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1. PRODUCT NAME

Miro-Amoxicillin Capsules 250 mg.

Miro-Amoxicillin Capsules 500 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Filled capsule contains Amoxicillin Trihydrate BP/EP equivalent to Amoxicillin 250 mg.
Each Filled capsule contains Amoxicillin Trihydrate BP/EP equivalent to Amoxicillin 500 mg.

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Capsules:

Amoxicillin 250 mg Capsules : Red / Buff coloured size '2' capsules containing white to off white powder printed with 'AMOXY 250' in black ink.

Amoxicillin 500 mg Capsules : Red / Buff Coloured size '0' Capsules containing white to off white powder printed with 'AMOXY 500 ' in black ink.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Amoxicillin is indicated for the treatment of the following infections due to susceptible strains of sensitive organisms:

Upper Respiratory Infections: Otitis media, pharyngitis, sinusitis and tonsillitis.

Lower Respiratory Infections: Bronchitis, bronchopneumonia and lobar pneumonia.

Urinary Tract Infections: Cystitis, cysto-pyelitis, urethritis, and gonococcal urethritis.

Prophylaxis: against β-haemolytic (viridans group) and β-haemolytic Streptococci before dental, oral or upper respiratory tract surgery or instrumentation.

Prophylaxis: of bacterial endocarditis in patients with any of the following conditions:
congenital cardiac malformations, rheumatic and other acquired valvular lesions, prosthetic heart valves, previous history of bacterial endocarditis, hypertrophic cardiomyopathy, surgically constructed systemic-pulmonary shunts, mitral valve prolapse with valvular regurgitation or mitral valve prolapse without valvular regurgitation but associated with thickening and/or redundancy of the valve leaflets.

Amoxicillin is further indicated for the treatment of cutaneous infections.

In emergency cases where the causative organism is not yet identified, therapy may be initiated with amoxicillin on the basis of clinical judgement, while awaiting the results of bacteriologic studies to determine its antimicrobial sensitivity.

4.2 Dose and method of administration

Normal Renal Function

Upper respiratory tract infections; genito-urinary tract infections; skin and soft tissue infections.

Adults – 250mg every eight hours.
Children (under 20 kg) – 20mg/kg/day in equally divided doses every eight hours.

In severe infections or those caused by less susceptible organisms, 500 mg every eight hours for adults and 40mg/kg/day in equally divided doses every eight hours for children may be needed.

Lower respiratory tract infections.
Adults – 500mg every eight hours.
Children (under 20 kg) – 40mg/kg/day in equally divided doses every eight hours.

Urethritis, gonococcal.
Adults - 3g as single dose. Cases of gonorrhoea with a suspected lesion of syphilis should have darkfield examinations before receiving **Miro-Amoxicillin** and monthly serological tests for a minimum of four months.

Acute, uncomplicated lower urinary tract infections in non-pregnant adult female.
Adults - 3g as single dose.
Note: Experience in neonates is too limited to make any recommendations regarding dosage or the appropriateness of the oral route.

The children's dosage is intended for individuals whose weight will not cause dosage to be calculated greater than that recommended for adults. Children weighing more than 20 kg should be dosed according to the adult recommendations.

Renal impairment
In renal impairment the excretion of the antibiotic will be delayed, and depending on the degree of impairment, it may be necessary to reduce the total daily dosage.

In patients receiving peritoneal dialysis, the maximum recommended dose is 500mg/day. Amoxicillin may be removed from the circulation by haemodialysis.

It should be recognised that in the treatment of chronic urinary tract infections, frequent bacteriological and clinical appraisals are necessary. Smaller doses than those recommended above should not be used. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least ten days treatment for any infection caused by haemolytic streptococci to prevent the occurrence of acute rheumatic fever or glomerulonephritis.

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Prophylaxis of endocarditis

Based on the recommendations of the British Society for Antimicrobial Chemotherapy

Condition		Adults' Dosage (including elderly)	Children' sDosage	Notes
Dental Procedures: Prophylaxis for patients undergoing extraction, scaling or surgery involving gingival tissues, and who have not received a penicillin in the previous month. (*N.B.* Patients with prosthetic heart valves should be referred to hospital- see below).	Patient not having general anaesthetic.	3g Amoxicillin orally, 1 hour before procedure. A second dose may be given 6 hours later, if considered necessary.	Under 10 years: Half adult dose. Under 5 years: Quarter adult dose.	*Note 1*: Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin. *Note 2*: To minimize pain on injection, Amoxicillin should be dissolved in sterile lignocaine 1% solution. (See section 4.2 DOSE AND METHOD OF ADMINISTRATION)
	Patient having general anaesthetic: oral antibiotics not appropriate.	1g Amoxicillin IM immediately before induction; with 500mg orally, 6 hours later.	Under 10 years: Half adult dose.	
Dental Procedures: Patients for whom referralto hospital is recommended: a) patients to be given a general anaesthetic who have been given a penicillin in the previous month. b) patients to be given a general anaesthetic who have a prosthetic heart valve. c) patients who have had one or more attacks of endocarditis.		Initially: 1g Amoxicillin IM with 120mg gentamicin IM, immediately prior to anaesthesia (if given) or 15 minutes prior to dental procedure. Followed by (6 hours later): 500mg Amoxicillin orally.	Under 10 years: The doses of Amoxicillin should be half the adult dose, the dose of gentamicin should be 2mg/kg.	See Note 2. *Note 3*: Amoxicillin and gentamicin should not be mixed in the same syringe. *Note 4*: Please consult the appropriate data sheet for full prescribing information on gentamicin.

