SCHEDULING STATUS:

S2

1. NAME OF THE MEDICINE

GRIPPON COLD AND FLU TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each tablet contains:	
Phenylephrine Hydrochloride	5 mg
Chlorphenamine Maleate	2 mg
Paracetamol	150 mg
Caffeine	15 mg

Contains sugar: lactose 75 mg

For the full list of excipients, see **section 6.1.**

3. PHARMACEUTICAL FORM

Tablets.

Pink cylindrical biconvex tablets with "GRIPPON" imprinted on the upper face and a break bar on the lower face.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

GRIPPON COLD AND FLU TABLETS is indicated for the relief of symptoms associated with colds and flu such as fever, nasal stuffiness, sneezing, headache and minor aches and pains.

4.2 Posology and method of administration

Adults: 2 tablets 3 times a day

Children 12 years and older: 1 tablet 3 times a day

Do not use continuously for more than ten (10) days without consulting your doctor.

Not intended for use in children under the age of 12.

DO NOT EXCEED THE RECOMMENDED DOSE.

Method of administration: Oral administration only.

4.3 Contraindications

- Known hypersensitivity to phenylephrine hydrochloride, chlorphenamine maleate, paracetamol and caffeine or to any of the excipients listed under Section 6.1.
- GRIPPON COLD AND FLU TABLETS should not be taken by asthmatic patients.
- Do not administer concurrently with monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Contraindicated in most types of cardiovascular disease, hypotension, hyperthyroidism, hyperexcitability, phaeochromocytoma, closed angle glaucoma,
  diabetes mellitus, peptic ulceration and epilepsy.
- Do not use in children under 12 years of age.
- Severe hepatic impairment (Child Pugh C).
- Patients with prostatic enlargement, paralytic ileus or pyloric stenosis
- Severe coronary disease, severe hypertension, cardiovascular disease
- Concomitant use of other sympathomimetic decongestants (see sections 4.4).
- Patients taking tricyclic antidepressants or beta blocking medicines (see section 4.5).
- Patients suffering from hepatitis or alcoholism, or recovering from any form of liver disease, should not take medicines containing paracetamol, such as GRIPPON COLD AND FLU TABLETS.

4.4 Special warnings and precautions for use

- Dosages in excess of those recommended may cause severe liver damage. Do not use with any other paracetamol-containing products. The concomitant use with other medicines containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure, which may require liver transplant or lead to death. Underlying liver disease increases the risk of paracetamol-related liver damage.

GRIPPON COLD & FLU TABLETS contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

- Consult your doctor if no relief is obtained with the recommended dosage.
- Do not use continuously for longer than 10 days without consulting your doctor
- Patients suffering from kidney or liver disease should take paracetamol under medical supervision.
- In patients with glutathione depleted states, the use of paracetamol may increase the risk of metabolic acidosis. Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis.
- Chlorphenamine maleate, in common with other medicines having anticholinergic effects, should be used with caution in patients with bronchitis, bronchiectasis
- Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP) Drug reaction with eosinophilia and systemic symptoms (DRESS)/ drug induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR,

treatment with GRIPPON COLD AND FLU TABLETS must immediately be discontinued and appropriate treatment instituted (see Section 4.8).

- With prolonged use some degree of tolerance and psychic dependency may occur.
- Use with caution in patients with porphyria, hypertension and cardiac arrhythmias.
- Children and elderly patients are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness and nervousness). The use of GRIPPON COLD & FLU TABLETS should be avoided in elderly patients with confusion.
- Use with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery.
- Use GRIPPON COLD & FLU TABLETS with caution in renal disease, alcohol dependence, chronic malnutrition or dehydration.
- Caution is advised if paracetamol, as in GRIPPON COLD & FLU TABLETS, is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.
- Concurrent use with medicines which can cause sedation, such as anxiolytics and hypnotics, may cause an increase in sedative effects.
- The effects of alcohol may be increased and therefore concurrent use should be avoided.
- GRIPPON COLD & FLU TABLETS contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take GRIPPON COLD & FLU TABLETS.
- GRIPPON COLD & FLU TABLETS contains Colour Erythrosine Red H8475 which may cause allergic reactions.

