*Note: Product Name, Item Code and Pharma Code Position & Orientation will be Changed Based on Folding Feasibility

MYDRON Amiodarone Hydrochloride Injection 50mg/ml

Brand or Product Name

MYDRON Amiodarone Hydrochloride Injection 50mg/ml

Description and Composition:
MYDRON Amiodarone Hydrochloride Injection 50mg/ml is a Sterile clear and colorless to pale- yellow solution for Injection containing 50 mg of Amiodarone Hydrochloride per mL. The product is filled as 150 mg (3mL) in 5 mL USP Type I amber glass vial, stoppered with 20 mm grey bromobutyl rubber stopper sealed with 20 mm aluminum flip off seal with red colour button.

Description after dilution (in 5% w/v Glucose in water (DW) Intravenous Infusion): Sterile clear and colorless to pale-yellow solution

Pharmacodynamics
ANTIARRHYTHMICS, CLASS III
ATC CODE: C01BD01 (C: Cardiovascular System)

Antiarrhythmic properties:
- Prolongation of phase 3 of the action potential or cardiac cells without modifying its height or ascension rate (Vaughan Williams class III). The isolated prolongation of phase 3 of the potential of action is due to slowing of the potassium current, with no change in the sodium or calcium current.
- Bradycardiac effect by reducing sinus automaticity.

This effect is not antagonized by atropine:
- Non-competitive alpha and beta-antiadrenergic effect.
- Slowed sinoatrial, atrial and nodal conduction, which is more pronounced the more rapid the rhythm.
- No changes in ventricular conduction.
- Increase in refractory periods and reduction in myocardial excitability on an atrial, nodal and ventricular level.
- Slowing of conduction and prolongation of refractory periods in the atrioventricular accessory channels.
- Absence of negative inotropic effect.

Pharmacokinetics
The quantity of amiodarone injected diminishes very rapidly in the blood as the tissues become impregnated and the product flows to the receptor sites; the effect peak after approximately 15min and decrease over a period of 4hrs.

Indication
Serious arrhythmias when treatment via oral route is not appropriate eg, atrial arrhythmia, with rapid ventricular rhythm; Wolf-Parkinson-White syndrome tachycardia; documented symptomatic and incapacitating ventricular arrhythmia. Cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.

Recommended dose

Method of Administration
Due to the formulation of the product, do not use concentrations of less than 2 ampoules in 500 ml. Use only isotonic glucose solution. Do not add any other products to the infusion vehicle.

Amiodarone must be administered via the central venous route except for cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock in which case, in the absence of a central venous route, the peripheral venous route may be used.

Serious arrhythmias when oral use is not suitable, except for cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock:

Infusion via the central venous route.
- Initial treatment: on average 5 mg/kg in glucose solution, preferably using an electric syringe, administered over 20 minutes to 2 hours, possibly repeated 2 or 3 times per 24- hour period. The short action of the medicinal product requires continuation of the infusion.
- Maintenance treatment: 10 to 20 mg/kg/day (on average 600 to 800 mg/24 h, up to 1.2 g/24 h) in 250 ml glucose solution, over a few days. Initiate replacement treatment by the oral route (3 tablets per day), starting from the first day of infusion. This dosage may be increased to 4 or even 5 tablets per day.

Cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock. As regards the administration route and in view of the situation in which this indication applies, the use of a central venous catheter is recommended if immediately available; otherwise, the medicinal product may be administered via the peripheral venous route using the largest peripheral vein with the highest flow possible.
- The initial intravenous dose is 300 mg (or 5 mg/kg) diluted in 20 ml of 5% glucose solution and rapidly injected.
- Additional intravenous administration of 150 mg (or 2.5 mg/kg) may be considered if ventricular fibrillation persists.
- Do not add any other products to the syringe.

Pediatric population
The safety and efficacy of amiodarone in children have not been established.

