Summary of Product Characteristic

Contents

Summary of Product Characteristic

1. Name of the Medicinal Product:

ROTAMAX 500 (Azithromycin Tablets USP 500 mg)

2. Quality and Quantitative Composition:

2.1 Qualitative Declaration

Each film coated tablet contains:
Azithromycin (Dihydrate) USP
Eq. to Azithromycin (Anhydrous)... 500 mg
Excipients.....q.s.
Colour : Titanium Dioxide BP

2.2 Quantitative Declaration

Components	Amount / Unit (mg)	Reference
Azithromycin Dihydrate Eq. to Azithromycin	524	USP (NF)
Microcrystalline cellulose	25	Ph Eur (BP)
Croscarmellose Sodium	10	Ph Eur (BP)
Povidone K-30%	5	Ph Eur (BP)
Maize Starch (F/P)	63	Ph Eur (BP)
Purified Water	q.s	Ph Eur (BP)
Magnesium Stearate	9.5	Ph Eur (BP)
Purified Talc	6.5	Ph Eur (BP)
Colloidal silicon dioxide	10.5	Ph Eur (BP)
Sodium Lauryl Sulphate	1.5	Ph Eur (BP)
Isopropyl Alcohol	q.s	Ph Eur (BP)
Titanium Dioxide	19	Ph Eur (BP)
Methylene Chloride	q.s	Ph Eur (BP)

3. Pharmaceutical Form:

Tablet (Oral use)

4. Clinical Particulars:

4.1 Therapeutic indications

Azithromycin is indicated for the following bacterial infections

- Acute bacterial sinusitis (adequately diagnosed)
- Acute bacterial otitis media (adequately diagnosed)

- Pharyngitis, tonsillitis
- Acute exacerbation of chronic bronchitis (adequately diagnosed)
- Mild to moderately severe community acquired pneumonia
- Infections of the skin and soft tissues of mild to moderate severity e.g. folliculitis, cellulitis, erysipelas
- Uncomplicated Chlamydia trachomatis urethritis and cervicitis

4.2 Posology and method of administration

Azithromycin is should be given as a single daily dose. Duration of the treatment for the different infection diseases is given below.

Children and adolescents with a body weight above 45 kg, adults and the elderly
The total dose is 1500 mg, administered as 500 mg once daily for 3 days. Alternatively, the same total dose (1500 mcg) can be administered in a period of 5 days, 500 mg on the first day and 250 mg on day 2 to 5.
In the case of uncomplicated Chlamydia trachomatis urethritis and cervicitis, the dose is 1000 mg as a single oral dose.
Children and adolescents with a body weight below 45 kg
Azithromycin tablets are not suitable for patients under 45 kg body weight. Other dosage forms are available for this group of patients.
Elderly patients
For elderly patients the same dose as for adults can be applied. Since elderly patients can be patients with ongoing proarrhythmic condition a particular caution is recommended due to the risk of developing cardiac arrhythmia and torsades de pointes.
Patients with renal impairment
Dose adjustment is not required in patients with mild to moderate renal impairment (GFR 10-80 ml/min) Caution should be exercised when azithromycin is administered to patients with severe renal impairment (GFR < 10 ml/min).
Patients with hepatic impairment
Dose adjustment is not required for patients with mild to moderate hepatic dysfunction.

Method of administration
Azithromycin should be given as a single daily dose. The tablets can be taken with or without food. The tablets should be taken with water.

4.3 Contraindications

Hypersensitivity to the active substance, erythromycin, any macrolide, ketolide antibiotic, or to any of the excipients listed in 6.1

4.4 Special warning and precautions for use

Hypersensitivity
As with erythromycin and other macrolides, rare serious allergic reactions, including angioneurotic oedema and anaphylaxis (rarely fatal), dermatologic reactions including acute generalized exanthematous pustulosis (AGEP), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) (rarely fatal) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported.

If an allergic reaction occurs, the medicinal product should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

Hepatic Impairment
Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur.

