

For the use only of Registered Medical Practitioner

1. Generic Name and Brand Name

Paracetamol, Phenylephrine Hydrochloride, Caffeine and Diphenhydramine Hydrochloride Tablets

PHENERGAN® COLD

Paracetamol: Box Warning About Its Liver Toxicity

pTaking more than daily dose may cause serious liver damage or allergic reactions (e.g., swelling of the face, mouth and throat, difficulty in breathing, itching or rash). The risk of liver injury primarily occurs when patient take multiple products containing paracetamol/acetaminophen at one time and exceed the current maximum dose of 4,000 mg within a 24-hour period.

2. Qualitative and Quantitative Composition

Each Film Coated Tablet Contains:

Paracetamol I.P.....500 mg

Phenylephrine Hydrochloride I.P.....5 mg

Caffeine (Anhydrous) I.P.....30 mg

Diphenhydramine Hydrochloride I.P.....25 mg

Excipients.....q.s.

Colours: Lake of Sunset Yellow FCF & Titanium Dioxide I.P.

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

For the treatment of fever associated with cold, nasal congestion in adults.

4.2 Posology and method of administration

Posology

The recommended adult dose is 1 tablet, to be taken two to three times daily or as directed by the Physician.

Special population

The normal adult dose is appropriate for the elderly.

Exercise caution in patient with mild to moderate hepatic and renal impairment.

In mild cases or in particularly sensitive patients, less frequent or reduced doses may be appropriate and adequate.

Do not use continuously for more than one week; re-evaluate if use beyond one week is required.

Method of Administration:

For oral administration only.

The patients should be advised to swallow tablet as whole and must not be chew, crush or break it. Do not exceed the stated dose.

4.3 Contraindications

It is contraindicated in patients with known hypersensitivity to any of the active ingredient(s) or to any of other components.

- Concomitant use of other sympathomimetic decongestants cause
- Pheochromocytoma
- Closed angle glaucoma
- Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, and heart disease. Patients who are taking tricyclic antidepressants, or beta-blocking drugs and those or who have taken within the last two weeks monoamine oxidase inhibitors.

This medicine is not recommended in children below 12 years of age.

4.4 Special warnings and precautions for use

Patients should be advised not to take other paracetamol-containing products concurrently. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Concomitant use of other decongestants or cold and flu medicines should be avoided.

The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Underlying liver disease increases the risk of paracetamol-related liver damage.

Medical advice should be sought before using this product in patients with these conditions:

- glutathione depletion due to metabolic deficiencies.
- An enlargement of the prostate gland
- Occlusive vascular disease (e.g. Raynaud's phenomenon)
- Cardiovascular disease

This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) (see interactions). Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

Diphenhydramine should be used with caution in patients with myasthenia gravis, epilepsy or seizure disorders, prostatic hypertrophy, urinary retention, narrow-angle glaucoma, asthma, bronchitis and chronic obstructive pulmonary disease (COPD), moderate to severe hepatic impairment and moderate to severe renal impairment.

Tolerance may develop with continuous use. Seek medical advice if sleeplessness persists, as insomnia may be a symptom of a serious underlying medical illness.

It may increase the effects of alcohol, therefore alcohol should be avoided. Avoid use of other antihistamine-containing preparations, including topical antihistamines and cough and cold medicines.

Use with caution in the elderly, who are more likely to experience side-effects. Avoid use in elderly patients with confusion.

Patients with rare hereditary problems of fructose intolerance, glucose-galactosemal absorption or sucrase-isomaltase insufficiency should not take this medicine.

Do not take with other flu, cold or decongestant products. Do not take anything else containing paracetamol while taking this medicine. Do not take more medicine than the label tells you to.

Seek immediate medical advice if you take too much of this medicine even if you feel well. If symptoms persist consult your doctor.