As this medicinal product contain benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

"Mydron Amiodarone Hydrochloride injection 50mg/ml is available in injection solution only and not able to deliver all approved dose regimens of Amiodarone Hydrochloride, other approved dosage forms and strengths of Amiodarone Hydrochloride should be used in such cases"

Mode of administration
Intravenous Administration

Contraindication
This medicinal products is contraindicated in the following cases:-
- Sinus bradycardia and sinoatrial block in patients without a pacemaker;
- Sick sinus syndrome in patients without a pacemaker (risk of sinus arrest);
- High-degree atrioventricular conduction disorders in patients without a pacemaker;
- Hyperthyroidism because of possible exacerbation by amiodarone
- Known hypersensitivity to iodine or amiodarone
- Circulatory collapse
- Severe hypotension
- In children aged under 2 years due to presence of benzyl alcohol;
- 2nd and 3rd trimesters of pregnancy
- Breast-feeding women;

Combination with medicinal products that may induce torsades de pointes:
- Class Ia antiarrhythmics (quinidine, hydroquinidine, disopyramide),
- Class III antiarrhythmics (sotalol, dofetilide, ibutilide)
- Other medicinal products such as: arsenic compounds, bepridil, cisapride, diphemanil, dolasetron IV, erythromycin IV, mizolastine, vincamine IV, moxifloxacin, spiramycin IV, toremifene *(see Interaction with other medicinal products and other forms of interaction),*

These contraindications do not apply to the use of amiodarone for cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.

As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

Warning and precautions

This product is to be used only by a registered medical practitioner with experience in cardiology.

Transplantation
In retrospective studies, amiodarone use in the transplant recipient prior to heart transplant has been associated with an increased risk of primary graft dysfunction (PGD).

PGD is a life-threatening complication of heart transplantation that presents as left, right or biventricular dysfunction occurring within the first 24 hours of transplant surgery for which there is no identifiable secondary cause (see section Adverse Effects). Severe PGD may be irreversible.

For patients who are on the heart transplant waiting list, consideration should be given to use an alternative antiarrhythmic drug as early as possible before transplant.

Related to the route of administration
Infusion via the central venous route: Serious arrhythmias when treatment via the oral route is not appropriate, except for cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.

Injectable amiodarone must be administered via the central venous route, as administration via the peripheral venous route can cause local effects, such as superficial phlebitis. Injectable amiodarone must be used exclusively as an infusion. Even a very slow direct intravenous injection may exacerbate hypotension, heart failure or severe respiratory failure *(see Undesirable effects).*

Cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock
- Administration via the peripheral venous route is generally not recommended due to the hemodynamic risks (severe hypotension, circulatory collapse); infusion via the central venous route must be used whenever possible.
- The use of a central venous catheter is recommended if immediately available; otherwise, the medicinal product may be administered via the peripheral venous route using the largest peripheral vein with the highest flow possible.
- Supervision in an intensive care unit with continuous monitoring of blood pressure and ECG must be implemented as soon as possible.
- Do not add any other products to the syringe.
- If treatment with amiodarone needs to be continued, it should be administered as an infusion and via the central venous route, with continuous monitoring of blood pressure and ECG.

Related to amiodarone
Use of amiodarone is not recommended with ciclosporin, diltiazem (for injection) and verapamil (for injection), certain antiparasitics (halofantrine, lumefantrine and pentamidine), certain neuroleptics (amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol) and methadone *(see Interaction with other medicinal products and other forms of interaction).*

Cardiac effects
- The onset of a new arrhythmia or the worsening of pre-existing and treated arrhythmia has been reported (see Undesirable effects).
- The arrhythmogenic effect of amiodarone is weak, or even lower than that of most antiarrhythmic drugs, and generally occurs with certain drug combinations *(see Interaction with other medicinal products and other forms of interaction)* or electrolyte balance disturbances.

Pulmonary signs
A few cases of interstitial pneumopathy have been reported with injectable amiodarone. The onset of dyspnea or a dry cough, alone or associated with a deterioration in the general condition, should suggest the possibility of pulmonary toxicity, such as interstitial pneumopathy, and requires radiological assessment *(See Undesirable effects).*

Furthermore, some cases of acute respiratory distress syndrome have been observed in patients treated with amiodarone in the period immediately after surgery. It is therefore recommended that these patients be closely monitored during artificial ventilation.

