Summary of Product Characteristic

Contents

Summary of Product Characteristic

1. Name of the Medicinal Product:
MEXZECAM - 15 (Meloxicam Tablets BP)

2. Quality and Quantitative Composition:

2.1 Qualitative Declaration

Each Uncoated tablet contains:
Meloxicam BP……..500 mg
Excipients……..Q.S.

2.2 Quantitative Declaration

Components	Amount / Unit (mg)
Meloxicam BP	15
Base Granules (Starch+Lactose+Ccs) IHS	226
Magnesium Stearate BP	2
Sodium Starch Glycollate BP	2
Colloidal Silicon Dioxide (Aerosil) BP	1
Talcum BP	2
Sodium Lauryl Sulphate BP	2
Total	250 mg

3. Pharmaceutical Form:
Tablet (Oral use)

4. Clinical Particulars:

4.1 Therapeutic indications
Meloxicam tablet is indicated for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis.
It is indicated for relief of the signs and symptoms of pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis in patients 2 years of age and older.

4.2 Posology and method of administration

Oral Use

Exacerbations of Osteoarthritis: 7.5 mg/day (half a 15 mg tablet); if necessary, in the absence of improvement, the dose may be increased to 15 mg/day.

Rheumatoid arthritis, Ankylosing Spondylitis: 15 mg/day (one 15 mg tablets).

According to the therapeutic response, the dose may be reduced to 7.5 mg/day (half a 15mg tablet).

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis.

DO NOT EXCEED THE DOSE OF 15 MG/DAY.

Meloxicam Orodispersible Tablets should be placed in the mouth on the tongue and allowed to dissolve slowly for five minutes (the tablet should not be chewed and should not be swallowed undissolved), before swallowing with a drink of 240 ml of water.

Water may be used to moisten the buccal mucosa in patients with a dry mouth.
The recommended dose for long term treatment of rheumatoid arthritis and ankylosing spondylitis in elderly patients is 7.5 mg (half a 15 mg tablet) per day. Patients with increased risks for adverse reactions should start treatment with 7.5 mg per day

Renal impairment
In dialysis patients with severe renal failure, the dose should not exceed 7.5 mg (half a 15 mg tablet) per day. No dose reduction is required in patients with mild to moderate renal impairment (i.e. patients with a creatinine clearance of greater than 25 ml/min).

Hepatic Impairment
No dose reduction is required in patients with mild to moderate hepatic impairment (for patients with severely impaired liver function)

Children and adolescents:
Meloxicam Orodispersible Tablets is contraindicated in children and adolescents aged under 16 years

4.3 Contraindications

This medicinal product is contra-indicated in the following situations:

- Third trimester of pregnancy
- Children and adolescents aged under 16 years;
- Hypersensitivity to meloxicam or to one of the excipients or hypersensitivity to substances with a similar action, e.g. NSAIDs, aspirin. Meloxicam should not be given to patients who have developed signs of asthma, nasal polyps, angioneurotic oedema or urticaria following the administration of aspirin or other NSAIDs;
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy;
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding);
- Active intestinal inflammatory disease (Crohn´s disease, ulcerative colitis);
- Severely impaired liver function;
- Non-dialysed severe renal failure;
- Gastrointestinal bleeding, cerebrovascular bleeding or other bleeding disorders;
- Severe heart failure;
- Meloxicam is contraindicated in treatment of perioperative pain after coronary artery bypass surgery (CABG).

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4.4 Special warning and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The recommended maximum daily dose should not be exceeded in case of insufficient therapeutic effect, nor should an additional NSAID be added to the therapy because this may increase the toxicity while therapeutic advantage has not been proven. The use of Meloxicam Orodispersible Tablets with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Meloxicam Orodispersible Tablets is not appropriate for the treatment of patients requiring relief from acute pain.In the absence of improvement after several days, the clinical benefit of the treatment should be reassessed.

Any history of oesophagitis, gastritis and/or peptic ulcer must be sought in order to ensure their total cure before starting treatment with meloxicam. Attention should routinely be paid to the possible onset of a recurrence in patients treated with meloxicam and with a past history of this type.

Gastrointestinal effects
GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk.

Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution is advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as heparin as curative treatment or given in geriatrics, anticoagulants such as warfarin, or other non-steroidal anti-inflammatory drugs, including acetylsalicylic acid given at anti-inflammatory doses.