4.5 Interaction with other medicines and other forms of interaction

Interactions with other medicines

- Chlorphenamine maleate may enhance the sedative effect of central nervous system depressants including *alcohol, barbiturates, hypnotics, narcotic analgesics*, *sedatives*, and *tranquillisers*.
- The effects of anticholinergic medicines such as *atropine* and *tricyclic antidepressants* may be enhanced by the concomitant administration of chlorphenamine maleate.
- Caffeine acts synergistically towards the hypertensive and tachycardic effects of sympathomimetics.
- Medicines that may reduce caffeine clearance: *allopurinol, some antiarrhythmics, cimetidine, disulfiram, fluvoxamine, interferon alfa, macrolide antibacterials, quinolones, oral contraceptives, thiabendazole and viloxazine.* The dose might need to be reduced with concomitant administration.
- Medicines that may increase caffeine clearance: *ritonavir*, *rifampicin* and *sulfinpyrazone*. Concomitant administration might require an increase in the dose or frequency of dose.
- Enzyme-inducing medicines may increase hepatic damage, as does excessive intake of alcohol. The speed of absorption of paracetamol may be increased by *metoclopramide or domperidone* and absorption reduced by *cholestyramine*. These interactions are considered to be of unlikely clinical significance in acute usage at the dosage regimen proposed.
- All sedatives (e.g. *hypnotics* or *anxiolytics*), including alcohol, will potentiate depressant effects on the central nervous system if taken with antihistamines (see section 4.4).
- Hypertensive interactions occur between *sympathomimetic amines*, such as *phenylephrine*, and *monoamine oxidase inhibitors* (see section 4.3).
- Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
- Concomitant use of *phenylephrine* with other *sympathomimetic amines* can increase the risk of cardiovascular side effects (see section 4.4).

- Phenylephrine may reduce the efficacy of beta blockers and other antihypertensives (*debrisoquine*, *guanethidine*, *reserpine* and *methyldopa*). The risk of hypertension and other cardiovascular side effects may be increased (see section 4.3).
- Tricyclic antidepressants (e.g. *amitriptyline*) may increase the risk of cardiovascular side effects with *phenylephrine* (see section 4.3).
- Concomitant use of *phenylephrine* with *digoxin* or *cardiac glycosides* may increase the risk of an irregular heartbeat or heart attack.
- Concomitant use of phenylephrine with *ergot alkaloids* (e.g. *ergotamine* and *methysergide*) may cause an increased risk of ergotism.
- The anticoagulant effect of *warfarin and other coumarins* may be enhanced by prolonged, regular daily use of *paracetamol* with an increased risk of bleeding. Occasional doses have no significant effect.
- The hepatotoxicity of paracetamol, as in GRIPPON COLD & FLU TABLETS, particularly after overdosage, may be increased by medicines which induce liver microsomal enzymes such as *carbamazepine, barbiturates (e.g., phenobarbital), fosphenytoin, phenytoin, primidone, tricyclic antidepressants, and alcohol.*
- Chronic *alcohol* intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.
- *Hepatotoxic medicines* - increased risk of hepatotoxicity of paracetamol, as in GRIPPON COLD & FLU TABLETS.
- *Enzyme inducing medicines* - increased risk of hepatotoxicity of paracetamol, as in GRIPPON COLD & FLU TABLETS. Possible decrease in therapeutic effects of GRIPPON COLD & FLU TABLETS.
- *Metoclopramide* - the speed of absorption of paracetamol, as in GRIPPON COLD & FLU TABLETS, may be increased by metoclopramide.

- *Cholestyramine* – the absorption of paracetamol, as in GRIPPON COLD & FLU TABLETS, is reduced if given within one hour of cholestyramine.
- Prolonged concurrent use of paracetamol, as in GRIPPON COLD & FLU TABLETS, with *salicylates* increases the risk of adverse renal effects.
- *Warfarin and anticoagulants* - concurrent, chronic, high-dose administration of paracetamol, as in GRIPPON COLD & FLU TABLETS, may increase the anticoagulant effect.
- Paracetamol, as in GRIPPON COLD & FLU TABLETS, is recommended as the general analgesic and antipyretic of choice in patients on oral anticoagulant therapy. However, caution is needed since, although it has no effect on the gastric mucosa or on platelet function, some studies (with *warfarin, anisindione, dicoumarol, or phenprocoumon*) and isolated reports have found an increased risk of bleeding in patients taking regular doses of paracetamol while on an oral anticoagulant. An increase in INR has also been reported in controlled studies of the use of paracetamol in patients stabilised on warfarin. Increased monitoring of anticoagulant therapy may be appropriate for those also taking paracetamol, as in GRIPPON COLD & FLU TABLETS, regularly.
- *Antiepileptics*: The plasma-paracetamol concentrations considered an indication for antidote treatment, should be halved in patients receiving enzyme inducing medicines such as *carbamazepine, phenobarbital, phenytoin, or primidone.*
- *Probenecid*: Pre-treatment with probenecid can decrease paracetamol clearance and increase its plasma half-life. Although urinary excretion of the sulphate and glucuronide conjugates of paracetamol are reduced, that of paracetamol is unchanged.
- *Antibacterials*: The plasma-paracetamol concentrations considered an indication for antidote treatment should be halved in patients receiving enzyme inducing medicines such as *rifampicin*. Severe hepatotoxicity at therapeutic doses or moderate overdoses of paracetamol has been reported in patients receiving *isoniazid*, alone or with other medicines for tuberculosis.