Hepatic signs
Severe hepatocellular failure, sometimes fatal, can develop within 24 hours following the start of injectable amiodarone treatment. Monitoring of liver function is recommended at the start of treatment, then regularly throughout treatment with amiodarone *(See Undesirable effects).*

Precautions for use
- Electrolyte disturbances, particularly hypokalemia: it is important to take into account situations liable to be associated with hypokalemia, which may favor the onset of proarrhythmic effects. Hypokalemia should be corrected before amiodarone is administered.
- Apart from in emergency situations, injectable amiodarone should only be administered in a specialized hospital setting and under continuous monitoring (ECG, BP).

Anesthesia
The anaesthesiologist should be informed that the patient is being treated with amiodarone before surgery.

Chronic amiodarone treatment is liable to add to the hemodynamic risk associated with general or local anesthesia, in terms of undesirable effects. Undesirable effects include in particular bradycardia, hypotension, reduced cardiac output and conduction disturbances.

Combination *(see Interaction with other medicinal products and other forms of interaction)* with beta-blockers other than sotalol (contraindicated combination) and esmolol (combination requiring precautions for use), with verapamil and diltiazem should only be considered in the prevention of life-threatening ventricular arrhythmias and for cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.

Interactions with other medicaments

Antiarrhythmic agents
Many antiarrhythmics depress cardiac automatism, conduction and contractility.

Concomitant use of antiarrhythmics of different classes can yield a positive therapeutic effect, but is most often a very delicate process requiring close clinical and ECG monitoring. Concomitant use of antiarrhythmics that may induce torsades de pointes (amiodarone, disopyramide, quinidine compounds, sotalol, etc.) is contraindicated.

Concomitant use of antiarrhythmics of the same class is not recommended except in exceptional cases, due to the increased risk of cardiac adverse effects.

Concomitant use with medicinal products that have negative inotropic properties, that are bradycardic and/or that slow atrioventricular conduction is a delicate process requiring clinical and ECG monitoring.

Medicinal products that may induce torsades de pointes
This serious arrhythmia can be induced by a certain number of medicinal products, whether antiarrhythmics or not. Hypokalemia (see "Potassium-lowering agents") is a predisposing factor, as is bradycardia (see "Bradycardic agents") or a congenital or acquired pre-existing prolongation in QT interval.

The medicinal products that may cause torsades de pointes are, in particular, class Ia and III antiarrhythmics and certain neuroleptics.

For erythromycin, spiramycin and vincamine, only the dosage forms administered via the IV route are involved in this interaction.

Use of a torsadogenic agent with another torsadogenic agent is generally contraindicated. However, methadone, as well as certain subgroups, is the exception to this rule:
- antiparasitics (halofantrine, lumefantrine, pentamidine) are only inadvisable with other torsadogenic agents;
- Neuroleptics that may induce torsades de pointes are also inadvisable, and not contraindicated, with other torsadogenic agents.

Bradycardiac agents
Many medicinal products can cause bradycardia. This is the case particularly with class Ia antiarrhythmic drugs, beta blockers, some class III antiarrhythmic drugs, some calcium channel blockers, digitalis drugs, pilocarpine and anticholinesterase agents.

Contraindicated combinations
Medicinal products that may induce torsades de pointes (except for antiparasitics, neuroleptics and methadone; see "Inadvisable combinations"):
- class Ia antiarrhythmics (quinidine, hydroquinidine, disopyramide),
- class III antiarrhythmics (dofetilide, ibutilide, sotalol),
- other medicinal products such as: arsenic compounds, bepridil, cisapride, diphemanil, dolasetron IV, erythromycin IV, mizolastine, vincamine IV, moxifloxacin, spiramycin IV, toremifene.

Increased risk of ventricular arrhythmias, particularly torsades de pointes.

Inadvisable combinations

Ciclosporin
Increase in serum ciclosporin concentrations due to reduced metabolism by the liver, with the risk of nephrotoxic effects.

Assay of serum ciclosporin concentrations, monitoring of renal function and adjustment of the ciclosporin dose during treatment with amiodarone.