When GI bleeding or ulceration occurs in patients receiving Meloxicam orodispersible tablets the treatment should be withdrawn.

Cardiovascular and cerebrovascular effects
Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical monitoring of blood pressure for patients at risk is recommended at baseline and especially during treatment initiation with Meloxicam Orodispersible Tablets.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for meloxicam.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with meloxicam orodispersible tablets after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Skin reactions
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDSs. Patients appear to be at highest risk for these reactions early in the course of therapy: The onset of the reaction occurring in the majority of cases within the first month of treatment. Meloxicam should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Parameters of liver and renal function
As with most NSAIDs, occasional increases in serum transaminase levels, increases in serum bilirubin or other liver function parameters, as well as increases in serum creatinine and blood urea nitrogen as well as other laboratory disturbances, have been reported. The majority of these instances involved transitory and slight abnormalities. Should any such abnormality prove significant or persistent, the administration of Meloxicam should be stopped and appropriate investigations undertaken.

Functional renal failure
NSAIDs, by inhibiting the vasodilating effect of renal prostaglandins, may induce a functional renal failure by reduction of glomerular filtration. This adverse event is dose-dependant. At the beginning of the treatment, or after dose increase, careful monitoring of diuresis and renal function is recommended in patients with the following risk factors:

• Elderly
• Concomitant treatments such as ACE inhibitors, angiotensin-II antagonists, sartans, diuretics (see section 4.5. Interaction with other medicinal products and other forms of interaction)
• Hypovolemia (whatever the cause)
• Congestive heart failure
• Renal failure
• Nephrotic syndrome
• Lupus nephropathy
• Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score 10)'

In rare instance NSAIDs may be the cause of interstitial nephritis, glomerulonephritis, renal medullary necrosis or nephrotic syndrome.
The dose of Meloxicam in patients with end-stage renal failure on haemodialysis should not be higher than 7.5 mg (half a 15 mg tablet). No dose reduction is required in patients with mild or moderate renal impairment (i.e. patients with a creatinine clearance of greater than 25 ml/min).

Sodium, potassium and water retention
Induction of sodium, potassium and water retention and interference with the natriuretic effects of diuretics may occur with NSAIDs. Furthermore, a decrease of the antyhypertensive effect of antyhypertensive drugs can occur. Consequently, oedema, cardiac failure or hypertension may be precipitated or exacerbated in susceptible patients as a result. Clinical monitoring is therefore necessary for patients at risk.

Hyperkalaemia
Hyperkalaemia can be favoured by diabetes or concomitant treatment known to increase kalaemia. Regular monitoring of potassium values should be performed in such cases.

Adverse reactions are often less well tolerated in elderly, fragile or weakened individuals, who therefore require careful monitoring. As with other NSAIDs, particular caution is required in the elderly, in whom renal, hepatic and cardiac functions are frequently impaired. The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Meloxicam orodispersible tablet, as any other NSAID may mask symptoms of an underlying infectious disease.

The use of meloxicam orodispersible tablet, as with any drug known to inhibit cyclooxygenase / prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving, or who are undergoing investigation of infertility, withdrawal of meloxicam should be considered.

4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have only been performed in adults.
Meloxicam is metabolised in liver, mostly by CYP 2C9 and CYP 3A4. Possibility of pharmacokinetic interactions between meloxicam and drugs inhibiting or being metabolised by CYP 2C9 and CYP 3A4 has to be considered.

Pharmacodynamic Interactions:
Other non-steroidal anti-inflammatory drugs (NSAIDs) and acetylsalicylic acid $\geq$ 3g/d:

Combination with other non-steroidal anti-inflammatory drugs, including acetylsalicylic acid given at anti-inflammatory doses ($\geq$ 1g as single intake or $\geq$ 3g as total daily amount) is not recommended.

Corticosteroids (e.g. Glucocorticoids):
The concomitant use with corticosteroids requests caution because of an increased risk of bleeding or gastrointestinal ulceration.

Anticoagulant or heparin administered in geriatrics or at curative doses:
Considerably increased risk of bleeding, via inhibition of platelet function and damage to the gastroduodenal mucosa. NSAIDs may enhance the effects of anticoagulants, such as Warfarin. The concomitant use of NSAIDs and anticoagulants or heparin administered in geriatrics or at curative dose is not recommended.
In remaining cases of heparin use caution is necessary due to an increased bleeding risk.