4.5 Drug Interactions

Enzyme-inducing drugs 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 colestyramine. These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed. Medical advice should be sought before taking paracetamol, caffeine, phenylephrine & diphenhydramine in combination with the following drugs

Monoamine oxidase inhibitors (including moclobemide)	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine Oxidase inhibitors.
Sympathomimetic amines	Concomitant use of phenylephrine with other sympathomimetics amines can increase the risk of cardiovascular side effects.
Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa)	Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
Tricyclic antidepressants (e.g. amitriptyline)	May increase the risk of cardiovascular side effects with phenylephrine.
Digoxin and cardiac glycosides	Concomitant use of phenylephrine with digoxin or cardiac glycosides may increase the risk of irregular heartbeat or heart attack.
Ergot alkaloids (e.g. ergotamine & methylsergide)	Concomitant use of phenylephrine hydrochloride may cause an increased risk of ergotism.
Warfarin and other coumarins	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.
Lithium	Caffeine can increase the elimination of lithium from the body. If taken concomitantly, it is recommended to reduce or moderate the intake of caffeine.

Diphenhydramine may potentiate the sedative effects of alcohol and other CNS depressants (e.g. tranquillizers, hypnotics and anxiolytics).

Monoamine oxidase inhibitors (MAOIs) prolong and intensify the anticholinergic effects of diphenhydramine. The product should be used with caution with MAOIs or within 2 weeks of stopping an MAOI.

As diphenhydramine has some antimuscarinic activity, the effects of some anticholinergic drugs (e.g. atropine, tricyclic antidepressants) may be potentiated therefore medical advice should be sought before taking diphenhydramine with such medicines.

Diphenhydramine is an inhibitor of the cytochrome p450 isoenzyme CYP2D6. Therefore, there may be a potential for interaction with drugs which are primarily metabolised by CYP2D6, such as metoprolol and venlafaxine. Diphenhydramine should not be used in patients receiving any of the above drugs unless directed by a doctor.

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)

Pregnancy

This product is not recommended for use in pregnancy due to the phenylephrine and caffeine content. There is a potential increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption during pregnancy. Pregnant women should seek medical advice before taking paracetamol containing formulation.

Diphenhydramine crosses the placenta. Because animal reproduction studies are not always predictive of human response and since there is inadequate experience with use of diphenhydramine in pregnant women, the potential risk for humans is unknown. Use of sedating antihistamines during the third trimester may result in reactions in the newborn or premature neonates. This drug is not recommended during pregnancy. Consult a doctor before use.

Breast-feeding

This product should not be used while breast-feeding without medical advice. Avoid the use of the product during lactation, unless the benefits to the mother outweigh the risks to the infant. If used, the lowest effective dose and shortest duration of treatment should be considered.

Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages.

Caffeine in breast milk may have a stimulating effect on breast-fed infants but significant toxicity has not been observed.

Phenylephrine may be excreted in breast milk.

Diphenhydramine has been detected in breast milk, but the effect of this on breastfed infants is unknown. Diphenhydramine is not recommended for use during lactation. Consult a doctor before use.

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Clinical studies of phenylephrine did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy

4.7 Effects on ability to drive and use machines

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

Diphenhydramine is a hypnotic and will produce drowsiness or sedation soon after the dose has been taken. It may also cause dizziness, blurred vision, cognitive and psychomotor impairment.

These can seriously affect the patient's ability to drive and use machines. If affected, do not drive or operate machinery.

4.8 Undesirable effects

Fixed drug eruption (FDE) has been reported with paracetamol

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labeled dose and considered attributable are tabulated below by system class. dverse reactions reported from extensive post-marketing experience are tabulated below by System Organ Class and frequency. The following convention has been utilised for the classification of undesirable effects: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1000$), very rare ($< 1/10,000$), not known (cannot be estimated from available data).

