SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Sea Mox Tablets 400 mg

2. qualitative and quantitative composition

Each Film Coated tablet contains: Moxifloxacin Hydrochloride 400 mg

3. Pharmaceutical Dosage form:
Tablets

4. Clinical particulars:

4.1. Therapeutic indications:

Sinus and lung infections such as sinusitis, pneumonia, and secondary infections in chronic bronchitis. Also for the treatment of bacterial conjunctivitis (pinkeye) and skin infections. Also effective in the treatment of mild to moderate pelvic inflammatory disease (i.e. infections of female upper genital tract, including salpingitis and endometritis, without an associated tubo-ovarian or pelvic abscess

4.2. Posology and method of administration:

PgsgJggy

The recommended dose is one 400 mg film-coated tablet once daily.

Renal/hepatic impairment

No adjustment of dosage is required in patients with mild to severely impaired renal function or in patients on chronic dialysis i.e. haemodialysis and continuous ambulatory peritoneal dialysis (see section 5.2 for more details).

Other special populations

No adjustment of dosage is required in the elderly and in patients with low bodyweight.

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Paediatric population

Moxifloxacin is contraindicated in children and adolescents (< 18 years). Efficacy and safety of moxifloxacin in children and adolescents have not been established (see section 4.3).

Method of administration

The film-coated tablet should be swallowed whole with sufficient liquid and may be taken independent of meals.

Duration of administration

Sea Mox 400 mg film-coated tablets should be used for the following treatment durations:

- Acute exacerbation of chronic bronchitis5 - 10 days
- Community acquired pneumonia 10 days
- Acute bacterial sinusitis 7 days
- Mild to moderate pelvic inflammatory disease 14 days

Sea Mox 400 mg film-coated tablets have been studied in clinical trials for up to 14 days treatment.

Sequential (intravenous followed by oral) therapy

In clinical studies with sequential therapy most patients switched from intravenous to oral therapy within 4 days (community-acquired pneumonia) or 6 days (complicated skin and skin structure infections). The recommended total duration of intravenous and oral treatment is 7 -14 days for community-acquired pneumonia and 7-21 days for complicated skin and skin structure infections

The recommended dose (400 mg once daily) and duration of therapy for the indication being treated should not be exceeded.

Therapeutic uses	Adult dosage/day
Acute Bacterial Sinusitis	400 mg for 10 days
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg for 5 days
Community Acquired Pneumonia	400 mg for 7-14 days

Uncom licated Skin and Skin Structure Infections (SSSI)	400 mg for 7 days
Complicated SSSI	400 mg for 7-21 days
Complicated Intra-Abdominal Infections	400 m for 5-14 da s

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4.3. Contraindications

Moxifloxacin Hydrochloride is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipients. Moxifloxacin Hydrochloride should be used cautiously in elderly, pregnancy, nursing mothers, pediatric population and patients with liver or kidney impairment.

4.4. Special warnings and precautions for use

Tendon Rupture and Tendinopathy: Moxifloxacin Hydrochloride can lead to an enhanced chance of inflammation and rupture of the tendons.

Central Nervous System Effects: Moxifloxacin Hydrochloride can lead to seizures, increased intracranial pressure tremors, hallucinations, restlessness, anxious behavior, confusion, depressive state, vivid dreams, and decreased sleep.

Clostridium Difficile-Associated Enterocolitis: Clostridium difficile-associated enterocolitis can be seen with Moxifloxacin Hydrochloride like other antibiotics.

Peripheral Neuropathy: Rarely large or small sized neurons may be affected by polyneuropathy due to Moxifloxacin Hydrochloride leading to altered sensations.

Prolongation of the QT Interval: Moxifloxacin Hydrochloride can lead to prolongation of the QT interval.

Phototoxicity: Phototoxic reactions can be seen with Moxifloxacin Hydrochloride.

Myasthenia Gravis: Moxifloxacin Hydrochloride can lead to deterioration of weakness of muscles in patients of myasthenia gravis. Hypersensitive reactions can be seen with moxifloxacin which can be fatal rarely.

Musculoskeletal Disorders: An increased incidence of musculoskeletal disorders i.e. joint pain and inflammation and Tendinopathy has been observed.