Genito-urinary Surgery or Instrumentation: Prophylaxis for patients who have no urinary tract infection and who are to have genito-urinary surgery or instrumentation under general anaesthesia. *Obstetric and Gynaecological Procedures and Gastro-intestinal Procedures:* Routine prophylaxis is recommended only for patients with prosthetic heart valves.		Initially: 1g Amoxicillin IM with 120mg gentamicin IM, immediately beforeinduction. Followed by (6 hours later): 500mg Amoxicillin orally or IM according to clinical condition.	Under 10 years: The doses of Amoxicillin should be half the adult dose; the dose of gentamicin should be 2mg/kg.	See Notes 2, 3 and 4 above.
Surgery or Instrumentation of the Upper Respiratory Tract	Patients other than those with prosthetic heart valves.	1g Amoxicillin IM immediately before induction. Followed by (6 hours later): 500mg Amoxicillin IM.	Under 10 years: Half adult dose.	See Note 2 above. *Note 5*: The second dose of Amoxicillin may be administered orally as Amoxicillin Syrup.
	Patients with prosthetic heart valves.	Initially: 1g Amoxicillin IM with 120mg gentamicin IM, immediately before induction. Followed by (6 hours later): 500mg Amoxicillin IM.	Under 10 years: The dose of Amoxicillin should be half the adult dose; the gentamicin dose should be 2mg/kg.	See Notes 2, 3, 4 and 5 above.

4.3 Contraindications

Amoxicillin is a penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (eg. penicillins, cephalosporins).

4.4 Special warnings and precautions for use

Serious, and occasionally fatal, hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral therapy. Before commencing therapy with any penicillin careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, appropriate therapy should be instituted and amoxicillin therapy discontinued.

Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, should also be administered as indicated.

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including amoxicillin. A toxin produced with *Clostridium difficile* appears to be the primary cause. The severity of the colitis may range from mild to life threatening. *Clostridium difficile* associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further. Mild cases usually respond to drug discontinuation alone. However in moderate to severe cases appropriate therapy with a suitable oral antibiotic agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated. Drugs which delay peristalsis, eg. opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition and should not be used.

Adequate fluid intake and urinary output must be maintained in patients receiving high doses of amoxicillin.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin 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.

Amoxicillin 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 occasionally result in overgrowth of non-susceptible organisms.

As with any potent drug, periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Aerobacter, Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.

Amoxicillin, an aminopenicillin, is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxicillin is used.

Amoxicillin should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to ampicillin-induced skin rashes.
Following single dose therapy of acute lower urinary tract infections, the urine should be cultured. A positive culture may be evidence of a complicated or upper urinary tract infection and call for longer or larger course of therapy.

Adequate fluid intake and urinary output must be maintained in patients receiving high doses of amoxicillin.

Use in Renal Impairment

Dosage should be adjusted in patients with renal impairment (see section 4.2 Dose and method of administration).

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

Oral administration of amoxicillin will result in high urine concentrations of amoxicillin. Since high urine concentrations of amoxicillin may result in false positive reactions when testing for the presence of glucose in urine using Clinitest, Benedict's Solution or Fehling's Solution, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix, or Testape) be used.

Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated oestriol, oestriol-glucuronide, conjugated oestrone and oestradiol has been noted. This effect may also occur with amoxicillin.

4.5 Interactions with other medicines and other forms of interactions

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with amoxicillin may result in increased and prolonged blood levels of amoxicillin.

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients. Similar reactions can be expected with amoxicillin.

In common with other antibiotics, amoxicillin 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 amoxicillin.

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin.

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4.6 Fertility, pregnancy and lactation

Effects on Fertility

No data available

Use in Pregnancy-Pregnancy Category A

Animal studies with amoxicillin have shown no teratogenic effects. The product has been in extensive clinical use since 1972 and its suitability in human pregnancy has been well documented in clinical studies.

Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Use in Labour and Delivery: Oral ampicillin class antibiotics are generally poorly absorbed during labour. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions and duration of contractions. However, it is not known whether the use of amoxicillin in humans during labour or delivery has immediate or delayed adverse effects on the foetus, prolongs the duration of labour or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Use in Lactation

Ampicillin class antibiotics are excreted in the milk; therefore, caution should be exercised when amoxicillin is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (undesirable effects)

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins.

The following adverse reactions have been reported as associated with the use of amoxicillin:

Infections and infestations Mucocutaneous candidiasis have been reported very rarely.

Gastrointestinal Nausea, vomiting, diarrhoea. Intestinal candidiasis and antibiotic associated colitis (including pseudomembranous colitis and haemorrhagic colitis) have been reported rarely. Black hairy tongue has been reported very rarely. (see section 4.4 Special warnings and precautions for use)

Hypersensitivity reactions Erythematous maculopapular rash, pruritus and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis and bullous, exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, hypersensitivity vasculitis and interstitial nephritis have been reported rarely.

Whenever such reactions occur, amoxicillin should be discontinued. (Note: Urticaria, other skin rashes and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids.) Anaphylaxis is the most serious reaction experienced (see section 4.4 Special warnings and precautions for use).

Liver A moderate rise in AST and/or ALT has occasionally been noted, but the significance of this finding is unknown. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

Haemic and Lymphatic systems Reactions such as anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia and leucopenia (including severe neutropenia or agranulocytosis) have been reported during therapy with other penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Prolongation of bleeding time and prothrombin time have also been reported rarely.

Renal and urinary tract disorders: Interstitial nephritis, crystalluria (see section 4.9 Overdose).

CNS effects: CNS effects have been seen rarely. They include aseptic meningitis, hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Miscellaneous 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.

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water/electrolyte imbalance should be treated symptomatically. During the administration of high doses of amoxicillin, adequate fluid intake and urinary output must be maintained to minimize the possibility of amoxicillin crystalluria. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see section 4.4 Special warnings and precautions for use).

Amoxicillin can be removed from the circulation by haemodialysis.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of Action

Microbiology
Amoxicillin is similar to ampicillin in its bactericidal action against Gram-positive and Gram-negative susceptible organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of the cell wall mucopeptide.

Amoxicillin is active *in vitro* against most strains of *Haemophilus influenzae*, Neisseria gonorrhoeae*, Neisseria meningitidis, Escherichia coli*, Proteus mirabilis** and Salmonellae. Because amoxicillin does not resist destruction by penicillinase, it is not active against penicillinase-producing organisms, particularly penicillinase-producing staphylococci. All strains of *Pseudomonas species, Klebsiella species, Enterobacter species*, indole-positive *Proteus species, Serratia marcescens, Citrobacter species*, penicillinase-producing *N. gonorrhoeae* and penicillinase-producing *H. influenzae* are resistant. *In vitro* studies have demonstrated the susceptibility of most strains of the following gram-positive bacteria: alpha- and beta-haemolytic streptococci, *Diplococcus pneumoniae*, non-penicillinase producing staphylococci and *Streptococcus faecalis*. These organisms are susceptible to amoxicillin at serum concentrations, which may be expected following the recommended doses. However, some of the organisms were susceptible to amoxicillin only at concentrations achieved in the urine. (see section 4.1 Therapeutic indications)

*Activity refers only to beta-lactamase negative strains.

Escherichia coli isolates are becoming increasingly resistant to amoxicillin *in vitro* due to the presence of penicillinase-producing strains.
Strains of gonococci which are relatively resistant to benzylpenicillin may be sensitive to amoxicillin.

The following *in vitro* data are available, but their clinical significance is unknown.

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***In vitro* data for amoxicillin *vs.* clinical pathogens**

Organism (n)	MIC_{90} (mcg/mL)
S. pneumoniae (3493)[1]	2
H. influenzae (3366)[1]	32
S. pyogenes (683)[1]	0.03
H. influenzae b-lac + (725)[1]	32
H. influenzae b-lac – (2587)[1]	1
Klebsiella pneumonia (1161)[1]	32
M. catarrhalis (864)[1]	16
MSSA (1232)[1]	32
Bacteroides fragilis group (80)[2]	64
Fusobacterium sp (23)[2]	8
Clostridium difficile (21)[2]	2
N. gonorrhoeae (34)[3]	128

[1] Data from the Augmentin Global Surveillance Study: June 1999- December 2000 from USA, Canada, Brazil, Mexico, Hong Kong, Australia, France, Belgium, Italy, Netherlands, Spain, Sweden and the UK.

[2] Data from 1994-1995, France (Dubreuil L et al, 1996. In vitro evaluation of nitazoxanide and tizoxanide against anaerobes and aerobic organisms. *Antimicrob Agents Chemother*. 40(10), 2266- 2270.)