- *Antivirals*: Severe hepatotoxicity has occurred after use of paracetamol in a patient taking *zidovudine* and *co-trimoxazole*. However, neither short-term nor long-term studies (the latter also in an individual patient) have shown any alteration of zidovudine elimination in patients taking zidovudine and paracetamol. Paracetamol, as in GRIPPON COLD & FLU TABLETS, has also been found to enhance the antiviral effect of *interferon alfa.*
- The use of medicines that induce hepatic microsomal enzymes such as *anticonvulsants* and *oral contraceptives* may increase the extent of metabolism of paracetamol, as in GRIPPON COLD & FLU TABLETS, resulting in reduced plasma concentrations of paracetamol and a faster elimination rate.
- Caution should be taken when paracetamol, as in GRIPPON COLD & FLU TABLETS, is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (see section 4.3). No fertility data available.

4.7 Effects on ability to drive and use machines

GRIPPON COLD & FLU TABLETS may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or perform potentially dangerous tasks, as impaired decision making could lead to accidents.

4.8 Undesirable effects

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000) and unknown (cannot be estimated from the available data)

System organ class	***Frequency***	***Undesirable effect***
Blood and lymphatic system disorders	Less frequent	Thrombocytopenia, agranulocytosis, leucopoenia, neutropenia, pancytopenia, anaemia
	Unknown	Haemolytic anaemia, blood dyscrasias
Immune system disorders	Less frequent	Anaphylaxis, cutaneous hypersensitivity reactions including skin rash (the rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions), angioedema, Stevens Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalised Exanthematous Pustulosis (AGEP).
	Unknown	Drug-induced hypersensitivity syndrome (DIHS), Hypersensitivity reactions characterised by urticaria, dyspnoea, and hypotension (see Section 4.4).
Metabolism and nutrition disorders	Unknown	Altered metabolism including glucose metabolism, anorexia or increased appetite, Pyroglutamic aciduria (5-oxoprolinuria) And high-anion gap metabolic acidosis
Psychiatric disorders	Unknown	Anxiety, fear, restlessness, tremor, irritability, confusion and Weakness, headache, sedation varying from slight drowsiness to deep sleep, inability to concentrate, depression, nightmares,

		insomnia, nervousness, confusion*, excitation*
Nervous system disorders	Frequent	Dizziness
	Unknown	Sensory disturbances
Eye disorders	Frequent	Blurred vision
Ear and labyrinth disorders	Unknown	Tinnitus, vertigo, hearing loss
Cardiac disorders	Unknown	Tachycardia, cardiac dysrhythmias, angina pectoris, palpitations, hypertension, hypotension with dizziness, and dyspnoea
Vascular disorders	Unknown	Headache, tingling, heaviness and weakness of the hands, Hypotension, high blood pressure with headache
Respiratory, thoracic and mediastinal disorders	Less frequent	Bronchospasm in patients sensitive to aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDS)
	Unknown	Tight chest, thickening of bronchial secretions
Gastrointestinal disorders	Frequent	Nausea, dry mouth
	Less frequent	Pancreatitis
	Unknown	Vomiting, diarrhoea, constipation, colic, epigastric pain, dyspepsia, abdominal pain, GI bleeding
Hepatobiliary disorders	Less frequent	Hepatic dysfunction, hepatitis, including jaundice
Skin and subcutaneous tissue disorders	Less frequent	Dermatitis, skin rashes
	Unknown	Fixed drug eruptions (FDE) (see section 4.4), exfoliative dermatitis, rash, urticaria, photosensitivity
Musculoskeletal and connective tissue disorders	Unknown	Muscular weakness and incoordination, tremors, muscle twitching, convulsions

Renal and urinary disorders	Less frequent	Renal colic, renal failure and sterile pyuria, nephropathy toxic
	Unknown	Difficulty with micturition, urinary retention, diuresis, renal papillary necrosis
General disorders and administration site conditions	Frequent	Fatigue
	Unknown	Lassitude
Investigations	Unknown	Transaminases increased

*Children and elderly patients are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

Post-marketing experience:

The following side effects have been reported, and frequencies are unknown: Fixed drug eruptions (FDE) and drug-induced hypersensitivity syndrome (DIHS) (see Section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) or via the eReporting platform (who-umc.org) found on the SAHPRA website.