Ergot alkaloids and azithromycin
In patients receiving ergot derivatives, ergotism has been precipitated by coadministration of some macrolide antibiotics. There are no data concerning the possibility of an interaction between ergotamine derivatives and azithromycin. However, because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administered.

Clostridium Difficile-associated diarrhea
Clostridium difficile associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.
C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C.difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Renal impairment
In patient with serve renal impairment (GFR< 10 ml/min) a 33% increase in systemic exposure to azithromycin was observed

Cardiovascular events
Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with other macrolides, including azithromycin. Therefore as the following situations may lead to an increased risk for ventricular arrhythmias (including torsade de pointes) which can lead to cardiac arrest, azithromycin should be used with caution in patients with ongoing proarrhythmic conditions (especially women and elderly patients) such as patients:

- With congenital or documented acquired QT prolongation.

- Currently receiving treatment with other active substances known to prolong QT interval such as antiarrhythmics of class IA (quinidine and procainamide) and class III (dofetilide, amiodarone and sotalol), cisapride and terfenadine; antipsychotic agents such as pimozide; antidepressants such as citalopram; and fluoroquinolones such as moxifloxacin and levofloxacin.

- With electrolyte disturbance, particularly in cases of hypokalaemia and hypomagnesaemia

- With clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.

Epidemiological studies investigating the risk of adverse cardiovascular outcomes with macrolides have shown variable results. Some observational studies have identified a rare short term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including azithromycin. Consideration of these findings should be balanced with treatment benefits when prescribing azithromycin.

Myasthenia gravis
Exacerbations of the symptoms of myasthenia gravis and new onset of myasthenia syndrome have been reported in patients receiving azithromycin therapy.

Paediatric Population
Safety and efficacy for the prevention or treatment of *Mycobacterium avium* complex in children have not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids
In a pharmacokinetic study investigating the effects of simultaneous administration of antacids with azithromycin, no effect on overall bioavailability was seen, although peak serum levels were reduced by approximately 25%. In patients receiving both azithromycin and antacids, the medicinal products should not be taken simultaneously. Azithromycin must be taken at least 1 hour before or 2 hours after antacids.

Cetirizine
In healthy volunteers, coadministration of a 5-day regimen of azithromycin with cetirizine 20 mg at steady-state resulted in no pharmacokinetic interaction and no significant changes in the QT interval.

Didanosine (Dideoxyinosine)
Co-administration of 120 mg/day azithromycin with 400 mg/day didanosine in 6 HIV- positive subjects did not appear to affect the steady-state pharmacokinetics of didanosine as compared with placebo.

Digoxin and colchicines
Concomitant administration of macrolide antibiotics, including azithromycin, with P-glycoprotein substrates such as digoxin, has been reported to result in increased serum levels of the P-glycoprotein substrate. Therefore, if azithromycin and P-gp substrates such as digoxin are administered concomitantly, the possibility of elevated serum concentrations of the substrate should be considered.

Zidovudine
Single 1000 mg doses and multiple doses of 600 mg or 1200 mg azithromycin had little effect on the plasma pharmacokinetics or urinary excretion of zidovudine or its glucuronide metabolite. However, administration of azithromycin increased the concentrations of phosphorylated zidovudine, the clinically active metabolite, in peripheral blood mononuclear cells. The clinical significance of this finding is unclear, but it may be of benefit to patients.

Azithromycin does not interact significantly with the hepatic cytochrome P450 system. It is not believed to undergo the pharmacokinetic drug interactions as seen with erythromycin and other

macrolides. Hepatic cytochrome P450 induction or inactivation via cytochrome metabolite complex does not occur with azithromycin.

Ergotamine derivates
Due to the theoretical possibility of ergotism, the concurrent use of azithromycin with ergot derivatives is not recommended

Pharmacokinetic studies have been conducted between azithromycin and the following drugs known to undergo significant cytochrome P450 mediated metabolism.

Astemizole, alfentanil
There are no known data on interactions with astemizole or alfentanil. Caution is advised in the coadministration of these medicines with Azithromycin because of the known enhancing effect of these medicines when used concurrently with the macrolide antibiotic erythromycin.