Injectable diltiazem
Risk of bradycardia and atrioventricular block.

If this combination cannot be avoided, close clinical supervision and continuous ECG monitoring are essential.

480 mm

240 mm

Injectable verapamil
Risk of bradycardia and atrioventricular block.

If this combination cannot be avoided, close clinical supervision and continuous ECG monitoring are essential.

Antiparasitics that may induce torsades de pointes (halofantrine, lumefantrine, pentamidine)
Increased risk of ventricular arrhythmia, particularly torsades de pointes.

If possible, discontinue 1 of the 2 treatments. If this combination cannot be avoided, prior evaluation of the QT interval and ECG monitoring are essential.

Neuroleptics that may induce torsades de pointes (amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol).
Increased risk of ventricular arrhythmia, particularly torsades de pointes.

Methadone
Increased risk of ventricular arrhythmia, particularly torsades de pointes.

Combinations requiring precautions for use

Oral anticoagulants
Increase in the anticoagulant effect and in the risk of bleeding.

More frequent control of INR. Possible dose adjustment of the oral anticoagulant during treatment with amiodarone and 8 days after treatment discontinuation.

Beta-blockers other than sotalol (contraindicated combination) and esmolol (combination requiring precautions for use)
Automaticity and conduction disorders (suppressed compensatory sympathetic mechanisms). ECG and clinical monitoring.

Beta-blockers in heart failure (bisoprolol, carvedilol, metoprolol, nebivolol)
Automaticity and cardiac conduction disorders with risk of excessive bradycardia. Increased risk of ventricular arrhythmia, particularly torsades de pointes.

Clinical and regular ECG monitoring.

Dabigatran
Increased serum dabigatran concentrations with an increased risk of bleeding.

Clinical monitoring and adjustment of the dabigatran dose if necessary, without exceeding 150 mg/day.

Digitalis drugs
Depressed automaticity (excessive bradycardia) and atrioventricular conduction disorders. If digoxin is used, increase in blood digoxin levels due to reduced digoxin clearance.

ECG and clinical monitoring, and, if necessary, assay of blood digoxin levels and digoxin dose adjustment.

Oral diltiazem
Risk of bradycardia or atrioventricular block, particularly in elderly subjects. ECG and clinical monitoring.

Certain macrolides (azithromycin, clarithromycin, roxithromycin) Increased risk of ventricular arrhythmia, particularly torsades de pointes. ECG and clinical monitoring during co-administration.

Oral verapamil
Risk of bradycardia and atrioventricular block, particularly in elderly subjects. ECG and clinical monitoring.

Esmolol
Contractility, automaticity and conduction disorders (suppressed compensatory sympathetic mechanisms). ECG and clinical monitoring.

Potassium-lowering agents: potassium-lowering diuretics (alone or in combination), stimulant laxatives, amphotericin B (IV route), glucocorticoids (systemic route), tetracosactide
Increased risk of ventricular arrhythmia, particularly torsades de pointes (hypokalemia is a predisposing factor).

Hypokalemia should be corrected before the medicinal product is administered and ECG, electrolyte and clinical monitoring performed.

Lidocaine
Risk of increased serum lidocaine concentrations, with the possibility of neurological and cardiac adverse effects, due to a reduction in its hepatic metabolism by amiodarone.

Clinical and ECG monitoring and, if necessary, assay of serum lidocaine concentrations. If necessary, adjustment of lidocaine dosage during treatment with amiodarone and after its discontinuation.

Orlistat
Risk of a reduction in serum amiodarone concentrations and of its active metabolite. Clinical monitoring and, if necessary, ECG monitoring.

Phenytoin (by extrapolation fosphenytoin)
Increase in phenytoin serum concentrations with signs of overdose, particularly neurological signs (reduced metabolism of phenytoin by the liver).

Clinical monitoring, assay of phenytoin serum concentrations and possible dose adjustment.

Simvastatin
Increased risk of adverse effects (concentration-dependent), such as rhabdomyolysis (reduced hepatic metabolism of the cholesterol-lowering drug).

