# Professional information for BENYLIN WITH CODEINE

## SCHEDULING STATUS

S2

## 1. NAME OF THE MEDICINE

Benylin with Codeine syrup

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains:

| | |
|---|---|
| Diphenhydramine hydrochloride | 12,5 mg |
| Codeine phosphate | 10,0 mg |
| Ammonium chloride | 125,0 mg |

*Excipients with known effect:*

Preservative:

| | |
|---|---|
| Sodium benzoate | 0,2 % *m/v* |
| Contains alcohol (ethanol 97 %) | 5 % *v/v* |

Contains sugar: Each 5 mL contains 1 g sucrose and 2,3 mL glucose.

Contains sweeteners: Each 5 mL contains 15,5 mg saccharin sodium and 20 mg sodium cyclamate.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Syrup.

A clear, dark brown syrup having a raspberry odour and taste.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Benylin with Codeine is indicated for the relief of cough.

### 4.2 Posology and method of administration

A maximum of four doses per day should not be exceeded.

Shake the bottle before use.

**Adults 18 years and older:** One to two 5 mL medicine measures (5 mL – 10 mL) every 4 hours.

Use the lowest effective dose for the shortest duration.

**DO NOT USE FOR LONGER THAN 3 DAYS.**

### 4.3 Contraindications

Known hypersensitivity to diphenhydramine hydrochloride, codeine phosphate, ammonium chloride or to any of the other ingredients in Benylin with Codeine (see section 6.1). Neither diphenhydramine hydrochloride nor codeine phosphate should be used with monoamine
oxidase inhibitors or within 14 days of stopping treatment with monoamine oxidase inhibitors (see section 4.5).

Contraindicated during acute asthma attacks, in the presence of acute alcoholism, head injuries and raised intracranial pressure, and in patients with impaired hepatic or renal function.

Contraindicated under 18 years of age for cough.

Contraindicated in CYP2D6 ultra-rapid metabolisers who convert codeine into its active metabolite more rapidly and completely than other people. These individuals may experience signs of

overdose/toxicity including symptoms such as extreme sleepiness, confusion, or shallow breathing, which may be life threatening (see section 4.4 and section 5.2 – Metabolism).

Codeine containing products are contraindicated in breastfeeding mothers (see section 4.6).

## 4.4 Special warnings and precautions for use

Risk of death in ultra-rapid metabolisers of codeine: These individuals convert codeine into its active metabolite, morphine, more rapidly and completely than other people. This rapid conversion results in higher than expected serum morphine levels (see section 5.2). Even at labelled dosage regimens, ultra-rapid metabolisers of codeine may have life-threatening or fatal respiratory depression or experience signs of overdose (such as extreme sleepiness, confusion, or shallow breathing) (see section 4.9). Respiratory depression and death have occurred in children who received codeine in the postoperative period following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolisers of codeine (i.e., multiple copies of the gene for cytochrome P450 isoenzyme 2D6 or high morphine concentrations).

Children who are ultra-rapid metabolisers of codeine with obstructive sleep apnoea when treated with codeine for post-tonsillectomy and/or adenoidectomy pain may be particularly sensitive to the respiratory depressant effects of codeine. Codeine is contraindicated in CYP2D6 ultra-rapid metabolisers (see section 4.3).

Codeine is an opioid medicine and carries the risk of misuse and abuse.

**Exceeding the prescribed dose, together with prolonged and continuous use of Benylin with Codeine may lead to dependency and addiction.**

There is an increased risk of addiction in patients with a personal or family history of substance abuse or mental health disorders. Caution is advised and the benefit and risk of Benylin with Codeine should be carefully assessed by a health care professional based on the individual needs of each patient.

Codeine belongs to a class of medicines called opioids. Opioids have been associated with the following conditions:

- Adrenal insufficiency, a potentially life-threatening condition. Adrenal insufficiency may present with non-specific symptoms and signs such as nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure, which has been reported more often following greater than 1 month of use. Advise patient to seek medical attention if they experience a constellation of these symptoms.
- Androgen deficiency, which may present with non-specific symptoms and signs such as low libido, impotence, erectile dysfunction, amenorrhea, or infertility. Advise patient to seek medical attention if they experience any of these symptoms.
- Serotonin syndrome, a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic medicines (see section 4.5). Warn patients of the symptoms of serotonin syndrome and to seek medical attention right away if symptoms develop. Instruct patients to inform their health care provider if they are taking, or plan to take serotonergic medications.
- Sleep-related breathing disorders such as sleep apnoea syndromes (including central sleep apnoea (CSA)) and hypoxia (including sleep-related hypoxia). Opioid use increases the risk of CSA in a dose dependent fashion. Advise patients to inform their health care provider if they have a history of sleep-related breathing disorders or if they experience symptoms of this disorder, for instance if anyone notices that they stop breathing whilst sleeping.
- Hyperalgesia may occur with the use of opioids, particularly at high doses. An unexplained increase in pain, or increased levels of pain can occur with increasing opioid dosages. If you are on any opioid for pain, consult a physician before using Benylin with Codeine.