Careful monitoring of the INR is required if it proves impossible to avoid such combination.

Thrombolytics and antiplatelet drugs:
Increased risk of bleeding, via inhibition of platelet function and damage to the gastroduodenal mucosa.

Selective serotonin reuptake inhibitors (SSRIs):
Increased risk of gastrointestinal bleeding.

Diuretics, ACE inhibitors and Angiotensin-II Antagonists:
NSAIDs may reduce the effect of diuretics and other antihypertensive drugs. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor or Angiotensin-II antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter.

Other antihypertensive drugs (e.g. Beta-blockers):
As for the latter, a decrease of the antihypertensive effect of beta-blockers (due to inhibition of prostaglandins with vasodilatory effect) can occur.

Calcineurin inhibitors (e.g. cyclosporin, tacrolimus):
Nephrotoxicity of calcineurin inhibitors may be enhanced by NSAIDs via renal prostaglandin mediated effects. During combined treatment renal function is to be measured. A careful monitoring of the renal function is recommended, especially in the elderly.

Intrauterine devices:
NSAIDs have been reported to decrease the efficacy of intrauterine devices.
A decrease of the efficacy of intrauterine devices by NSAIDs has been previously reported but needs further confirmation.

4.6 Pregnancy and lactation

Pregnancy
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, meloxicam should not be given unless clearly necessary. If meloxicam is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

• Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
• Renal dysfunction, which may progress to renal failure with oligohydroamniosis; the mother and the neonate, at the end of pregnancy, to:
• Possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
• Inhibition of uterine contractions resulting in delayed or prolonged labour.
Consequently, meloxicam is contraindicated during the third trimester of pregnancy.

Lactation
While no specific experience exists for meloxicam, NSAIDs are known to pass into mother's milk. Administration is not recommended in women who are breastfeeding.

4.8 Undesirable effects
a) General Description
Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment.
The most commonly-observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed.

The frequencies of adverse drug reactions given below are based on corresponding occurrences of reported adverse events in 27 clinical trials with a treatment duration of at least 14 days. The information is based on clinical trials involving 15197 patients who have been treated with daily oral doses of 7.5 or 15 mg meloxicam tablets or capsules over a period of up to one year.

Adverse drug reactions that have come to light as a result of reports received in relation to administration of the marketed product are included.

Adverse reactions have been ranked under headings of frequency using the following convention:
Very common (> 1/10); common (> 1/100, < 1/10); uncommon (> 1/1000, < 1/100); rare (> 1/10000, < 1/1000); very rare (< 1/10000)

b) Table of adverse reactions

Blood and lymphatic system disorders

Uncommon:	Anaemia
Rare:	Blood count abnormal (including differential white cell count), leukopenia, thrombocytopenia

Very rare cases of agranulocytosis have been reported.

Immune system disorders

Uncommon:	Hypersensitivity, allergic reactions other than anaphylactic or anaphylactoid reactions
Not known:	Anaphylactic reaction, anaphylactoid reaction

Psychiatric disorders

Rare:	Mood altered, nightmares
Not known:	Confusional state, disorientation
Nervous system disorders	
Common:	Headache
Uncommon:	Dizziness, somnolence

Eye disorders

Rare:	Visual disturbance including vision blurred; conjunctivitis

Ear and labyrinth disorders

Uncommon:	Vertigo
Rare:	Tinnitus

Cardiac disorders

Rare:	Palpitations

Cardiac failure has been reported in association with NSAID treatment.

Vascular disorders

Uncommon:	Blood pressure increased (see section 4.4), flushing

Respiratory, thoracic and mediastinal disorders

Rare:	Asthma in individuals allergic to aspirin or other NSAIDs

Gastrointestinal disorders

Very common:	Dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhoea
Uncommon:	Occult or macroscopic gastrointestinal haemorrhage, stomatitis, gastritis, eructation
Rare:	Colitis, gastroduodenal ulcer, oesophagitis
Very rare:	Gastrointestinal perforation
Not known	Pancreatitis

Gastrointestinal haemorrhage, ulceration or perforation may sometimes be severe and potentially fatal, especially in elderly

Hepatobiliary disorders

Uncommon:	Liver function disorder (e.g. raised transaminases or bilirubin)
Very rare:	Hepatitis

Skin and subcutaneous tissue disorders

Uncommon:	Angioedema, pruritus, rash
Rare:	Stevens-Johnson syndrome, toxic
	epidermal necrolysis, urticaria
Very rare:	Dermatitis bullous, erythema multiforme
Not known:	Photosensitivity reaction

Renal and urinary disorders

Uncommon:	Sodium and water retention, hyperkalaemia (see section 4.4.Special warnings and special precautions for use and section 4.5.), renal function test abnormal (increased serum creatinine and/or serum urea)
Very rare:	Acute renal failure in particular in patients with risk factors (see section 4.4.)