SPECIAL POPULATIONS

Elderly population: If elderly patients are using steroids there are enhanced chances of tendinopathy in them.

Children: There are no studies regarding the safety of moxifloxacin in persons aged < 18 years of age. Moxifloxacin has been known to cause arthropathy in young animals.

Pregnancy: It is a Category C drug. Moxifloxacin was not found to be teratogenic in animal studies.

Lactation: It is secreted during lactation.

Kidney dysfunction: Dosage adjustment is not needed in patients with impaired kidney function.

Liver dysfunction: Liver dysfunction does not affect the pharmacokinetics of moxifloxacin and hence dosage adjustments are not needed.

4.5.Interaction with other medicinal products and other forms of interaction

Drug-Drug Interactions

An additive effect on QT interval prolongation of moxifloxacin and other medicinal products that may prolong the QTc interval cannot be excluded. This might lead to an increased risk of ventricular arrhythmias. Therefore, co-administration of moxifloxacin with any of the following medicinal products is contraindicated:

- Anti-arrhythmic class IA (e.g. quinidine, hydroquinidine, disopyramide)
- Anti-arrhythmic class Ill (e.g. amiodarone, sotalol, dofetilide, ibutilide)

Antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride)

Tricyclic antidepressive agents

Certain antimicrobial agents (e.g. saquinavir, sparfloxacin, erythromycin IV, pentamidine

Antimalarial (particularly halofantrine)

Certain antihistaminics (e.g. terfenadine, astemizole, mizolastine)

Others (e.g. cisapride, vincamine IV, bepridil, diphemanil).

Moxifloxacin should be used with caution in patients who are taking medication that can reduce potassium levels (e.g. loop and thiazide-type diuretics, laxatives and enemas [high doses], corticosteroids, amphotericin B) or medication that is associated with clinically significant bradycardia.

Drug-Food Interactions

Olmesartan may be administered with or without food. Absorption is not affected by lipid-rich meals or yoghurt.

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4.6. Pregnancy and lactation:

Pregnancy
The safety of moxifloxacin in human pregnancy has not been evaluated.. Animal studies have shown reproductive toxicity . The potential risk for humans is unknown. Due to the experimental risk of damage by fluoroquinolones to the weight-bearing cartilage of immature animals and reversible joint injuries described in children receiving some fluoroquinolones, moxifloxacin must not be used in pregnant women.

Breastfeeding
There is no data available in lactating or nursing women. Preclinical data indicate that small amounts of moxifloxacin are secreted in milk. In the absence of human data and due to the experimental risk of damage by fluoroquinolones to the weight-bearing cartilage of immature animals, breast-feeding is contraindicated during moxifloxacin therapy.

4.7. Undesirable effects

Adverse reactions based on all clinical trials with moxifloxacin 400 mg (oral and sequential therapy) sorted by frequencies are listed below:
Apart from nausea and diarrhoea all adverse reactions were observed at frequencies below 3%.
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
Frequencies are defined as:
- common (2 1/100 to < 1/10)
- uncommon (2 1/1,000 to < 1/100) . rare (2 1/10,000 to < 1/1,000)
- very rare (< 1/10,000)

System Organ Class (MedDRA)	Common	U ncommon	Rare	Very Rare
Infections and infestations	Superinfections due to resistant bacteria or fungi e.g. oral and vaginal candidiasis			

Blood and lymphatic system disorders		Anaemia Leucopenia(s) Neutropenia Thrombocytopenia Thrombocythemia Blood eosinophilia Prothrombin time prolonged/INR increased		Prothrombin level increased/lNR decreased Agranulocytosis
Immune system disorders		Allergic reaction	Anaphylaxis incl. very rarely life-threatening	