Codeine should be used with caution in patients with convulsive disorders, head injuries, and in conditions in which intracranial pressure is raised (see section 4.3).

Codeine should be used with caution in patients with compromised respiratory function, such as bronchial asthma, pulmonary oedema,
obstructive airways disease, acute respiratory depression, severe lung disease, obesity, obstructive sleep apnoea and in patients at risk of paralytic ileus.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in patients with obstructive bowel disorders and in patients with myasthenia gravis. The dosage should be reduced in elderly and debilitated patients.
The prolonged use of high doses of codeine has produced dependence of the morphine type.

The use of Benylin with Codeine should be discontinued and quick medical attention should be sought at the earliest sign of codeine toxicity including symptoms such as extreme sleepiness, confusion, or shallow breathing, which may be life threatening.

Diphenhydramine hydrochloride has anticholinergic properties and should be used with care in respiratory conditions such as emphysema, chronic bronchitis, or acute or chronic bronchial asthma and if the patient has glaucoma, urinary retention and prostatic hypertrophy.
Diphenhydramine hydrochloride should be used with caution in patients with liver impairment or cardiovascular disease.

Do not use with any other product containing diphenhydramine, even ones used on skin.

Benylin with Codeine should not be used with alcohol.

- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedations, respiratory depression, coma, and death (see section 4.5).
- Diphenhydramine may enhance the sedative effects of CNS depressants including alcohol, sedatives, and tranquilisers.

The use of Benylin with Codeine may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant medicines.

In infants and children it may act as a cerebral stimulant. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors and convulsions.

Large doses may precipitate fits in epileptics. Deepening coma, extrapyramidal effects and photosensitivity of the skin may occur.

Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects.

The positive results of skin tests may be suppressed.

Patients should not use Benylin with Codeine for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician. Patients should stop use and consult a physician if a cough persists or get worse, or if new symptoms occur.
Benylin with Codeine is intended for short-term use only. It should not be used continuously without medical review.

Benylin with Codeine contains sugar: sucrose and glucose.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Benylin with Codeine.

Benylin with Codeine contains sodium benzoate. An increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

## 4.5 Interaction with other medicines and other forms of interaction

The anticholinergic effects of atropine and tricyclic antidepressants may be enhanced by diphenhydramine hydrochloride. Monoamine oxidase inhibitors (MAOIs) may enhance the anticholinergic effects (see section 4.3).

Diphenhydramine hydrochloride may mask the warning symptoms of damage caused by ototoxic medicines such as aminoglycoside antibiotics, and may affect the metabolism of other medicines in the liver.

**CNS depressants (alcohol, sedatives, tranquilisers)**

Concomitant use with central nervous system depressants (e.g. barbiturates, chloral hydrate, benzodiazepines, phenothiazines, alcohol and centrally acting muscle relaxants) may cause additive CNS depression and respiratory depression.

Diphenhydramine hydrochloride may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, phenothiazines and tricyclic antidepressants.

**Opioid analgesics**

Concurrent use with other opioid receptor agonists may cause additive CNS depression, respiratory depression and hypotensive effects.

**CYP2D6 inhibitors**

Codeine analgesia is believed to be dependent upon the cytochrome P450 isoenzyme CYP2D6 catalysed o-demethylation to form the active metabolite morphine although other mechanisms have been cited. An interaction with quinidine, methadone, and paroxetine (CYP2D6 inhibitors) leading to decreased plasma concentrations of morphine has been described, which may have the potential to decrease codeine analgesia.

**Serotonergic medicines**

The concomitant use of opioids with other medicines that affect the serotonergic neurotransmitter system, such as selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT3 receptor antagonists, medicines that effect the serotonin neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), and monoamine oxidase inhibitors (MAOIs) (used to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue), may result in serotonin syndrome.

## 4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

**Pregnancy**

Codeine crosses the placenta. Neonates who have been exposed to codeine in utero can develop withdrawal syndrome (neonatal abstinence syndrome) after delivery. Cerebral infarction has been reported in this setting.