Atorvastatin
Coadministration of atorvastatin (10 mg daily) and azithromycin (500 mg daily) did not alter the plasma concentrations of atorvastatin (based on a HMG CoA-reductase inhibition assay). However, postmarketing cases of rhabdomyolysis in patients receiving azithromycin with statins have been reported.

Carbamazepine
In a pharmacokinetic interaction study in healthy volunteers, no significant effect was observed on the plasma levels of carbamazepine or its active metabolite in patients receiving concomitant azithromycin.

Cisapride
Cisapride is metabolized in the liver by the enzyme CYP 3A4. Because macrolides inhibit this enzyme, concomitant administration of cisapride may cause the increase of QT interval prolongation, ventricular arrhythmias and torsades de pointes.

Cimetidine:
In a pharmacokinetic study investigating the effects of a single dose of cimetidine, given 2 hours before azithromycin, on the pharmacokinetics of azithromycin, no alteration of azithromycin pharmacokinetics was seen.

Coumarin Type Oral Anticoagulants
In a pharmacokinetic interaction study, azithromycin did not alter the anticoagulant effect of a single 15-mg dose of warfarin administered to healthy volunteers. There have been reports received in the postmarketing period of potentiated anticoagulation subsequent to coadministration of azithromycin and coumarin type oral anticoagulants. Although a causal relationship has not been established, consideration should be given to thefrequency of monitoring prothrombin time when azithromycin is used in patients receiving coumarintypeoral anticoagulants.

Cyclosporin
In a pharmacokinetic study with healthy volunteers that were administered a 500 mg/day oral dose of azithromycin for 3 days and were then administered a single 10 mg/kg oral dose of cyclosporin, the resulting cyclosporin C_{max} and AUC_{0-5} were found to be significantly elevated. Consequently, caution

should be exercised before considering concurrent administration of these drugs. If coadministration of these drugs is necessary, cyclosporin levels should be monitored and the dose adjusted accordingly.

Efavirenz
Coadministration of a 600 mg single dose of azithromycin and 400 mg efavirenz daily for 7 days did not result in any clinically significant pharmacokinetic interactions.

Fluconazole
Coadministration of a single dose of 1200 mg azithromycin did not alter the pharmacokinetics of a single dose of 800 mg fluconazole. Total exposure and halflife of azithromycin were unchanged by the coadministration of fluconazole, however, a clinically insignificant decrease in C_{max} (18%) of azithromycin was observed.

Indinavir
Coadministration of a single dose of 1200 mg azithromycin had no statistically significant effect on the pharmacokinetics of indinavir administered as 800 mg three times daily for 5 days.

Methylprednisolone
In a pharmacokinetic interaction study in healthy volunteers, azithromycin had no significant effect on the pharmacokinetics of methylprednisolone.

Midazolam
In healthy volunteers, coadministration of azithromycin 500 mg/day for 3 days did not cause clinically significant changes in the pharmacokinetics and pharmacodynamics of a single 15 mg dose of midazolam.

Nelfinavir
Coadministration of azithromycin (1200 mg) and nelfinavir at steady state (750 mg three times daily) resulted in increased azithromycin concentrations. No clinically significant adverse effects were observed and no dose adjustment is required.

Rifabutin
Coadministration of azithromycin and rifabutin did not affect the serum concentrations of either medicinal product. Neutropenia was observed in subjects receiving concomitant treatment of azithromycin and rifabutin. Although neutropenia has been associated with the use of rifabutin, a causal relationship to combination with azithromycin has not been established.

Sildenafil
In normal healthy male volunteers, there was no evidence of an effect of azithromycin (500 mg daily for 3days) on the AUC and C_{max} of sildenafil or its major circulating metabolite.

Terfenadine
Pharmacokinetic studies have reported no evidence of an interaction between azithromycin and terfenadine. There have been rare cases reported where the possibility of such an interaction could not be entirely excluded; however there was no specific evidence that such an interaction had occurred.

