6183

60 mm

37.5 mm

For the use of a Registered Medical Practitioner or Hospital or Laboratory Only

MYCLAV

(Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)

NAME AND STRENGTH OF ACTIVE INGREDIENT
Each 5 ml after reconstitution contains:
Amoxicillin Trihydrate USP
equivalent to Amoxicillin 200 mg
Potassium Clavulanate, diluted Ph. Eur.
equivalent to Clavulanic Acid 28.5 mg
DOSAGE FORM
Powder for oral suspension.
PRODUCT DESCRIPTION
White to off- white free flowing powder, which on reconstitution gives white to off-white coloured liquid suspension.
Flavour: Raspberry and Orange
CLINICAL PHARMACOLOGY
Pharmacodynamics
ATC Code
Anatomical Therapeutic Chemical (ATC) code: J01CR02.
Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors.
Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) anticipates this defence mechanism by blocking the beta-lactamase enzymes, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.
Clavulanate by itself has little antibacterial activity; however, in association with amoxicillin as MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) it produces an antibiotic agent of broad spectrum with wide application in hospital and general practice.
Pharmacodynamic Effects
In the list below, organisms are categorised according to their *in vitro* susceptibility to MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)

***In vitro* susceptibility of micro-organisms to** *Amoxicillin/ clavulanic acid*
Where clinical efficacy of MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) has been demonstrated in clinical trials this is indicated with an asterisk (*).
Organisms that do not produce beta-lactamase are identified (with †). If an isolate is susceptible to amoxicillin, it can be considered susceptible to MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)

Commonly susceptible species

Gram-positive aerobes:
Bacillius anthracis
Enterococcus faecalis
Listeria monocytogenes
Nocardia asteroides
*Streptococcus pyogenes**†
*Streptococcus agalactiae**†
Streptococcus spp. (other beta-hemolytic)*†
Staphylococcus aureus (methicillin susceptible)*
Staphylococcus saprophyticus (methicillin susceptible)
Coagulase negative *staphylococcus* (methicillin susceptible)

Gram-negative aerobes:
Bordetella pertussis
*Haemophilus influenzae**
Haemophilus parainfluenzae
Helicobacter pylori
*Moraxella catarrhalis**
Neisseria gonorrhoeae
Pasteurella Multocida
Vibrio cholerae

Other:
Borrelia burgdorferi
Leptospira ictterohaemorrhagiae
Treponema pallidum

Gram positive anaerobes:
Clostridium spp.
Peptococcus niger
Peptostreptococcus magnus
Peptostreptococcus micros
Peptostreptococcus spp.

Gram-negative anaerobes:
Bacteroides fragilis
Bacteroides spp.
Capnocytophaga spp.
Eikenella corrodens
Fusobacterium nucleatum
Fusobacterium spp.
Porphyromonas spp.
Prevotella spp.

Species for which acquired resistance may be a problem

Gram-negative aerobes:
*Escherichia coli**
Klebsiella oxytoca
*Klebsiella pneumoniae**
Klebsiella spp.
Proteus mirabilis
Proteus vulgaris
Proteus spp.
Salmonella spp.
Shigella spp.

Gram-positive aerobes:
Corynebacterium spp.
Enterococcus faecium
*Streptococcus pneumoniae**†
Viridans group *streptococcus*

Inherently resistant organisms

Gram-negative aerobes:
Acinetobacter spp.
Citrobacter freundii Enterobacter spp.
Hafnia alvei
Legionella pneumophila
Morganella morganii
Providencia spp.
Pseudomonas spp.
Serratia spp.
Stenotrophomas maltophilia
Yersinia enterolitica

Others:
Chlamydia pneumoniae
Chlamydia psittaci
Chlamydia spp.
Coxiella burnetti
Mycoplasma spp.