**Lactation**

*Ammonium chloride*

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

*Diphenhydramine*

Diphenhydramine crosses the placenta and is excreted into breast milk, but levels have not been reported.

*Codeine*

Codeine is contraindicated in breastfeeding women (see section 4.3).
At labelled doses codeine and its active metabolites are present in breast milk at very low concentrations.

In women with normal codeine metabolism (normal CYP2D6 activity), the amount of codeine secreted into human milk is low and dose dependent. Despite the common use of codeine products to manage postpartum pain, reports of adverse events in infants are rare.
However, some women are ultra-rapid metabolisers of codeine. These women achieve higher-than expected serum levels of codeine's active metabolite, morphine, leading to higher-than-expected levels of morphine in breast milk and potentially dangerously high serum morphine levels in their breastfed infants. Deaths have occurred in nursing infants who were exposed to high levels of morphine in breast milk because their mothers were ultra-rapid metabolisers of codeine. Maternal use of codeine can lead to serious adverse reactions, including death, in nursing infants.

This combination of ammonium chloride, codeine and diphenhydramine is contraindicated in breastfeeding, and should not be used during pregnancy.

## 4.7 Effects on ability to drive and use machines

Benylin with Codeine can cause side effects, such as drowsiness, dizziness, incoordination and blurred vision and may affect the ability to drive and use machinery. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights as impaired decision making could lead to accidents.

## 4.8 Undesirable effects

**Blood and the lymphatic system disorders**

*Less frequent:* thrombocytopenia

*Frequency unknown:* agranulocytosis, leucopenia and haemolytic anaemia

**Immune system disorders**

*Less frequent:* hypersensitivity

*Frequency unknown:* allergic reactions, anaphylaxis

**Endocrine disorders**

*Less frequent:* epigastric pain

**Metabolism and nutrition disorders**

*Less frequent:* anorexia, increased appetite

**Psychiatric disorders**

*Less frequent:* euphoria, confusion, changes of mood, agitation, hallucination, insomnia, irritability, nervousness

**Nervous system disorders**

*Frequent:* sedation, drowsiness

*Less frequent:* headache, restlessness, seizure, abnormal coordination, dizziness, paraesthesia, tremor

**Eye disorders**

*Less frequent:* blurred vision, miosis

**Ear and labyrinth disorders**

*Less frequent:* tinnitus, vertigo

**Cardiac disorders**

*Less frequent:* bradycardia, palpitations, tachycardia

**Vascular disorders**

*Less frequent:* hypotension, facial flushing, orthostatic hypotension

**Respiratory, thoracic and mediastinal disorders**

*Less frequent:* tightness of the chest, dry throat, nasal dryness, respiratory depression

**Gastrointestinal disorders**

*Frequent:* nausea, vomiting, constipation

*Less frequent:* dry mouth, diarrhoea, dyspepsia

**Skin and subcutaneous tissue disorders**

*Less frequent:* urticaria, pruritus and itching of the nose, sweating, rash, dermatitis

**Musculoskeletal, connective tissue and bone disorders**

*Less frequent:* muscular weakness

**Renal and urinary disorders**

*Less frequent:* difficulty in micturition, dysuria, antidiuretic effect, ureteric or biliary spasm, urinary retention

**General disorders and administration site conditions**

*Less frequent:* hypothermia, asthenia, chest discomfort

**Injury, poisoning and procedural complications**

*Less frequent:* increased intracranial pressure

**Post-marketing experience**

***Gastrointestinal disorders:***

*Less frequent:* Increased risk of abdominal pain, including pancreatitis.

Codeine is an opioid medicine. Opioids have been associated with the following:

- sedation;
- vertigo;
- bronchospasm;
- gastrointestinal disorder, such as dyspepsia, nausea, vomiting, constipation;
- euphoric mood;
- medicine dependence can develop following long-term use of high doses.

**Reporting of suspected adverse reactions:**

Reporting suspected adverse reactions after authorisation of Benylin with Codeine is important. It allows continued monitoring of the benefit/risk balance of Benylin with Codeine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse**

**Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

For further information, please contact the Consumer Care Contact Centre:

www.kenvuecontact.eu.

## 4.9 Overdose

**Ammonium chloride:**

Large doses of ammonium chloride may cause nausea, vomiting, drowsiness, thirst, headache, hyperventilation, profound acidosis and hypokalaemia. Excessive doses may give rise to hepatic encephalopathy.

**Diphenhydramine hydrochloride:**

Overdosage may be fatal especially in infants and children.

