinations, hyperexcitability, colitis ischaemic.
In the event of massive overdose the following symptoms may be observed: coma, respiratory depression, convulsions.

Bromide intoxication has been observed during concomitant use with bromide-containing over the counter drugs or with overdose of dextromethorphan hydrobromide.

Management:

Activated charcoal can be administered to asymptomatic patients who have ingested overdoses of dextromethorphan within the preceding hour.

For patients who have ingested dextromethorphan and are sedated or comatose, naloxone, in the usual doses for treatment of opioid overdose, can be considered. Benzodiazepines for seizures and benzodiazepines and external cooling measures for hyperthermia from serotonin syndrome can be used.

Pseudoephedrine
Overdose may result in:

Metabolism and nutrition disorders: hyperglycaemia, hypokalaemia.

Psychiatric disorders: CNS stimulation, insomnia; irritability, restlessness, anxiety, agitation; confusion, delirium, hallucinations, psychoses.

Nervous system disorders: convulsions, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness in children.

Eye disorders: mydriasis.

Cardiac disorders: palpitations, tachycardia, reflex bradycardia, supraventricular and ventricular arrhythmias, dysrhythmias, myocardial infarction.

Vascular disorders: hypertension, hypertensive crisis.

Gastrointestinal disorders: nausea, vomiting, ischaemic bowel infarction.

Musculoskeletal and connective tissue disorders: rhabdomyolysis.

Renal and urinary disorders: acute renal failure, difficulty in micturition

Triprolidine
Overdosage of an H1 receptor antagonist may result in CNS depression, hyperthermia, anticholinergic syndrome (mydriasis, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, hypotension, hypertension, nausea, vomiting, agitation, confusion, hallucinations, psychosis, seizures, or dysrhythmias. Rhabdomyolysis and renal failure may rarely develop in patients with prolonged agitation, coma, or seizures

Management
Treatment of overdose should be symptomatic and supportive: Necessary measures should be taken to maintain and support respiration and control convulsions. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

Naloxone has been used successfully to reverse central or peripheral opioid effects of dextromethorphan in children (0.01 mg/kg body weight).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pseudoephedrine has a direct and indirect sympathomimetic activity and is an orally effective upper respiratory decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the central nervous system. Pseudoephedrine produces its decongestant effect within 30 minutes, persisting for at least 4 hours.

Dextromethorphan has an antitussive action. It controls coughs by depressing the medullary cough centre. A single oral dose of 10 - 20 mg dextromethorphan produces its antitussive action within 1 hour and lasts for at least 4 hours.

Triprolidine provides antihistamine activity by antagonising H_1-receptors. After oral administration of a single dose of 2.5 mg triprolidine to adults the onset of action, as determined by the ability to antagonise histamine-induced weals and flares in the

skin, is within 1 to 2 hours. Peak effects occur at about 3 hours and, although activity declines thereafter, significant inhibition of histamine-induced weals and flares still occur 8 hours after the dose.

5.2 Pharmacokinetic properties

After the administration of 2.5 mg triprolidine hydrochloride and 60 mg pseudoephedrine hydrochloride to healthy adult volunteers, the peak plasma concentration (C_{max}) of triprolidine is approximately 5.5 ng/ml - 6.0 ng/ml occurring at about 1.5 - 2.0 hours (T_{max}) after drug administration. Its plasma half-life is approximately 3.2 hours. The C_{max} of pseudoephedrine is approximately 180 ng/ml with T_{max} approximately 1.5 - 2.0 hours after drug administration. The plasma half-life is approximately 5.5 hours (urine pH maintained between 5.0 - 7.0). The plasma half-life of pseudoephedrine is increased in subjects with alkaline urine and decreased in subjects with acid urine.

Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Genetically controlled O-demethylation (CYD2D6) is the main determinant of dextromethorphan pharmacokinetics in human volunteers. It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3- hydroxymorphinan and 3-methoxymorphinan have been identified as conjugated products in the urine.

Dextrorphan, which also has antitussive action, is the main metabolite. In some individuals metabolism proceeds more slowly and unchanged dextromethorphan predominates in the blood and urine.

5.3 Preclinical safety data

It has been estimated that 0.5 to 0.7% of a single dose of pseudoephedrine ingested by a mother will be excreted in the breast milk over 24 hours.

In rats and rabbits, systemic administration of triprolidine up to 75 times the human daily dosage did not produce teratogenic effects.

Systemic administration of pseudoephedrine up to 50 times the human daily dosage in rats, and up to 35 times the human daily dosage in rabbits did not produce teratogenic effects.

There is insufficient information available to determine whether dextromethorphan has teratogenic potential.

No studies have been conducted in animals to determine whether pseudoephedrine, dextromethorphan or triprolidine have the potential to impair fertility.

The active ingredients of Benylin Dual Action Dry Syrup are well-known constituents of medicinal products and their safety profiles are well documented. The results of pre-clinical studies do not add anything of relevance for therapeutic purposes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (70%)
Sucrose
Sodium benzoate (E211)
Methyl parahydroxybenzoate (E218)
Ponceau 4R (E124)
Ethanol
Blackberry flavour
Levomenthol
Vanillin
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate.
Keep the bottle in the outer carton.

6.5 Nature and contents of container

Benylin Dual Action Dry Syrup is stored in 30ml, 40ml, 50ml, 100ml and 200ml amber glass bottles closed with metal roll-on closures or HDPE screw caps fitted with saran - or steran (PVDC)-faced wads.

Alternatively the product is available in amber glass bottles with a three piece plastic child resistant tamper evident closure fitted with a polyvinylidine chloride (PVDC) faced wad or polyethylene expanded polyethylene laminated wad.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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10 DATE OF REVISION OF THE TEXT

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