			shock . Allergic oedema / angiooedema (incl. laryngeal oedema, potentially lifethreatening.	
Metabolism and nutrition disorders		Hyperlipidemia	Hyperglycemia Hyperuricemia	Hypoglycemia
Psychiatric disorders		Anxiety reactions Psychomotor hyperactivity/ agitation	Emotional lability Depression (in very rare cases potentially culminating in selfinjurious behaviour, such as suicidal ideations/ thoughts, or suicide attempts, Hallucination	Depersonalization Psychotic reactions (potentially culminating in self- injurious behaviour, such as suicidal ideations/ thoughts, or suicide attempts,
Nervous system disorders	Headache Dizziness	Par- and Dysaesthesia Taste disorders (incl. ageusia in very rare cases) Confusion and disorientation Sleep disorders (predominantly insomnia) Tremor Vertigo Somnolence	Hypoaesthesia Smell disorders (incl. anosmia) Abnormal dreams Disturbed coordination (incl. gait disturbances, esp. due to dizziness or vertigo) Seizures incl. grand mal convulsions Disturbed attention Speech disorders Amnesia Peripheral neuropathy and polyneuropathy	Hyperaesthesia

Eye disorders		Visual disturbances incl. diplopia and blurred vision (especially in the course of CNS reactions.		Transient loss of vision (especially in the course of CNS reactions.
Ear and labyrinth disorders			Tinnitus Hearing impairment incl. deafness (usually reversible)	

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Cardiac disorders	QT prolongation in patients with hypokalaemia	QT prolongation Palpitations Tachycardia Atrial fibrillation Angina pectoris	Ventricular tachyarrhythmias Syncope (i.e., acute and short lasting loss of consciousness	IJnspecified arrhythmias Torsade de Pointes Cardiac arrest
Vascular disorders		Vasodilatation	Hypertension Hypotension	
Respiratory, thoracic and mediastinal disorders		Dyspnea (including asthmatic conditions)		
Gastrointestinal disorders	Nausea Vomiting Gastrointestinal and abdominal pains Diarrhoea	Decreased appetite and food intake Constipation Dyspepsia Flatulence Gastritis Increased amylase	Dysphagia Stomatitis Antibiotic associated colitis (incl. pseudomembranous colitis, in very rare cases associated with lifethreatening complications.	
Hepatobiliary disorders	Increase in transaminases	Hepatic impairment (incl. LDH increase) Increased bilirubin Increased gammaglutamyl-transferase Increase in blood alkaline phosphatase	Jaundice Hepatitis (predominantly cholestatic)	Fulminant hepatitis potentially leading to life-threatening liver failure.
Skin and subcutaneous tissue disorders		Pruritus Rash Urticaria Dry skin		Bullous skin reactions like Stevens-Johnson syndrome or toxic epidermal necrolysis

				(potentially lifethreatening
Musculoskeletal and connective tissue disorders		Arthralgia Myalgia	Tendonitis Muscle cramp Muscle twitching Muscle weakness	Tendon rupture Arthritis Muscle rigidity Exacerbation of symptoms of myasthenia gravis
Renal and urinary disorders		Dehydration	Renal impairment (incl. increase in BUN and creatinine) Renal failure.	

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General disorders and administration site conditions		Feeling unwell (predominantly asthenia or fatigue) Painful conditions (incl. pain in back, chest, pelvic and extremities) Sweating	Oedema	

There have been very rare cases of the following side effects reported following treatment with other fluoroquinolones, which might possibly also occur during treatment with moxifloxacin: hypernatraemia, hypercalcaemia, haemolytic anaemia, rhabdomyolysis, photosensitivity reactions (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.8. Undesirable effects

Summary of the safety profile

4.9 Overdose

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Concomitant administration of charcoal with a dose of 400 mg oral moxifloxacin will reduce systemic availability of the drug by more than 80%. The use of charcoal early during absorption may be useful to prevent excessive increase in the systemic exposure to moxifloxacin in cases of oral overdose.

5.0. Pharmacological Properties:

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Quinolone antibacterials, fluoroquinolones, ATC code: JOIMA14

Mechanism of action

Moxifloxacin has in vitro activity against a wide range of Gram-positive and Gram-negative pathogens.
The bactericidal action of moxifloxacin results from the inhibition of both type Il topoisomerases (DNA gyrase and topoisomerase IV) required for bacterial DNA

replication, transcription and repair. It appears that the C8methoxy moiety contributes to enhanced activity and lower selection of resistant mutants of Gram-positive bacteria compared to the C8-H moiety. The presence of the bulky bicycloamine substituent at the C-7 position prevents active efflux, associated with thenorA or pmrA genes seen in certain Gram-positive bacteria.