System Organ Class	Common $\geq 1/100$, $< 1/10$	Rare $\geq 1/10,000$, $< 1/1000$	Very Rare $< 1/10,000$	Not known (cannot be estimated from available data)
Blood and lymphatic system disorders	-	-	blood dyscrasias including thrombocytopenia, leukopenia, pancytopenia, neutropenia and agranulocytosis	-
Cardiac Disorders	-	Palpitations, tachycardia or reflex bradycardia	-	Elevated blood pressure, cardiac arrhythmias. Tachycardia, palpitations
Eye Disorders	-	Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma.	-	Blurred vision
General disorders and administration site conditions	Fatigue	-	-	-

Gastrointestinal Disorders	Dry mouth	-	-	Gastrointestinal disturbances. Nausea, vomiting, diarrhoea
Immune System Disorders	-	Allergies (not including angioedema)	Anaphylaxis	Hypersensitivity reactions including rash, urticaria, dyspnoea and angioedema
Musculoskeletal and connective tissue Disorders	-	-	-	Muscle twitching
Nervous System Disorders	Sedation, drowsiness, disturbance in attention, unsteadiness	-	-	Excitability, dizziness and headache. Convulsions, paraesthesia, dyskinesias. Serotonin syndrome
Psychiatric Disorders	-	-	-	Nervousness, insomnia, restlessness, anxiety and irritability. confusion*, paradoxical excitation* (eg. increased energy, restlessness, nervousness)
Renal and urinary disorders	-	-	Sterile pyuria	Urinary difficulty, Dysuria, urinary retention. This is most likely to occur in men with an enlarged prostate.
Respiratory, thoracic and mediastinal disorders	-	-	Bronchospasms in patients sensitive to aspirin and other NSAIDs	Thickening of bronchial secretions
Hepatobiliary disorders	-	-	Hepatic dysfunction	-
Skin and subcutaneous tissue disorders	-	allergic dermatitis	Cutaneous hypersensitivity reactions including skin rashes, pruritus, sweating, purpura, urticaria and angioedema. serious skin reactions.	Toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens-Johnson syndrome (SJS), Acute Generalized exanthematous pustulosis (AGEP). Tingling and coolness of the skin. photosensitivity reactions.

Metabolism and nutrition disorders	-	-	-	High anion gap metabolic acidosis
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*The elderly are more prone to confusion and paradoxical excitation.

4.9 Overdose

Paracetamol

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 4000 mg or more of paracetamol may lead to liver damage if the patient has risk factors. Overdose may cause liver failure which may require liver transplant or lead to death.

Risk factors

If the patient

A) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

B) Regularly consumes ethanol in excess of recommended amounts.

Or

C) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms and signs

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion and have peaked after 4-6 days. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Treatment

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. .

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol; however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Caffeine

Symptoms and signs

Overdose of caffeine may result in epigastric pain, vomiting, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).

It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related liver toxicity.

Treatment

No specific antidote is available, but supportive measures such as beta adrenoceptor antagonists to reverse the cardiotoxic effects may be used.

Phenylephrine

Symptoms and signs

Phenylephrine overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include, irritability, restlessness, hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However, the amount required to produce serious phenylephrine toxicity would be greater than that required to cause paracetamol-related liver toxicity.

Treatment

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking drugs such as phentolamine.

If overdose is confirmed or suspected, seek immediate advice from your Poison Centre and refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

Diphenhydramine

Symptoms and signs

Diphenhydramine Overdose is expected to result in effects similar to the adverse effects that are ordinarily associated with the use of diphenhydramine, including drowsiness, hyperpyrexia, and anticholinergic effects, among others. Additional symptoms during overdose may include mydriasis, fever, flushing, agitation, tremor, dystonic reactions, hallucinations and ECG changes. Large overdose may cause rhabdomyolysis, convulsions, delirium, toxic psychosis, arrhythmias, coma and cardiovascular collapse. Moreover, with higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

Treatment

If overdose is confirmed or suspected, seek immediate advice from your Poison Centre and refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

5. Pharmacological properties

5.1 Mechanism of action

Paracetamol

Paracetamol increases the pain threshold by inhibiting two isoforms of cyclooxygenase, COX-1 and COX-2, which are involved in prostaglandin (PG) synthesis. Prostaglandins are responsible for eliciting pain sensations

Phenylephrine

It is an alpha-1 adrenergic agonist that mediates vasoconstriction and mydriasis depending on the route and location of administration.