In infants & children CNS stimulations predominates over CNS depression causing ataxia, excitement, tremors, psychoses, hallucinations and convulsions; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow. In adults, CNS depression with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse.

**Codeine phosphate:**

Produces central stimulation with exhilaration and, in children, convulsions, followed by vomiting, drowsiness, respiratory depression and cyanosis, and coma.

***Treatment***

Naloxone hydrochloride is used to counteract the respiratory depression and coma produced by excessive doses of codeine. A dose of 0,4 to 2 mg is given intravenously, repeated at intervals of 2 to 3 minutes if necessary, up to 10 mg. In children, an initial dose of 10 µg per kg body weight may be given intravenously followed, if necessary, by a larger dose of 100 µg per kg.

Further treatment is symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Category and class: A: 10.1 Antitussives and expectorants.

Pharmacotherapeutic group: Antihistamines for systemic use.

ATC code: R06AA52.

Diphenhydramine hydrochloride is an antihistaminic and, by its atropine-like action, relieves cough.

Codeine is a centrally acting cough suppressant.

Ammonium chloride reduces the secretion viscosity and facilitate elimination of mucus through reflex stimulation of bronchial secretion by its irritant and/or other chemical properties.

### 5.2 Pharmacokinetic properties

**Absorption**

*Ammonium chloride*

Ammonium chloride is readily absorbed by the gastrointestinal tract.

*Codeine*

Codeine is rapidly and well absorbed following tablet and liquid oral administration with a bioavailability of 50 – 80 %. Codeine can be detected in plasma as early as 0,17 to 1 hour (h) after oral administration.

$T_{max}$ of codeine 30 mg and 60 mg occurred at 0,75 to 1 h and 0,61 to 1,3 h with $C_{max}$ of 61 to 89,1 ng/mL and 122,8 to 214,2 ng/mL, respectively. Area under the curve (AUC) for codeine 30 mg and 60 mg are 216 to 354,6 ng h/mL and 417 to 734 ng h/mL. Codeine can be taken with or without food.

*Diphenhydramine*

Diphenhydramine is well absorbed from the gastrointestinal tract. After a single-dose of 25 mg diphenhydramine, a maximum concentration of 44,2 ng/mL was reached at 2,3 hours. After multiple oral doses of 50 mg diphenhydramine four times during each day to four subjects, minimum diphenhydramine plasma concentrations at steady state on the third day ranged from 57 – 150 ng/mL.

**Distribution**

*Ammonium chloride*

Ammonia moves freely between muscle and plasma, but most plasma ammonia exists as ammonium ion, which enters tissues only by active transport. The two major interorgan carriers of nitrogen in the body are alanine, which is taken up by liver, and glutamine, which is taken up by the gut and kidney. Severe hepatic and renal impairment can therefore lead to ammonium accumulation.

*Codeine*

Codeine enters the tissues rapidly and is concentrated in the kidney, lung, liver and spleen. Codeine is less than 10 % protein bound with a $V_d$ between 3 to 4 L/kg.

*Diphenhydramine*

Diphenhydramine is widely distributed throughout the body, including the central nervous system. The volume of distribution at steady state (Vss) following 1,25 mg/kg oral administration of diphenhydramine in young adults (31,9 ± 10,4 years), children (8,9 ± 1,7 years), and elderly (69,4 ± 4,3 years) was 14,6 ± 4,0, 17,9 ± 5,9, and 10,2 ± 3,0 L/kg, respectively.

Diphenhydramine is highly protein bound (80-85 %), with free medicine concentrations of 24,0 ± 1,9 % and 14,8 ± 1,5 % measured in Asian and Caucasian plasma. In adults with liver disease, protein binding is lower, although the volume of distribution is comparable to healthy adults.

**Metabolism**

*Ammonium chloride*

Ammonium chloride is metabolised in the liver to form urea and hydrochloric acid.

*Codeine*

Codeine is metabolised by *O*- and *N*-demethylation in the liver to morphine, norcodeine, and other metabolites including normorphine and hydrocodone. Approximately 50 % undergoes pre-systemic metabolism in the gut and liver.

Metabolism to morphine is mediated by the cytochrome P450 isoenzyme CYP2D6, which shows genetic polymorphism. A significant proportion of the population are poor or rapid metabolisers of codeine due to genetic differences in metabolism. As a result, they experience unpredictable opioid analgesic effects or adverse effects. Ethnicity is a factor in the occurrence of CYP2D6 variability. Patients, who are poor CYP2D6 metabolizers (PMs), have a deficiency or are completely lacking this enzyme and will not obtain the adequate effect. Approximately 7 to 10 % of Caucasians, 0,5 to 1 % of Chinese, Japanese, and Hispanics, 1 % of Arabs and 3 % of African Americans are poor metabolisers.