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Pharmacodynamic investigations have demonstrated that moxifloxacin exhibits a concentration dependent killing rate. Minimum bactericidal concentrations (MBC) were found to be in the range of the minimum inhibitory concentrations (MIC).

Effect on the intestinal flora in humans

The following changes in the intestinal flora were seen in volunteers following oral administration of moxifloxacin:Escherichia coli, Bacillus spp., Enterococcus spp., and Klebsiella spp. were reduced, as were the anaerobes Bacteroides vulgatus, Bifidobacterium spp., Eubacterium spp., and Peptostreptococcus spp.. For Bacteroides fragilis there was an increase. These changes returned to normal within two weeks.

Mechanism of resistance

Resistance mechanisms that inactivate penicillins, cephalosporins, aminoglycosides, macrolides and tetracyclines do not interfere with the antibacterial activity of moxifloxacin. Other resistance mechanisms such as permeation barriers (common in Pseudomonas aeruginosa) and efflux mechanisms may also effect susceptibility to moxifloxacin.
In vitro resistance to moxifloxacin is acquired through a stepwise process by target site mutations in both type Il topoisomerases, DNA gyrase and topoisomerase IV. Moxifloxacin is a poor substrate for active efflux mechanisms in Gram-positive organisms.

Cross-resistance is observed with other fluoroquinolones. However, as moxifloxacin inhibits both topoisomerase Il and IV with similar activity in some Gram-positive bacteria, such bacteria may be resistant to other quinolones, but susceptible to moxifloxacin.

Breakpoints

EUCAST clinical MIC and disk diffusion breakpoints for moxifloxacin (01.01.2011):

Organism	Susceptible	Resistant
Staphylococcus spp.	0.5 mg/l 2 24 mm	> I mg/l < 21 mm
S. pneumoniae	0.5 mg/l 22 mm	> ().5 mg/l 22 mm

Streptococcus Groups A, B, C, G	0.5 mg/l 2 18 mm	> 1 mg/l < 15 mm
H. influenzae	0.5 mg/l 2 25 mm	0.5 mg/l 2 25 mm
M. catarrhalis	s 0.5 mg/l 2 23 mm	> 0.5 mg/l < 23 mm
Enterobacteriaceae	0.5 mg/l 2 20 mm	> 1 mg/l < 17 mm
Non-species related breakpoints*	s 0.5 mg/l	> 1 mg/l

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* Non-species related breakpoints have been determined mainly on the basis of pharmacokinetic/pharmacodynamic data and are independent of MIC distributions of specific species. They are for use only for species that have not been given a species-specific breakpoint and are not for use with species where interpretative criteria remain to be determined.

Microbiological Susceptibility

The prevalence of acquired resistance may vary geographically and with time for selected species and local information of resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought where the local prevalence of resistance is such that utility of the agent in at least some types of infections is questionable.

Commonly susceptible species
Aerobic Gram-positive micro-organisms Gardnerella vaginalis Staphylococcus aureus* (methicillin-susceptible) Streptococcus agalactiae (Group B) Streptococcus milleri group* (S. anginosus, S. constellatus and S. intermedius) Streptococcus pneumoniae* Streptococcus pyogenes* (Group A) Streptococcus viridans group (S. viridans, S. mutans, S. mitis, S. sanguinis, S. salivarius, S. thermophilus)
Aerobic Gram-negative micro-organisms Acinetobacter baumanii Haemophilus influenzae* Haemophilus parainfluenzae* Legionella pneumophila Moraxella (Branhamella) catarrhalis*
Anaerobic micro-organisms Fusobacterium spp. Prevotella spp.