Caffeine

Inhibition of nucleotide phosphodiesterase enzymes, adenosine receptors, regulation of calcium handling in cells, and participates in adenosine receptor antagonism.

Diphenhydramine

It is a first-generation H1 receptor antihistamine that is used extensively for the treatment of seasonal allergies, insect bites and stings, and rashes.

5.2 Pharmacodynamic Properties

Paracetamol

Its exact mechanism of action has not been fully established- despite this, it is often categorized alongside NSAIDs (nonsteroidal anti-inflammatory drugs) due to its ability to inhibit the cyclooxygenase (COX) pathways. It is thought to exert central actions which ultimately lead to the alleviation of pain symptoms.

One theory is that Paracetamol increases the pain threshold by inhibiting two isoforms of cyclooxygenase, COX-1 and COX-2, which are involved in prostaglandin (PG) synthesis. Prostaglandins are responsible for eliciting pain sensations. It does not inhibit cyclooxygenase in peripheral tissues and, therefore, has no peripheral anti-inflammatory effects. Though acetylsalicylic acid (aspirin) is an irreversible inhibitor of COX and directly blocks the active site of this enzyme, studies have shown that paracetamol blocks COX indirectly. Studies also suggest that Paracetamol selectively blocks a variant type of the COX enzyme that is unique from the known variants COX-1 and COX-2. This enzyme has been referred to as *COX-3*. The antipyretic actions of paracetamol are likely attributed to direct action on heat-regulating centers in the brain, resulting in peripheral vasodilation, sweating, and loss of body heat. The exact mechanism of action of this drug is not fully understood at this time, but future research may contribute to deeper knowledge.

Phenylephrine

It is an alpha-1 adrenergic agonist that mediates vasoconstriction and mydriasis depending on the route and location of administration. Systemic exposure to phenylephrine also leads to agonism of alpha-1 adrenergic receptors, raising systolic and diastolic pressure as well as peripheral vascular resistance. Increased blood pressure stimulates the vagus nerve, causing reflex bradycardia.

Caffeine

It exerts several actions on cells, but the clinical relevance is poorly understood. One probable mechanism is the inhibition of nucleotide phosphodiesterase enzymes, adenosine receptors, regulation of calcium handling in cells, and participates in adenosine receptor antagonism. Phosphodiesterase enzymes regulate cell function via actions on second messenger's cAMP and cGMP. This causes lipolysis through activation of hormone-sensitive lipases, releasing fatty acids and glycerol.

Diphenhydramine

It is a first-generation H1 receptor antihistamine that is used extensively for the treatment of seasonal allergies, insect bites and stings, and rashes. However, it also has antiemetic, antitussive, hypnotic, and antiparkinson properties. As histamine receptors exist both peripherally and in the central nervous system, diphenhydramine has been shown to cause sedation due to its competitive antagonism of histamine H1 receptors within the central nervous system. While its use in allergy therapy can sometimes fall out of favor due to its sedative effect, diphenhydramine has been repurposed for use within many non-prescription over-the-counter sleep aids and cough-and-cold medications that have been marketed for "night time" use.

5.3 Pharmacokinetic properties

Paracetamol

Animal and clinical studies have determined that acetaminophen has both antipyretic and analgesic effects. This drug has been shown to lack anti-inflammatory effects. As opposed to the *salicylate* drug class, Paracetamol does not disrupt tubular secretion of uric acid and does not affect acid-base balance if taken at the recommended doses. Paracetamol does not disrupt hemostasis and does not have inhibitory activities against platelet aggregation. Allergic reactions are rare occurrences following Paracetamol use.

Caffeine

Caffeine stimulates the central nervous system (CNS), heightening alertness, and sometimes causing restlessness and agitation. It relaxes smooth muscle, stimulates the contraction of cardiac muscle, and enhances athletic performance. Caffeine promotes gastric acid secretion and increases gastrointestinal motility. It is often combined in products with analgesics and ergot alkaloids, relieving the symptoms of migraine and other types of headaches. Finally, caffeine acts as a mild diuretic.