You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com

4.9 Overdose

Caffeine:

Overdosage symptoms include restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystoles. Large doses of caffeine can cause headache.

Chlorphenamine maleate:

The estimated lethal dose of chlorphenamine is 25 – 50 mg/kg body mass. Symptoms and signs include sedation, paradoxical excitation of the central nervous system (CNS), toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular including dysrhythmias.

Management should be as clinically indicated. Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered, provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and dysrhythmias vigorously. CNS convulsions may be treated with IV diazepam. Haemoperfusion may be used in severe cases.

Phenylephrine hydrochloride:

Tachycardia may occur with an overdose sufficient to stimulate the beta receptors of the heart. Mania has also followed the use of large oral doses of phenylephrine hydrochloride.

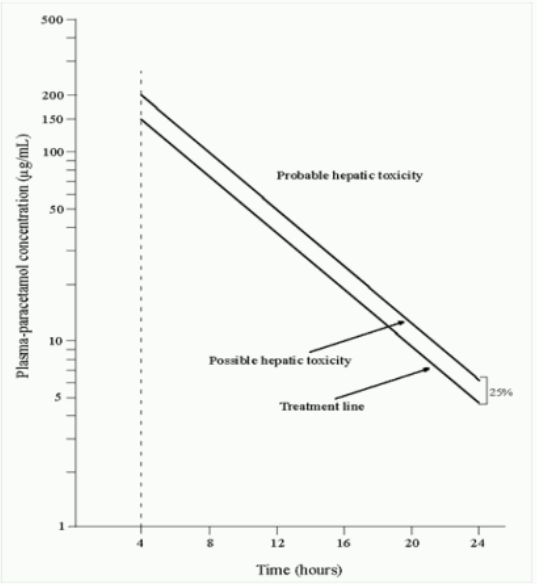
Paracetamol*:*

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of medicine that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine. Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during

the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage. Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given intravenously over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four hours, and then 100 mg/kg in 1000 ml dextrose injection over the next sixteen hours. The volume of intravenous fluid should be modified for children. Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses. A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below.



Reference: Martindale – The complete Drug Reference

The nomogram should be used only in relation to a single acute ingestion. Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”.

Prothrombin index correlates best with survival. For overdose with an extended/modified release preparation the value of the nomogram is unknown. As there is no information on the plasma levels of paracetamol after an overdose of extended/modified release paracetamol preparations, all patients with suspected or known overdose with such preparations should receive N-acetylcysteine. Because of lack of data for extended/ modified release formulations, a level below the “treatment line” of the nomogram may not exclude the possibility of toxicity. Monitor all patients with significant ingestions for at least ninety-six hours.

5. PHARMACOLOGICAL PROPERTIES

A 5.8. Preparations for the common cold

WHO ATCC code: R05X Respiratory System: Other cold preparations

5.1 Pharmacodynamic properties

Paracetamol is an analgesic and antipyretic compound. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

Phenylephrine hydrochloride is a sympathomimetic decongestant.

Chlorphenamine maleate is a potent antihistamine (H_1-antagonist). Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H_1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity. Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 – 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of paracetamol to plasma proteins is variable; 20 – 30 % may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 – 100 % of paracetamol may be recovered in the urine within the first day. However, practically no paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

Caffeine is absorbed readily after oral doses. Maximum 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 1-methyluric acid and 1-methylxanthine.

Phenylephrine hydrochloride is irregularly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by monoamine oxidase in the gut and liver. Orally administered phenylephrine thus has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

Chlorphenamine maleate is well absorbed from the gastrointestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours. Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22 % of an oral dose is excreted unchanged in the urine.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Colour erythrosine red
- Gelatin
- Lactose
- Purified water
- Starch [E1400]
- Stearic acid [E570]
- Talc [E553(b)]

6.2 Incompatibilities

No information available.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C in a well-closed container protected from light.

Exposure to air should be kept to a minimum.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

20's blister pack: Blisters composed of printed aluminium foil and PVC film.

250's Securitainer pack: White polypropylene Securitainer with a white LDPE cap.

500's Securitainer pack: White polypropylene Securitainer with a white LDPE cap.

Not all pack sizes are marketed.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

www.adcock.com

Customer Care: 0860 ADCOCK (232625)

8. REGISTRATION NUMBERS:

C 773 (Act 101/1965).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

August 1970

10. DATE OF REVISION OF THE TEXT

11 September 2025

Botswana: S3 B9311090

Namibia: NS1 12/5.8/0095