"Other" micro-organisms
Chlamydophila (Chlamydia) pneumoniae*
Chlamydia trachomatis*
Coxiel/a burnetii
Mycop/asma genitalium
Mycoplasma hominis

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Mycop/asma pneumoniae*
Species for which acquired resistance may be a problem
Aerobic Gram-positive micro-organisms Enterococcus faecalis * Enterococcus faecium * Staphylococcus aureus (methicillin-resistant)+
Aerobic Gram-negative micro-organisms Enterobacter cloacae* Escherichia coli* Klebsiella*pneumoniae*#* Klebsiella oxytoca Neisseria gonorrhoeae* + Proteus mirabilis*
Anaerobic micro-organisms Bacteroides fragilis* Peptostreptococcus spp. *
Inherently resistant organisms
Aerobic Gram-negative micro-organisms Pseudomonas aeruginosa
*Activity has been satisfactorily demonstrated in susceptible strains in clinical studies in the approved clinical indications. N ESBL-producing strains are commonly resistant to fluoroquinolones +Resistance rate > 50% in one or more countries

5.2 Pharmacokinetic properties

Absorption and Bioavailabilitv

Following oral administration moxifloxacin is rapidly and almost completely absorbed. The absolute bioavailability amounts to approximately 91%. Pharmacokinetics are linear in the range of 50 - 800 mg single dose and up to 600 mg once daily dosing over 10 days. Following a 400 mg oral dose peak concentrations of 3.1 mg/l are reached within 0.5 - 4 h post administration. Peak and trough plasma concentrations at steady-state (400 mg once daily) were 3.2 and 0.6 mg/l, respectively. At steady-state the exposure within the dosing interval is approximately 30% higher than after the first dose.

Distribution

Moxifloxacin is distributed to extravascular spaces rapidly; after a dose of 400 mg an AUC of 35 m•gh/l is observed. The steady-state volume of distribution (Vss) is approximately 2 1/kg. In vitro and ex vivo experiments showed a protein

binding of approximately 40 - 42% independent of the concentration of the drug. Moxifloxacin is mainly bound to serum albumin.

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The following peak concentrations (geometric mean) were observed following administration of a single oral dose of 400 mg moxifloxacin:

Tissue	Concentration	Site: Plasma ratio
Plasma	3.1 mg/l	
Saliva	3.6 mg/l	0.75 - 1.3
Blister fluid	1.6[1] mg/l	1.71
Bronchial mucosa	5.4 mg/kg	1.7 - 2.1
Alveolar macrophages	56.7 mg/kg	18.6 - 70.0
Epithelial lining fluid	20.7 mg/l	5 -7
Maxillary sinus	7.5 mg/kg	2.0
Ethmoid sinus	8.2 mg/kg	2.1
Nasal polyps	9.1 mg/kg	2.6
Interstitial fluid	1.0[2] mg/l	0.8 - 1.4[23]
Female genital tract*	10.2[4] mg/kg	1.724

* intravenous administration of a single 400 mg dose

[1] 10 h after administration

[2] unbound concentration from 3 h up to 36 h post dose

[4] at the end of infusion

Biotransformation

Moxifloxacin undergoes Phase Il biotransformation and is excreted via renal and biliary/faecal pathways as unchanged drug as well as in the form of a sulpho-compound (Ml) and a glucuronide (M2). Ml and M2 are the only metabolites relevant in humans, both are microbiologically inactive.

In clinical Phase I and in vitro studies no metabolic pharmacokinetic interactions with other drugs undergoing Phase I biotransformation involving cytochrome P450 enzymes were observed. There is no indication of oxidative metabolism.

Elimination

Moxifloxacin is eliminated from plasma with a mean terminal half life of approximately 12 hours. The mean apparent total body clearance following a 400 mg dose ranges from 179 to 246 ml/min. Renal clearance amounted to about 24 - 53 ml/min suggesting partial tubular reabsorption of the drug from the kidneys. After a 400 mg dose, recovery from urine (approximately 19% for unchanged drug, approximately 2.5% for MI, and approximately 14% for M2) and faeces (approximately 25% of unchanged drug, approximately 36% for Ml, and no recovery for M2) totalled to approximately 96%.

Concomitant administration of moxifloxacin with ranitidine or probenecid did not alter renal clearance of the parent drug.

Elderly and patients with low body weight

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Higher plasma concentrations are observed in healthy volunteers with low body weight (such as women) and in elderly volunteers.