Infections caused by amoxicillin-susceptible organisms are amenable to MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) treatment due to its amoxicillin content. Mixed infections caused by amoxicillin susceptible organisms in conjunction with MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) -susceptible beta-lactamase producing organisms may therefore be treated with MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml).
Pharmacokinetics
Absorption
The two components of MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml), amoxicillin and clavulanate, are each fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) is optimized when taken at the start of a meal.
The mean AUC values for amoxicillin are essentially the same following twice a day dosing with the Amoxicillin /clavulanic acid 875/125 mg tablet or three times a day dosing with the Amoxicillin / clavulanic acid 500/125 mg tablet, in adults. No differences between the 875 mg twice daily and 500 mg three times daily dosing regimes are seen when comparing the amoxicillin $T_{1/2}$, or C_{max} after normalisation for the different doses of amoxicillin administered. Similarly, no differences are seen for the clavulanate $T_{1/2}$, C_{max} or AUC values after appropriate dose normalization.
The time of dosing of Amoxicillin /clavulanic acid relative to the start of a meal has no marked effects on the pharmacokinetics of amoxicillin in adults. In a study of the Amoxicillin /clavulanic acid 875/125 mg tablet, the time of dosing relative to ingestion of a meal had a marked effect on the pharmacokinetics of clavulanate. For clavulanate AUC and C_{max}, the highest mean values and smallest inter-subject variabilities were achieved by administering Amoxicillin /clavulanic acid at the start of a meal, compared to the fasting state or 30 or 150 minutes after the start of a meal.
The mean C_{max}, T_{max}, $T_{1/2}$ and AUC values for amoxicillin and clavulanate are given below for an 875 mg/125 mg dose of amoxicillin /clavulanic acid administered at the start of a meal.
Mean Pharmacokinetic Parameters

Drug Administration	Dose (mg)	C_{max} (mg/L)	T_{max}* (hours)	AUC (mg.h/L)	$T_{1/2}$ (hours)
Amoxicillin / Clavulanic acid 1g					
Amoxicillin	875	12.4	1.5	29.9	1.36
Clavulanate	125	3.3	1.3	6.88	0.92

*Median values
Amoxicillin serum concentrations achieved with Amoxicillin and clavulanic acid are similar to those produced by the oral administration of equivalent doses of amoxicillin alone.
Distribution
The pharmacokinetics of the two components of Amoxicillin and clavulanic acid are closely matched. Both clavulanate and amoxicillin have low levels of serum binding; about 70% remains free in the serum.
Doubling the dosage of Amoxicillin and clavulanic acid approximately doubles the serum levels achieved.
Non-Clinical Information
No further information of relevance.
THERAPEUTIC INDICATIONS
MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.
MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml), for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered.
- Upper respiratory tract infections (including ENT) e.g., recurrent tonsillitis, sinusitis, otitis media.
- Lower respiratory tract infections e.g., acute exacerbations of chronic bronchitis, lobar and bronchopneumonia.
- Urinary tract infections e.g., cystitis, urethritis, pyelonephritis
- Skin and soft tissue infections e.g. cellulitis, animal bites.
- Dental infections e.g., severe dental abscess with spreading cellulitis.

Susceptibility to MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) will vary with geography and time (see Pharmacological Properties, Pharmacodynamics for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.
Mixed infections caused by amoxicillin-susceptible organisms in conjunction with MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) susceptible beta-lactamase- producing organisms may be treated with MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml). These infections should not require the addition of another antibiotic resistant to beta-lactamases.
DOSAGE AND ADMINISTRATION
Dosage depends on the age, weight and renal function of the patient and the severity of the infection.
Dosages are expressed throughout in terms of amoxicillin/clavulanate content except when doses are stated in terms of an individual component.
To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of *MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)* is optimised when taken at the start of a meal.
Treatment should not exceed 14 days without review.
Therapy can be started parenterally and continued with an oral preparation.
Myclav Powder for Oral Suspension bottle presentations for suspension may be supplied with a plastic dosing device. For preparation of the suspensions see *Instructions for Use/Handling*.
The usual recommended daily dosage is:
- 25/3.6 mg/kg/day in two divided doses for mild to moderate infections (upper respiratory tract infections e.g. recurrent tonsillitis, lower respiratory infections and skin and soft tissue infections).
- 45/6.4 mg/kg/day in two divided doses for the treatment of more serious infections (upper respiratory tract

300 mm

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infections e.g. otitis media and sinusitis, lower respiratory tract infections e.g. bronchopneumonia and urinary tract infections).

