SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Multi-Action ACTIFED Dry Coughs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Multi-Action ACTIFED Dry Coughs contains 1.25 mg triprolidine hydrochloride, 30 mg pseudoephedrine hydrochloride and 10 mg dextromethorphan hydrobromide in each 5 ml.

Excipients with known effect:

Sorbitol solution (E420)

Sucrose

Methyl hydroxybenzoate (E218)

Ponceau 4R (E124)

Ethanol

Sodium benzoate (E211)

Sodium

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Liquid

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Multi-Action ACTIFED Dry Coughs is indicated for the symptomatic relief of upper respiratory tract disorders which are benefited by the combination of a nasal decongestant, a histamine H_1-receptor antagonist, and an antitussive.

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

10 ml every 4 - 6 hours up to four times a day. Not more than 4 doses should be given in any 24 hours.

Children under 12 years:

Multi-Action ACTIFED Dry Coughs is contraindicated in children under the age of 12 years (see section 4.3)

The Elderly:

There have been no specific studies of Multi-Action ACTIFED Dry Coughs in the elderly. Experience has indicated that normal adult dosage is appropriate.

Hepatic dysfunction:

Caution should be exercised when administering Multi-Action ACTIFED Dry Coughs to patients with hepatic impairment.

Renal dysfunction:

Caution should be exercised when administering Multi-Action ACTIFED Dry Coughs to patients with moderate renal impairment.

Method of Administration

For oral use

Multi-Action ACTIFED Dry Coughs may be diluted 1:1 (1 in 2) or 1:3 (1 in 4) with unpreserved Syrup BP. These dilutions have a shelf life of 4 weeks if stored at 25°C.

4.3 Contraindications

Multi-Action ACTIFED Dry Coughs is contraindicated in individuals with known hypersensitivity to dextromethorphan, pseudoephedrine, triprolidine or to any of the excipients listed in section 6.1.

Concomitant use of other sympathomimetic decongestants, beta-blockers, selective serotonin reuptake inhibitors (SSRIs) or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment (see section 4.5). The concomitant use of this product and MAOIs may cause a rise in blood pressure and/or hypertensive crisis. There is a risk of serotonin syndrome with dextromethorphan (see section 4.5).

Cardiovascular disease

Severe hypertension or uncontrolled hypertension

Diabetes mellitus

Phaeochromocytoma

Hyperthyroidism

Closed angle glaucoma

Severe acute or chronic kidney disease/renal failure

Dextromethorphan, should not be given to patients in, or at risk of developing respiratory failure.

Not to be used in children under the age of 12 years.

4.4 Special warnings and precautions for use

Multi-Action ACTIFED Dry Coughs may cause drowsiness. This product should not be used to sedate a child.

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.

Patients with difficulty in urination and/or enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones or patients with a susceptibility to angle-closure should not take this product unless directed by a physician.

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 ischemic 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.

Caution should be exercised when using the product in the presence of hepatic impairment or moderate to severe renal impairment or in occlusive vascular disease.

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.

This product should be used with caution in atopic children due to histamine release.

Drug dependence, tolerance and potential for abuse

For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).

Drug withdrawal syndrome

The drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.

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).

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 this medicine should be discontinued.

This product should not be taken with any other cough and cold medicines.

This medicine contains 208 mg of alcohol (ethanol) in each 5 ml. The amount in each 5 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 10 mg sodium benzoate (E211) in each 5 ml.

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

The colouring in this medicine (Ponceau 4R, E124) may cause allergic reactions.

This medicine contains 2.8 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.

This medicine contains 1 g sorbitol in each 5 ml. 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.

4.5 Interaction with other medicinal products and other forms of interaction

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. This product should not be used in patients taking monoamine inhibitors or within 14 days of stopping treatment as there is a risk of hypertensive crisis and serotonin syndrome (pyrexia, hallucination, gross excitation, coma, hypertension, arrhythmias).