Theophylline

There is no evidence of a clinically significant pharmacokinetic interaction when azithromycin and theophylline are co-administered to healthy volunteers. As interactions of other macrolides with theophylline have been reported, alertness to signs that indicate a rise in theophylline levels is advised.

Triazolam
In 14 healthy volunteers, coadministration of azithromycin 500 mg on Day 1 and 250 mg on Day 2 with 0.125 mg triazolam on Day 2 had no significant effect on any of the pharmacokinetic variables for triazolam compared to triazolam and placebo.

Trimethoprim/sulfamethoxazole
Coadministration of trimethoprim/sulfamethoxazole DS (160 mg/800 mg) for 7 days with azithromycin 1200 mg on Day 7 had no significant effect on peak concentrations, total exposure or urinary excretion of either trimethoprim or sulfamethoxazole. Azithromycin serum concentrations were similar to those seen in other studies.

4.6 Pregnancy and lactation

Pregnancy
There are no adequate data from the use of azithromycin in pregnant women. In reproduction toxicity studies in animals azithromycin was shown to pass the placenta, but no teratogenic effects were observed. The safety of azithromycin has not been confirmed with regard to the use of the active substance during pregnancy. Therefore azithromycin should only be used during pregnancy if the benefit outweighs the risk.

Lactation
Azithromycin has been reported to be secreted into human breast milk, but there are no adequate and well controlled clinical studies in nursing women that have characterized the pharmacokinetics of azithromycin excretion into human breast milk.

Because it is not known whether azithromycin may have adverse effects on the breast-fed infant, nursing should be discontinued during treatment with azithromycin. Among other things diarrhoea, fungus infection of the mucous membrane as well as sensitisation is possible in the nursed infant. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Nursing may be resumed thereafter.

Fertility
In fertility studies conducted in rat, reduced pregnancy rates were noted following administration of azithromycin. The relevance of this finding to humans is unknown.

4.8 Undesirable effects

The frequency grouping is defined using the following convention: Very common (≥1/10); Common (≥ 1/100 to <1/10);Uncommon (≥1/1,000 to <1/100); Rare (≥ 1/10,000 to <1/1,000); Very Rare (< 1/10,000);and Not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Summary of Product Characteristic

System organ class	Very common ≥ 1/10	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare/ isolated reports (<1/10,000)	Not Known
Infections and infestations			Candidiasis, Oral candidiasis Vaginal infection Pneumonia Fungal Infection Bacterial Infection Pharyngitis Gastroenteritis Respiratory disorder, Rhinitis,			Pseudo-membranous colitis
Blood and lymphatic system disorders			Leukopenia Neutropenia Eosinophilia			Thrombocytopenia, Haemolytic anaemia
Immune system disorders			Angioedema Hypersensitivity			Anaphylactic reaction
Metabolism and nutrition disorders		Anorexia				
Psychiatric disorders			Nervousness, Insomnia	Agitation		Aggression Anxiety Delirium Hallucination
Nervous system disorders		Headache , dizziness, Dysgeusia, Paraesthesia	Hypoaesthesia Somnolence			Syncope Convulsion Psychomotor hyperactivity Anosmia Ageusia Parosmia Myasthenia gravis
Eye disorders		Visual				Blurred vision

		impairment				
Ear and labyrinth disorders		Deafness	Ear disorder Vertigo Hearing Impaired, Tinnitus			
Cardiac disorders			Palpitations			Torsades de pointes Arrhythmia including ventricular tachycardia Electro-cardiogram QT prolonged
Vascular disorders			Hot flush			Hypotension
Respiratory, thoracic and mediastinal disorders			Dyspnoea Epistaxis			
Gastrointestinal disorders	Diarrhoea, Abdominal pain, Nausea, flatulence	Vomiting dyspepsia	Constipation Dysphagia Gastric dysphagia Abdominal distension Dry mouth Eructation Mouth ulceration Salivary Hypersecretion			Pancreatitis, Tongue and teeth discoloration
Hepatobiliary disorders			Hepatitis	Hepatic function abnormal Jaundice cholestatic		Hepatic failure Hepatitis fulminant Hepatic necrosis
Skin and subcutaneous tissue disorders		Pruritus, Rash	Stevens-Johnson Syndrome, Photosensitivity reaction Urticaria	Allergic reactions including Angioneurotic oedema Acute generalised		Toxic epidermal necrolysis Erythema Multiforme