No clinical data are available on doses above 45/6.4 mg/kg/day in children under 2 years.

There are no clinical data for MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) to make dosage recommendations for children under 2 months old. For Children aged 2 months to under 2 years, other alternative product with different strength may be used. The table below give dosage guidance for children.

Children over 2 years

25/3.6 mg/kg/day	2 - 6 years (13 - 21 kg)	5.0 ml *MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)* twice daily.
	7 - 12 years (22 - 40 kg)	10.0 ml *MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)* twice daily.
45/6.4 mg/kg/day	2 - 6 years (13 - 21 kg)	10.0 ml *MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)* twice daily.

Renal Impairment

No adjustment in dose is required in patients with creatinine clearance greater than 30 mL/min. MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)are not recommended in patients with a creatinine clearance of less than 30 mL/min.

Hepatic Impairment

Dose with caution; monitor hepatic function at regular intervals. There are insufficient data on which to base a dosage recommendation.

MODE OF ADMINISTRATION

Oral

CONTRAINDICATIONS

- in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins.
- in patients with a previous history of *amoxicillin/clavulanic acid* associated jaundice/hepatic dysfunction.

WARNINGS AND PRECAUTIONS

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml), careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) must be discontinued immediately and appropriate alternative therapy instituted.

These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity (see Contraindications). Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction.

Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) (see Adverse Reactions).

Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous (i.v.) steroids and airway management (including intubation) may also be required.

MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately, and the patient investigated further.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving Amoxicillin and Clavulanic Acid and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Changes in liver function tests have been observed in some patients receiving Amoxicillin and Clavulanic Acid. The clinical significance of these changes is uncertain but MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) should be used with caution in patients with evidence of hepatic dysfunction.

Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.

In patients with renal impairment MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) are not recommended.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria (see Overdose).

MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)contains 2.5 mg of aspartame (E951) per ml, a source of phenylalanine. This medicine should be used with caution in patients with phenylketonurics. Warning – Unsuitable for phenyl ketonurics.

Not to be used in patients with known hypersensitivity to Penicillin.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Adverse effects on the ability to drive or operate machinery have not been observed.

ADVERSE REACTIONS

Data from large clinical trials were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e., those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

The following convention has been used for the classification of frequency:

very common ≥1/10
common ≥1/100 to <1/10
uncommon ≥1/1000 to <1/100
rare ≥1/10,000 to <1/1000
very rare <1/10,000.

Infections and infestations

Common Mucocutaneous candidiasis

Blood and lymphatic system disorders

Rare Reversible leucopenia (including neutropenia) and thrombocytopenia
Very rare Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding time and prothrombin time

Immune system disorders

Very rare Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis

Nervous system disorders

Uncommon Dizziness, headache
Very rare Reversible hyperactivity, aseptic meningitis, convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Cardiac disorders

Very rare Kounis syndrome (see *Warnings and Precautions*).

Gastrointestinal disorders

Adults

Very common Diarrhoea
Common Nausea, vomiting

Children

Common Diarrhoea, nausea, vomiting

All populations

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) at the start of a meal.

Uncommon Indigestion
Very rare Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis – see *Warnings and Precautions*)
Black hairy tongue
Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

Hepatobiliary disorders

Uncommon A moderate rise in AST and/or ALT has been noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown.
Very Rare Hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children.

Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

Skin and subcutaneous tissue disorders

Uncommon Skin rash, pruritus, urticaria
Rare Erythema multiforme
Very rare Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS)

If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.

Renal and urinary disorders

Very rare Interstitial nephritis, crystalluria *(see Overdose)*

DRUG INTERACTIONS

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) and allopurinol.

In common with other antibiotics, MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)

In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure.