Moclobemide: Risk of hypertensive crisis.

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

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.

Cardiac glycosides: Increased risk of dysrhythmias.

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

Oxytocin: Risk of hypertension.

Anticholinergic drugs: Enhances effects of anticholinergic drugs (such as tricyclic antidepressants).

Antimuscarinic drugs: May have an additive muscarinic action with other drugs such as atropine and some antidepressants.

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

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

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 breastfeeding infant.

There are no adequate and well-controlled clinical studies in pregnant or breastfeeding women for the combination of dextromethorphan, pseudoephedrine and triprolidine.

This medicine contains ethanol and therefore should not be taken during pregnancy and whilst breastfeeding.

Pregnancy

Triprolidine

There are no or limited amount of data from the use of triprolidine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Pseudoephedrine

There are no or limited amount of data from the use of pseudoephedrine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

Dextromethorphan

There are no or limited amount of data from the use of dextromethorphan in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Breastfeeding

Pseudoephedrine

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 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

There are no adequate and well-controlled studies for triprolidine in breastfeeding women. 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

Dextromethorphan

There are no adequate and well-controlled studies of dextromethorphan in breastfeeding women. It is not known whether dextromethorphan or its metabolites are excreted in breast milk.

Fertility

No studies have been conducted in animals to determine whether triprolidine, pseudoephedrine or dextromethorphan have potential to impair fertility. There is no experience of the effect of Multi-Action ACTIFED Dry Coughs on human fertility.

4.7 Effects on ability to drive and use machines

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When taking this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine

- However, you would not be committing an offence (called 'statutory defence') if:
  - The medicine has been taken to treat a medical or dental problem and
  - You have taken it according to the information provided with the medicine and
  - It was not affecting your ability to drive safely.

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://www.gov.uk/drug-driving-law.

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

Psychiatric Disorders	Common	Insomnia
	Common	Nervousness
	Rare	Confusional state
	Rare	Depression
	Rare	Sleep Disorder
	Not Known	Anxiety
	Not Known	Drug dependence (see section 4.4)
	Not Known	Euphoric mood
	Not Known	Excitability
	Not Known	Hallucinations
	Not Known	Irritability
	Not Known	Paranoid delusions
	Not Known	Restlessness
Nervous System Disorders	Very Common	Headache
	Common	Dizziness
	Common	Paradoxical stimulation
	Common	Psychomotor impairment
	Common	Somnolence
	Rare	Extrapyramidal disorder
	Rare	Seizure
	Rare	Tremor
	Not Known	Cerebrovascular accident
	Not Known	Paraesthesia
	Not Known	Posterior reversible encephalopathy syndrome (PRES) (see section 4.4) / Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)
	Not Known	Psychomotor hyperactivity
Eye Disorders	Common	Vision blurred

Cardiac Disorders	Rare	Palpitations
	Not Known	Dysrhythmias
	Not Known	Myocardial infarction/myocardial ischaemia
	Not Known	Tachycardia
Vascular Disorders	Rare	Hypotension
	Not known	Hypertension
Respiratory, Thoracic and Mediastinal Disorders	Common	Increased viscosity of bronchial secretion
	Not Known	Dry Throat
	Not Known	Epistaxis
	Not Known	Nasal dryness
	Not Known	Respiratory depression
Gastrointestinal Disorders	Common	Dry mouth
	Common	Gastrointestinal disorder
	Common	Nausea
	Not Known	Abdominal pain
	Not Known	Diarrhoea
	Not known	Ischaemic colitis
	Not Known	Vomiting
Hepatobiliary Disorders	Rare	Liver disorder
Skin and Subcutaneous Tissue Disorders	Not Known	Angioedema
	Not Known	Pruritus
	Not Known	Rash
	Not Known	Severe skin reactions including acute generalised exanthematous pustulosis (AGEP)
	Not Known	Urticaria
Renal and Urinary Disorders	Common	Urinary Retention (in men in whom prostatic enlargement could have been an important predisposing factor
	Not Known	Dysuria

General Disorders and Administration Site Conditions	Not Known Not Known	Drug withdrawal syndrome 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Signs and symptoms

The signs of acute toxicity from Multi-Action ACTIFED Dry Coughs may include drowsiness, lethargy, dizziness, ataxia, 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.