Ultra-rapid metabolisers convert codeine to morphine more rapidly and completely. In ultra-rapid metabolisers (UMs), there is an increased risk of developing side effects of opioid toxicity even at low doses. General symptoms of opioid toxicity include mental status depression, hypoventilation, miosis and hypoperistalsis (see section 4.9). The prevalence of the presence of this CYP2D6 genotype varies and is estimated at 0,5 to 2 % in Asians; 1 to 10 % in Caucasians; 3 to 6,5 % in African Americans; and 16 to 29 % in North Africans, Ethiopians, and Arabs.

*Diphenhydramine*

Diphenhydramine undergoes first-pass metabolism with an absolute bioavailability of 72 % ± 8 %. It is extensively metabolised in the liver by demethylation to *N*-demethyl diphenhydramine (DMDP), and the extent of DMDP measured in plasma is highly correlated with the clearance of diphenhydramine. DMDP is subsequently demethylated to *N,N*-didemethyl diphenhydramine. Because only the latter, minor metabolic pathway of *N,N*-didemethylation appears to be mediated by cytochrome P450 2D6, diphenhydramine disposition in humans is not determined by CYP2D6 activity. Rather, clinical pharmacokinetics data suggest that diphenhydramine may be an inhibitor of CYP2D6 without being extensively metabolised by this cytochrome P450 isozyme. *N,N*-didemethyl diphenhydramine is further metabolised by oxidative deamination to diphenylmethoxyacetic acid.

**Elimination**

*Ammonium chloride*

Ammonium chloride causes a transient diuresis and is primarily excreted in the urine.

*Codeine*

Codeine and its active metabolites such as morphine are excreted almost entirely by the kidneys, mainly as conjugates with glucuronic acid. Only 3 % to 16 % of a given dose of codeine, when taken as a single ingredient or with paracetamol, is excreted unchanged in urine. The $t_{1/2}$ for codeine 30 mg and 60 mg is 1,5 to 2,2 h and 2,1 to 4,5 h, respectively. For codeine taken with paracetamol, $t_{1/2}$ is similar to single ingredient codeine. However, in a study of patients on haemodialysis, the mean $t_{1/2}$ was 13 ± 3,3 h compared to healthy subjects in the study with 114 of 4,5 ± 0,8 h. Renally impaired patients should be dosed and titrated carefully due to possible medicine and metabolite accumulation.

Codeine has a reported systemic clearance of 252 mL/min. Although no specific dosing recommendations are available for patients with hepatic dysfunction, smaller doses and prolonged dosing intervals should be considered to avoid medicine accumulation.

*Diphenhydramine*

The half-life of diphenhydramine in young adults, children, and elderly was 9,2 ± 2,5, 5,4 ± 1,8, and 13,5 ± 4,2 hours, respectively. The half-life of diphenhydramine was 15,2 ± 1,5 hours in adults with liver cirrhosis. The clearance of diphenhydramine in young adults, children, and elderly was 23,3 ± 9,4, 11,7 ± 3,1, and 49,2 ± 22,8 mL/min/kg, respectively. Negligible amount of diphenhydramine is excreted unchanged in the urine.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Caramel Clarkes (colourant)

Citric acid (E330)

Ethanol 97 %

Glucose

Glycerine (E422)

H & R special flavour (flavourant)

L-menthol (flavourant)

Ponceau 4R (colourant) (E124)

Purified water

Raspberry flavour (flavourant)

Saccharin sodium (E954)

Sodium benzoate (E211)

Sodium citrate (E331)

Sodium cyclamate (E952(iv))

Sucrose.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years.

### 6.4 Special precautions for storage

Store in a cool place.

Store at or below 25 °C.

Keep the bottle in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

### 6.5 Nature and contents of container

Amber glass bottles containing 100 mL with a plastic measuring cup.

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

## 8. REFERENCE NUMBER

G830 (Act 101/1965)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2 October 1974.

## 10. DATE OF REVISION OF THE TEXT

12 July 2024

## EXPORT REGISTRATION DETAILS

| | |
|---|---|
| Botswana: | B9321915 S3 |
| Kenya: | H2002/122 POM |
| Malawi: | PMPB/PL 353/8 |
| Mozambique: | 1009 |
| Namibia: | 14/10.1/0365 NS2 |
| Uganda: | 1649/25/97 |
| Zambia: | 082/049 POM |