			Dermatitis Dry skin Hyperhidrosis	exanthematouspustulosis (AGEP)		DRESS (Drug reaction with eosinophilia and systemic symptoms)
Musculoskeletal and connective tissue disorders		Arthralgia	Osteoarthritis Myalgia Back pain Neck pain			
Renal and urinary disorders			Dysuria Renal pain	Renal failure acute, Nephritis interstitial		
Reproductive system and breast disorders			Metrorrhagia Testicular disorder			
General disorders and administration site conditions		Fatigue	Oedema Asthenia Malaise Face edema Chest Pain Pyrexia Peripheral pain			
Investigations		Lymphocyte count decreased Eosinophil count increased Blood bicarbonate decreased Monocytes increased, Neutrophils increased	Blood urea increased Blood creatinine increased Blood potassium abnormal Blood alkaline phosphate increased Chloride increased Glucose increased Platelets increased Hematocrit decreased Bicarbonate			

			increased Abnormal sodium			

Adverse reactions possibly or probably related to Mycobacterium Avium Complex prophylaxis and treatment based on clinical trial and post0marketing surveillance. These adverse reactions differ from those reported with immediate release or the prolonged release formulations, either in kind or in frequency:

System Organ Class	Adverse reaction	Frequency
Metabolism and Nutrition Disorders	Anorexia	Common
Nervous System Disorders	Dizziness Headache Paraesthesia Dysgeusia	Common
	Hypoesthesia	Uncommon
Eye Disorders	Visual impairment	Common
Ear and Labyrinth Disorders	Deafness	Common
	Hearing impaired Tinnitus	Uncommon
Cardiac Disorders	Palpitations	Uncommon
Gastrointestinal Disorders	Diarrhoea Abdominal pain Nausea Flatulence Abdominal discomfort Loose stools	Very common
Hepatobiliary Disorders	Hepatitis	Uncommon
Skin and Subcutaneous Tissue Disorders	Rash Pruritus	Common
	Steven-Johnson syndrome Photosensitivity reaction	Uncommon
Musculoskeletal and Connective Tissue Disorders	Arthralgia	Common
General Disorders and Administration Site Conditions	Fatigue	Common
	Asthenia Malaise	Uncommon

4.9 Overdose and treatment

Adverse events experienced in higher than recommended doses were similar to those seen at normal doses.

Symptoms

The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea.

Treatment
In the event of overdose, general symptomatic and supportive measures are indicated as required.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antibacterials for systemic use, macrolides.
Azithromycin is a macrolide antibiotic belonging to the azalide group.
The molecule is constructed by adding a nitrogen atom to the lactone ring of erythromycin A. The chemical name of azithromycin is 9-deoxy-9a-aza-9a-methyl-9a-homoerythromycin A. The molecular weight is 749.0.

Mechanism of action
Azithromycin is an azalide, a sub-class of the macrolide antibiotics. By binding to the 50S ribosomal sub-unit, azithromycin avoids the translocation of peptide chains from one side of the ribosome to the other. As a consequence of this, RNA-dependent protein synthesis in sensitive organisms is prevented.

5.2 Pharmacokinetic Properties

Absorption
Bioavailability of azithromycin after oral administration is approximately 37%. Peak plasma concentrations are attained after 2-3 hours. The mean maximum concentration observed (C_{max}) after a single dose of 500 mg is approximately 0.4 µg/ml.

Distribution
Orally administered azithromycin is widely distributed throughout the body.

Pharmacokinetic studies have demonstrated that the concentrations of azithromycin measured in tissues are noticeably higher (up to 50 times the maximum observed concentration in plasma) than those measured in plasma. This indicates that the agent strongly binds to tissues (steady-state distribution volume approx. 31 l/kg).