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.

In the event of massive overdose the following symptoms may be observed: coma, respiratory depression, convulsions.

Dextromethorphan overdose is also associated with hallucinations, mixed; psychotic disorder; seizure; CNS depression; clumsiness; dizziness; dysarthria; lethargy; hypertension; serotonin syndrome; tremor; miosis and mydriasis.

Fatal cases of dextromethorphan overdose have been reported very rarely.

Pseudoephedrine

Overdose may result in:

Hyperglycaemia, hypokalaemia, CNS stimulation, insomnia, irritability, restlessness, anxiety, agitation, confusion, delirium, hallucinations, psychoses, seizure, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness in children, mydriasis, palpitations, tachycardia, reflex bradycardia, supraventricular and

ventricular arrhythmias, dysrhythmias, myocardial infarction, hypertension, vomiting, ischaemic bowel infarction, acute renal failure. difficulty in micturition.

Triprolidine

Overdose 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, seizure, 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.

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

Benzodiazepines for seizures and benzodiazepines and external cooling measures for hyperthermia from serotonin syndrome can be used.

5.1 Pharmacodynamic properties

Triprolidine

Pharmacotherapeutic group: Other antihistamines for systemic use

ATC code: R06AX07

Pseudoephedrine

Pharmacotherapeutic group: Sympathomimetics

ATC code: R01BA02

Dextromethorphan

Pharmacotherapeutic group: Cough Suppressant, Opium alkaloids and derivatives
ATC code: R05DA09

There is no available information on the pharmacodynamic properties for the combination of dextromethorphan, pseudoephedrine and triprolidine in humans. The information presented below describes the pharmacodynamic properties of the single ingredients.

Triprolidine provides symptomatic relief in conditions believed to depend wholly or partially upon the triggered release of histamine. It is a potent competitive histamine H_1-receptor antagonist of the pyrrolidine class with mild central nervous system depressant properties which may cause drowsiness. 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. Dextromethorphan has an antitussive action. It controls coughs by depressing the medullary cough centre.

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 occurs 8 hours after the dose. Pseudoephedrine produces its decongestant effect within 30 minutes, persisting for at least 4 hours.

A single oral dose of 10 - 20 mg dextromethorphan produces its antitussive action within 1 hour and lasts for at least 4 hours.

5.2 Pharmacokinetic properties

There is no available information on the pharmacokinetic properties for the combination of dextromethorphan, pseudoephedrine and triprolidine in humans. The information presented below describes the pharmacokinetic properties of the single active ingredients.

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 markedly decreased by acidification of urine and increased by alkalinisation.

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

The active ingredients of Multi-Action ACTIFED Dry Coughs are well-known constituents of medicinal products and their safety profiles are well documented.

Triprolidine

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

Pseudoephedrine

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (70 %) (E420)

Sucrose

Sodium benzoate

Methyl hydroxybenzoate (E218)

Ponceau 4R (E124) (sodium)

Ethanol (96%)

Blackberry AD16554 (ethanol)

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. Store in the original container to protect from light.

6.5 Nature and contents of container

100 ml amber glass bottles with a 2 piece or a 3 piece plastic child resistant, tamper evident closure fitted with a polyvinylidene chloride (PVDC) faced wad.

A spoon with a 5ml and a 2.5ml measure is supplied with this product.

6.6 Special precautions for disposal

No special requirements

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

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited

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High Wycombe

Buckinghamshire

HP12 4EG

UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 15513/0010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 October 1998

10 DATE OF REVISION OF THE TEXT

14/01/2026