[3] Data from 1994-1995, UK (Wise R et al, 1996. In vitro activity of the tricyclic β-lactam GV104326.

Antimicrob Agents Chemother. 40(5), 1248-1253.)

A positive ß-lactamase test predicts resistance to penicillin, ampicillin and amoxicillin.

Rates of resistance to amoxicillin for Common Pathogens in Australia

Organism	Average % resistance
B. fragilis	100
Enterobacter spp.	96
Klebsiella spp.	98
M. catarrhalis	94
P. aeruginosa	100
S. aureus (methicillin-susceptible)	85
Enterococcus faecalis	0.2
Enterococcus faecium	80
E. coli	45.4
H. influenzae	20.3
P. mirabilis	14

S. pneumoniae	0.6 (fully resistant) 3.2 (intermediate resistance)

Breakpoints
Streptococcus pneumoniae: S </= -2 mcg/ml; I = 4 mcg/ml; R >/= 8 mcg/ml

Note: Because amoxicillin has greater *in vitro* activity against *S. pneumoniae* than does ampicillin, the majority of *S. pneumoniae* strains with intermediate susceptibility to ampicillin are fully susceptible to amoxicillin.

Susceptibility Tests

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (eg. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections. This information gives only an approximate guidance on probabilities whether organisms will be susceptible to amoxicillin.

Susceptibility to amoxicillin will vary with geography and time and local susceptibility data should be consulted where available and microbiological sampling and susceptibility testing performed where necessary.

Cross-resistance: Other ß-lactams, ß-lactam/ß-lactamase inhibitor combinations and cephalosporins.

Resistance mechanisms: Production of penicillinase, altered penicillin binding proteins.

Clinical Trials

No data available

5.2 Pharmacokinetic properties

Absorption

Amoxicillin is stable in the presence of gastric acid and is rapidly and well absorbed after oral administration, even in the presence of food.

Distribution

Amoxicillin diffuses rapidly into most body tissues and fluids, with the exception of brain and spinal fluid except when meninges are inflamed.

Amoxicillin has been shown to diffuse into sputum and saliva and is excreted mainly via the urine where it exists in a high concentration.

The amount to be found in the bile is variable depending on normal biliary secretory function.

Excretion

The half-life of amoxicillin is 6l.3 minutes with normal renal function and in the absence of renal function 16-20 hours.

Amoxicillin is excreted in the urine both unchanged and as penicilloic acid. About 75% of a 1g dose is excreted in the urine in 6 hours in the presence of normal renal function (60% is biologically active and 15% is penicilloic acid). However about 32% of a 3g dose is excreted via the urine as the biologically active component in 8 hours (by which time most of the urinary excretion is complete). This proportional difference in the amount excreted from the different doses reflects a lack of linearity between doses and extent of absorption with a levelling off at higher doses of oral amoxicillin.

Excretion of amoxicillin can be delayed by concurrent administration of probenecid thus prolonging its therapeutic effect.

Amoxicillin is not highly protein-bound, being only 17% protein-bound in serum as measured by ultrafiltration or equilibrium dialysis.

Orally administered doses of 250mg and 500mg amoxicillin result in average peak serum levels one to two hours after administration of 5.0mcg/mL and 6.6 - 10.8mcg/mL respectively. Detectable serum levels of amoxicillin are present 8 hours after ingestion of a single dose.

5.3 Preclinical safety data

Genotoxicity

No data available

Carcinogenicity

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each capsule contains :

Croscarmellose Sodium , Magnesium stearate.

Capsule shell components:

Cap:
Brilliant blue E133
Carmoisine E122
Sunset yellow E110
Titanium dioxide E171

Body:
Quinoline yellow E104
Sunset yellow E110
Titanium dioxide E171

Shell composition:
Purified Water
Methyl Parahydroxybenzoate E218
Propyl Parahydroxybenzoate E216
Gelatin (TSE Free)
Sodium lauryl sulphate

Printing ink components:
Absolute alcohol
Isopropyl alcohol
Shellac
Black iron oxide
Butyl alcohol
Propylene glycol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

For HDPE bulk pack: 24 months

6.4 Specials precautions for storage conditions

Store below 30°C

6.5 Nature and contents of container

Pack size of 500 capsules are available in HDPE screw-top containers with an aluminium tagger

6.6 Special precautions for disposal

No special requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Miro Healthcare Limited
Registered Office at Hayes Knight
5 William Laurie Place
Albany
Auckland 0632

9. DATE OF FIRST APPROVAL

22/07/2010

10. DATE OF REVISION

28/10/2022

NEW ZEALAND DATA SHEET

Summary table of changes:

Section 1 & 4.1	**Product name change**