At the recommended dose no accumulation appears in the serum. Accumulation appears in tissues where levels are much higher than in serum. Three days after administration of 500 mg as a single dose or in partial doses concentrations of 1,3-4,8 µg/g, 0,6-2,3 µg/g, 2,0-2,8 µg/g and 0-0,3 µg/ml have been measured in resp. lung, prostate, tonsil and serum.

In experimental *in vitro* and *in vivo* studies azithromycin accumulates in phagocytes. Release is stimulated by active phagocytosis. In animal models this process contributes to the accumulation of azithromycin in tissue.

Binding of azithromycin to serum proteins is variable and varies from 50% at 0,05 mg/l to 18% at 0,5 mg/l, depending on the serum concentration.

Elimination
The terminal plasma elimination half-life closely reflects the elimination half-life from tissues of 2-4 days.

Approximately 12% of an intravenously administered dose is excreted in unchanged form with the urine over a period of 3 days; the major proportion in the first 24 hours. Concentrations of up to 237 µg/ml azithromycin, 2 days after a 5-day course of treatment, have been found in human bile. Ten metabolites have been identified (formed by N and O demethylation, by hydroxylation of the desosamine and aglycone rings, and by splitting of the cladinose conjugate). Investigations suggest that the metabolites do not play a role in the microbiological activity of azithromycin.

5.3 Preclinical safety Data

In animal studies using exposures 40 times those achieved at the clinical therapeutic dosages, azithromycin was found to have caused reversible phospholipidosis, but as a rule there were no associated toxicological consequences. The relevance of this finding to humans receiving azithromycin in accordance with the recommendations is unknown.

Electrophysiological investigations have shown that azithromycin prolongs the QT interval.

Carcinogenic potential:
Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Mutagenic potential:
There was no evidence of a potential for genetic and chromosome mutations in *in-vivo* and *in-vitro* test models.

Reproductive toxicity:
Teratogenic effects were not observed in rat reproductive toxicity studies. In rats, azithromycin doses of 100 and 200 mg/kg body weight/ day led to mild retardation in fetal ossification and in maternal weight gain. In peri- and postnatal studies in rats mild retardations in physical and reflex development were noted following treatment with 50 mg/kg/day azithromycin and above.

6. Pharmaceutical Particulars:

6.1 List of excipients
Microcrystalline cellulose, Croscarmellose Sodium, Maize Starch, Povidone K-30% ,Purified Water, Purified Talc, Magnesium Stearate, Colloidal Silicon Dioxide, Sodium Lauryl Sulphate, Isopropyl Alcohol, Titanium Dioxide, Methylene Chloride

6.2 Incompatibilities
None known

6.3 Shelf life
36 months

6.4 Special precautions for storage

Summary of Product Characteristic

Preserve in tight containers. Store at controlled room temperature.
Keep out of reach of children.

6.5 Nature and contents of container
3 tablets packed in Alu-PVC blister and such 10 blisters are packed in a printed carton with insert.

7. Marketing Authorization Holder:

APPLICANT
ROTAMEDICS PHARMACY LIMITED,
RESERVATION ROAD G.R.A ILORIN
ILORIN KWARA
Tel: 07055888798

Email: rotamedics@gmail.com

MANUFACTURER
RELAX BIOTECH PVT LTD,
862/1, G.I.D.C., MAKARPURA, City: VADODARA 39101
Dist.: VADODARA GUJARAT STATE, INDIA.

8. Marketing Authorization Number (s):

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9. Product license / registration Number (s)

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10. Manufacturer Name:

Name: NOVOPHARM FORMULATIONS (P) LTD.
C/O RELAX BIOTECH PVT. LTD.
Address: 862/1 G.I.D.C, Industrial Estate, Makarpura,
Vadodara-390010, Gujarat, India.

11. Date of first authorization/renewal of the authorization:

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12. Date of revision of the text:

April 2022