The dose of 20 mg of simvastatin per day should not be exceeded.

If the therapeutic goal is not achieved at this dosage, use another statin not concerned by this type of interaction.

Tacrolimus
Increased blood tacrolimus concentrations due to inhibition of its metabolism by amiodarone. Assay of blood tacrolimus concentrations, monitoring of kidney function and tacrolimus dose adjustment during co- administration and on discontinuation of amiodarone.

Bradycardic agents
Increased risk of ventricular arrhythmia, particularly torsades de pointes. Clinical and ECG monitoring.

Combination to be taken into account

Pilocarpine
Risk of excessive bradycardia (additive effects of bradycardic agents).

Pregnancy and lactation

Pregnancy
In the absence of a teratogenic effect in animals, no teratogenic effects are expected in humans and there are not yet enough relevant data in order to evaluate the possible teratogenic effect of amiodarone when administered during the first trimester of pregnancy.

Since the foetal thyroid gland begins to bind iodine from week 14 of amenorrhoea, no effect on the foetal thyroid gland are expected in the event of previous administration.

Iodine overload with the use of this product beyond this period may give rise to biological or clinical (goitre) foetal hypothyroidism.

Consequently, the use of this medicinal product is contraindicated from the 2nd trimester of pregnancy.

Lactation
Amiodarone and its metabolite, together with iodine, pass into breast milk at concentrations greater than those in maternal plasma. Due to the risk of hypothyroidism in the newborn infant, breast- feeding is contraindicated in the event of treatment with this medicinal product.

Side effects
The undesirable effects have been classified by system-organ and by incidence as follows:

Cardiac disorders:

Common: Bradycardia.

Very rare: Marked bradycardia and, more exceptionally, sinus arrest, reported in certain cases, particular in elderly patients; Proarrhythmic effect.

Gastrointestinal disorders:
Very common: Nausea.

Systemic disorders and administration site abnormalities:
Common: Possible inflammatory reaction, such as superficial phlebitis when administered via the direct peripheral venous route, reactions at the injection site, such as pain, erythema, edema, necrosis, extravasation, infiltration, inflammation, phlebitis and cellulitis.

Hepatobiliary disorders:
Cases of liver damage have been reported based on elevated serum transaminases.

Very rare: Generally moderate and isolated elevation in transaminases regressing after dosage reduction, or even spontaneously; Acute liver damage with elevation in blood transaminases and/or jaundice, sometimes with a fatal outcome, requiring treatment discontinuation. Chronic liver damage during long-term treatment (via the oral route). The histology corresponds to pseudoalcoholic hepatitis. As clinical and laboratory signs are not explicit (variable hepatomegaly, elevation in blood transaminases between 1.5 and 5 times normal), regular monitoring of liver function is justified. Chronic hepatic damage should be suspected in case of elevation, even moderate, in blood transaminases occurring after treatment lasting more than 6 months. The clinical and laboratory abnormalities usually regress after treatment discontinuation. A few irreversible cases have been reported.

Immune system disorders:
Very rare: Anaphylactic shock.

Cases of angioedema have been reported.

Endocrine disorders:
Thyroid effects.

Very common: Unless there are clinical signs of thyroid dysfunction, "unrelated" blood thyroid hormone changes (increased T4, normal or slightly reduced T3) do not warrant treatment discontinuation.

Common: Hypothyroidism causes usual symptoms: weight gain, cold intolerance, apathy, drowsiness. A marked increase in TSH levels confirms the diagnosis. Euthyroidism is usually obtained gradually within 1 to 3 months of stopping treatment. Treatment discontinuation is not essential: if justified by the indication, treatment with amiodarone can be continued in combination with thyroid hormone replacement therapy using levothyroxine. Levothyroxine doses can be adjusted according to TSH levels.

Hyperthyroidism is more difficult to identify: symptoms are fewer (slight, unexplained weight loss, reduced efficacy of anti-angina and/or antiarrhythmic therapy); psychiatric symptoms in elderly patients, even thyrotoxicosis.