USE IN SPECIAL POPULATION

Pregnancy

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered Amoxicillin and Clavulanic Acid have shown no teratogenic effects. In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with Amoxicillin and Clavulanic Acid may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Lactation

Amoxicillin and Clavulanic Acid may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.

OVERDOSAGE

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically with attention to the water electrolyte balance.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see Warnings and Precautions).

MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml) can be removed from the circulation by haemodialysis.

STORAGE

The dry powder should be stored in unopened containers in a dry place at below 30°C. Reconstituted suspension should be stored in a refrigerator (2-8°C) but do not freeze and should be used within 7 days.

PRESENTATION

MYCLAV (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml)

A clear glass 125 ml bottle without circular ring mark. The dilution mark for 70 ml oral suspension is shown on the label affixed to the bottle. This glass bottle & a leaflet is packed in a carton.

Instructions for Use

Tap bottle gently until all the powder flows freely. Add water up to 70 ml dilution mark which is shown on the label affixed to the Bottle. Replace the cap and shake the bottle until all the powder is suspended. Add more water until the level of the fill lines is attained and shake again. When first reconstituted, allow to stand for 5 minutes to ensure full dispersion.

Myclav (Amoxicillin and Clavulanic acid Powder for Oral Suspension USP 228.5mg/5ml):

MAL No. MAL24086015AZ

PRODUCT REGISTRATION HOLDER
HEALOL PHARMACEUTICALS SDN BHD
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumpur,
Malaysia.

Manufactured in India by:
UNICHEM LABORATORIES LTD.
Village Bhatauli Kalan, Baddi, Dist. Solan (H.P.) - 173 205.

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Date of Package insert revision:
January, 2025

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Page 2. Back Side

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 17/01/2025
Agency Name: UNICORN CREATION		**Open Size:** 300 x 240 mm (Open)
Product: Myclav POS 228.5mg/5ml Leaflet		**Pre-folded size :** 37.5 x 60 mm (L x W)
Item Code: 13006970	**Location:** Baddi I	**Market:** Malaysia (The text is market specific)
Specification: 40 gsm Bible Paper (Front Back Printing)		**Pharmacode :** 6183
Colour Code: Text in Black		

Reason: Prescribing leaflet artwork for 156.25 mg, Malaysia developed based on the word text file received vide e-mail dt. 24.12.2018 for 156.25 from our RA. 10.01.19, Brand name Generic name text & Heading of preservative, modified as per changes received from Healol through mail from RA. 25.01.2019 : Modifications to be done as per customer's requirement based on inputs received vide email dt. 25.01.2019 from our RA. 29.01.2019 : 'Serous and occasionally……therapy instituted' retained in the text under Warnings & Precautions- Reference : Email dt. 28.01.2019 from our RA. 19.06.19, text modified under headings DOSAGE AND ADMINISTRATION & WARNINGS AND PRECAUTIONS To the right of existing text ,add 24.07.2019 : Modifications done to develop a combined leaflet of 156.25 & 228.5 strengths, Ref. : Email dt. 23.07.2019 from Regulatory. 01.08.2019 : Modification done as per the review file comment shared on 01.08.2019 by RA. 02.08.19 Text modified as per comment received from Healol RA , 16.05.2023 Correction made as per input received from Healol Malaysia.
06.06.2023 Correction made it inline with Innovator PI as per NPRA Malaysia. 07.06.2023 – Correction made as per requirement of Medical Dept. 13.06.2023 – Correction made as per requirement of NPRA Malaysia. 16.06.2023 – Correction made as per requirement of NPRA Malaysia. 16.06.2023 – PI revised as per Malyasian innovator pack. 19.12.2023- correction updated as per RA comment &
Size changed from 240 x 180 mm to 300 x 240 mm. 06.02.2024 - Correction updated as per RA mail.
08.02.2024 - Correction updated as per RA mail 08/02/2024. 05.04.2024 - Correction updated as per RA mail 04/04/2024.
21.05.2024 - Correction updated as per RA mail dated 17/05/2024 and 20/05/2024.
13.01.2025 - MAL No. & Pharmacode Added.