Phenylephrine

Phenylephrine is an alpha-1 adrenergic agonist that raises blood pressure, dilates the pupils, and causes local vasoconstriction. Ophthalmic formulations of phenylephrine act for 3-8 hours while intravenous solutions have an effective half-life of 5 minutes and an elimination half-life of 2.5 hours. Patients taking ophthalmic formulations of phenylephrine should be counselled about the risk of arrhythmia, hypertension, and rebound miosis. Patients taking an intravenous formulation should be counselled regarding the risk of bradycardia, allergic reactions, extravasation causing necrosis or tissue sloughing, and the concomitant use of oxytocic drugs.

Diphenhydramine

Diphenhydramine has anti-histaminic (H1-receptor), anti-emetic, anti-vertigo and sedative and hypnotic properties. The anti-histamine action occurs by blocking the spasmogenic and congestive effects of histamine by competing with histamine for H1 receptor sites on effector cells, preventing but not reversing responses mediated by histamine alone. Such receptor sites may be found in the gut, uterus, large blood vessels, bronchial muscles, and elsewhere. Anti-emetic action is by inhibition at the medullary chemoreceptor trigger zone. Anti-vertigo action is by a central antimuscarinic effect on the vestibular apparatus and the integrative vomiting center and medullary chemoreceptor trigger zone of the midbrain.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Paracetamol

Preclinical safety data on paracetamol in the literature have not revealed findings which are of relevance to the recommended dosage and use of the product.

Phenylephrine

Phenylephrine has been used to induce cardiac myocyte hypertrophy in cultures of rat neonatal myocytes at doses of 100 μ M and 10 μ M. To the best of our knowledge there have been no human studies associating therapeutic phenylephrine use with the development of cardiac myocyte hypertrophy.

Diphenhydramine

It has been used to induce cardiac myocyte hypertrophy in cultures of rat neonatal myocytes at doses of 100 μ M and 10 μ M. To the best of our knowledge there have been no human studies associating therapeutic use with the development of cardiac myocyte hypertrophy.

Caffeine

In several well documented studies, caffeine resulted in slight reproductive effects at high doses (e.g. reduced number of pups born alive per litter) occurring in the presence of general toxicity (body weight gain) in parental rats and mice. In well documented 90 day-studies performed in rats and mice, no significant differences in sperm morphology, vaginal cytology and histopathology of the gonads were seen

7. Description

Light orange coloured, elongated, biconvex & both side plain film coated tablets.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not known.

8.2 Shelf Life

Refer Pack

8.3 Packaging Information

Refer Pack

8.4 Storage condition

Refer Pack

9. Patient Counseling Information

Administration Instructions to Patients

- Use this medication exactly as prescribed by your doctor. Take this tablet with or after food.
- This medicine is not recommended in children below 12 years of age.
- Pregnant women and lactating mothers should not take this medicine.
- Not to share this medication with other patients even though symptoms are similar. Also, don't use medication prescribed for other patients.
- This medicine is not advisable in patients with severe liver and/or kidney dysfunction.
- Not to use with any other medicine containing paracetamol (prescription or over-the-counter - OTC). Users to ask a doctor or pharmacist, if they are not sure about presence of paracetamol in the drug taken for other illnesses. Also, not to use this medicine with other cough and cold relief products without consulting your doctor.
- This medicine (as it contains diphenhydramine) may cause drowsiness and has an additive effect with alcohol. Patients should be warned not to engage in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc. after taking this medicine.

10. Details of manufacturer

Refer Pack for manufacturer details.

Marketed by:

Abbott Healthcare Pvt. Ltd.

Angel Space, Bldg. D-4, Gala No. 1 to 3 & 11 to 13 Ground Floor, 101 to 106 & 111 to 116 First Floor, 201 to 206 & 211 to 216 2nd Floor, Pimpas, Dist. Thane, Bhiwandi-421 302, Maharashtra, India.

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11. Details of permission or licence number with date

Mfg. Lic. No. 4/UA/LL/2014 dated 15-Jul-22

12. Date of revision

Version 1.0, dated 11-Mar-26

For Product Complaints/Adverse events or Queries please write to
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