A marked drop in ultrasensitive TSH levels confirms the diagnosis. It is essential to discontinue amiodarone treatment, which is usually sufficient to trigger clinical recovery within 3 to 4 weeks. As serious cases can be fatal, urgent appropriate treatment should be instituted.

When thyrotoxicosis is a cause for concern, either directly or due to its effects on the fragile myocardial balance, the variable efficacy of synthetic antithyroid drugs makes it necessary to recommend high-dose corticosteroids (1 mg/kg) over a sufficiently long period (3 months). Cases of hyperthyroidism have been reported up to several months following amiodarone discontinuation.

Nervous system disorders:
Very rare: Benign intracranial hypertension (pseudotumor cerebri).

Respiratory, thoracic and mediastinal disorders:
Very rare: Acute respiratory distress syndrome, generally associated with an interstitial pneumopathy, occasionally with a fatal outcome, have been observed, sometimes in the period immediately after surgery (a possible interaction with high doses of oxygen has been suggested). Discontinuation of amiodarone should be considered and the value of corticosteroid treatment taken into consideration (see Special warnings and precautions for use). Bronchospasm and/or apnea in cases of severe respiratory failure, particularly in asthmatic patients.

Skin and subcutaneous tissue disorders:
Very rare: Sweating, hair loss.

Vascular disorders:
Common: Generally moderate and transient fall in blood pressure. Cases of severe hypotension or circulatory collapse have been reported, particularly after overdose or excessively rapid administration.

Very rare: Hot flushes.

Injury, poisoning and procedural complications
Frequency 'not known': Potentially fatal primary graft dysfunction post cardiac transplant (See section Warnings and Precautions)

Symptoms and Treatment of Overdose
No information regarding amiodarone overdose via the IV route is available.

A few cases of sinus bradycardia, ventricular rhythm disorders, particularly torsades de pointes, and hepatic impartment have been reported. Treatment must be symptomatic. Given the kinetic profile of the substance, cardiac monitoring, in particular, over a sufficiently long period of time, is recommended. Amiodarone and its metabolites are not dialyzable.

Incompatibilities
The use of PVC material or medical devices plasticized with DEHP di(2-ethylhexyl) phthalate can result in the release of DEHP in contact with amiodarone solution for injection. To minimize the patient's exposure to DEHP, it is recommended that the final amiodarone dilution be prepared prior to infusion using equipment that does not contain any DEHP, such as equipment made of DEHP-free PVC, polyolefins (polyethylene, polypropylene) or glass.

Storage condition
Storage condition for unopened vial: Store below 30°C. Store in the original package in order to protect from light.

Shelf Life
The shelf-life of unopened vials is 24 months.

Shelf life after dilution according to directions:

Amiodarone Hydrochloride Solution Stability	Concentration (mg/mL)	Container	Comments
5% Dextrose in Water (D W)	1 and 6	PVC	Physically compatible, with amiodarone at 2 hours at 20-25°C
5% Dextrose in Water (D W)	1 and 6	Polyolefin, Glass	Physically compatible, with amiodarone at 24 hours at 20-25°C.

From a microbiological point of view, the product should be used immediately.

Shelf life after first opening the container: Unused portion after first opening is to be discarded immediately.

Presentation
MYDRON Amiodarone Hydrochloride Injection is a sterile solution for injection containing 50 mg/mL of Amiodarone Hydrochloride. The product is filled as 150 mg in 5 mL USP Type I amber glass vial with 20mm neck diameter, stoppered with 20 mm grey bromobutyl rubber stoppers and sealed with 20 mm aluminium flip off seals with red colour button.

10 X 5.0 mL colourless glass vial packed in unit carton (without diluent) along with a package insert.

Manufactured by:
GLAND PHARMA LIMITED
Sy. No. 143-148, 150 & 151,
Near Gandimaisamma Cross Roads,
D.P. Pally, Dundigal Post,
Dundigal - Gandimaisamma Mandal,
Medchal – Malkajgiri District,
Hyderabad - 500043,
Telangana, India

Product Registration Holder & Imported by:
UNIMED SDN BHD
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200, Kuala Lumpur, Malaysia.

Revision date: 06/01/2026

1313XXXXXX-XX