5.3. Preclinical Safety Data:

Effects on the haematopoetic system (slight decreases in the number of erythrocytes and platelets) were seen in rats and monkeys. As with other quinolones, hepatotoxicity (elevated liver enzymes and vacuolar degeneration) was seen in rats, monkeys and dogs. In monkeys CNS toxicity (convulsions) occurred. These effects were seen only after treatment with high doses of moxifloxacin or after prolonged treatment.

Moxifloxacin, like other quinolones, was genotoxic in in vitro tests using bacteria or mammalian cells. Since these effects can be explained by an interaction with the gyrase in bacteria and - at higher concentrations - by an interaction with the topoisomerase Il in mammalian cells, a threshold concentration for genotoxicity can be assumed. In in vivo tests, no evidence of genotoxicity was found despite the fact that very high moxifloxacin doses were used. Thus, a sufficient margin of safety to the therapeutic dose in man can be provided. Moxifloxacin was noncarcinogenic in an initiation-promotion study in rats.

Many quinolones are photoreactive and can induce phototoxic, photomutagenic and photocarcinogenic effects. In contrast, moxifloxacin was proven to be devoid of phototoxic and photogenotoxic properties when tested in a comprehensive programme of in vitro and in vivo studies. Under the same conditions other quinolones induced effects.

At high concentrations, moxifloxacin is an inhibitor of the rapid component of the delayed rectifier potassium current of the heart and may thus cause prolongations of the QT interval. Toxicological studies performed in dogs using oral doses of 2 90 mg/kg leading to plasma concentrations 2 16 mg/l caused QT prolongations, but no arrhythmias. Only after very high cumulative intravenous administration of more than 50fold the human dose (> 300 mg/kg), leading to plasma concentrations of 2 200 mg/l (more than 40fold the therapeutic level), reversible, non-fatal ventricular arrhythmias were seen.

Quinolones are known to cause lesions in the cartilage of the major diarthrodial joints in immature animals. The lowest oral dose of moxifloxacin causing joint toxicity in juvenile dogs was four times the maximum recommended therapeutic dose of 400 mg (assuming a 50 kg bodyweight) on a mg/kg basis, with plasma concentrations two to three times higher than those at the maximum therapeutic dose.

Toxicity tests in rats and monkeys (repeated dosing up to six months) revealed no indication regarding an oculotoxic risk. In dogs, high oral doses (2 60 mg/kg) leading to plasma concentrations 2 20 mg/l caused changes in the electroretinogram and in isolated cases an atrophy of the retina.

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Reproductive studies performed in rats, rabbits and monkeys indicate that placental transfer of moxifloxacin occurs. Studies in rats (p.o. and i.v.) and monkeys (p.o.) did not show evidence of teratogenicity or impairment of fertility following administration of moxifloxacin. A slightly increased incidence of vertebral and rib malformations was observed in foetuses of rabbits but only at a dose (20 mg/kg i.v.) which was associated with severe maternal toxicity. There was an increase in the incidence of abortions in monkeys and rabbits at human therapeutic plasma concentrations. In rats, decreased foetal weights, an increased prenatal loss, a slightly increased duration of pregnancy and an increased spontaneous activity of some male and female offspring was observed at doses which were 63 times the maximum recommended dose on a mg/kg basis with plasma concentrations in the range of the human therapeutic dose.

6. Pharmaceutical particulars

6.3. List of excipients

Croscarmellose Sodium
Polyvinylpyrrolidone K-30
Lactose Monohydrate (200 Mesh)
Silica Colloidal Anhydrous
Microcrystalline Cellulose PH102
Magnesium Stearate
Isopropyl Alcohol
Opadry Il Orange
Purified Water

6.4. Incompatibilities None stated.

6.5. Shelf life 2 Years

6.6. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.7. Nature and contents of container

Sea Mox Tablet 400mg for commercial use is available in Alu-Alu blister pack of 5 tablets. 1 blister is packed in printed carton with the product name and batch details along with the information of the manufacturer.

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6.8. Special precautions for disposal and other handling Not stated

7. Marketing Authorisation Holder:
The Searle Company Limited
1st Floor, N.I.C.L. Building, Abbasi
Shaheed Road, P. O. Box. 5696,
Karachi - 75530, Pakistan.