General disorders and administration site conditions

Uncommon:	Oedema including oedema of the lower limbs.

c) Information characterising Individual serious and/or Frequently occurring Adverse Reactions
Very rare cases of agranulocytosis have been reported in patients treated with meloxicam and other potentially myelotoxic drugs.

d) **Adverse reactions which have not been observed yet in relation to the product, but which are generally accepted as being attributable to other compounds in the class**
Organic renal injury probably resulting in acute renal failure: very rare cases of interstitial nephritis, acute tubular necrosis, nephrotic syndrome, and papillary necrosis have been reported.

4.9 Overdose and treatment
Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Severe poisoning may result in hypertension, acute renal failure, hepatic dysfunction, respiratory depression, coma, convulsions, cardiovascular collapse and cardiac arrest. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAID and may occur following an overdose.

Patients should be managed with symptomatic and supportive care following an NSAID overdose. Accelerated removal of meloxicam by 4 g oral doses of cholestyramine given three times a day was demonstrated in a clinical trial.

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

5. Pharmacological Properties:

Summary of Product Characteristic

5.1Pharmacodynamic Properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory agents, oxicams

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam family, with anti-inflammatory, analgesic and antipyretic properties.
The anti-inflammatory activity of meloxicam has been proven in classical models of inflammation. As with other NSAID, its precise mechanism of action remains unknown. However, there is at least one common mode of action shared by all NSAID (including meloxicam): inhibition of the biosynthesis of prostaglandins, known inflammation mediators.

Mechanism of action
Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of Meloxicam, like that of other NSAIDs, may be related to prostaglandin synthetase (cyclo-oxygenase) inhibition.

5.2 Pharmacokinetic Properties

Absorption
The absolute bioavailability of meloxicam capsules was 89% following a single oral dose of 30 mg compared with 30 mg IV bolus injection. Following single intravenous doses, dose-proportional pharmacokinetics were shown in the range of 5 mg to 60 mg. After multiple oral doses the pharmacokinetics of meloxicam capsules were dose-proportional over the range of 7.5 mg to 15 mg. Mean Cmax was achieved within four to five hours after a 7.5 mg meloxicam tablet was taken under fasted conditions, indicating a prolonged drug absorption. With multiple dosing, steady state concentrations were reached by Day 5. A second meloxicam concentration peak occurs around 12 to 14 hours post-dose suggesting biliary recycling.

Food and Antacid Effects
Administration of meloxicam capsules following a high fat breakfast (75 g of fat) resulted in mean peak drug levels (i.e., Cmax) being increased by approximately 22% while the extent of absorption (AUC) was unchanged. The time to maximum concentration (Tmax) was achieved between 5 and 6 hours. In comparison, neither the AUC nor the Cmax values for meloxicam suspension were affected following a similar high fat meal, while mean Tmax values were increased to approximately 7 hours. No pharmacokinetic interaction was detected with concomitant administration of antacids. Based on these results, Mexzecam can be administered without regard to timing of meals or concomitant administration of antacids

Distribution
The mean volume of distribution (Vss) of meloxicam is approximately 10 L. Meloxicam is ~ 99.4% bound to human plasma proteins (primarily albumin) within the therapeutic dose range. The fraction of protein binding is independent of drug concentration, over the clinically relevant concentration range, but decreases to ~ 99% in patients with renal disease. Meloxicam penetration into human red blood cells, after oral dosing, is less than 10%. Following a radiolabeled dose, over 90% of the radioactivity detected in the plasma was present as unchanged meloxicam. Meloxicam concentrations in synovial fluid, after a single oral dose, range from 40% to 50% of those in plasma. The free fraction in synovial

fluid is 2.5 times higher than in plasma, due to the lower albumin content in synovial fluid as compared to plasma. The significance of this penetration is unknown.

Metabolism
Meloxicam is almost completely metabolized to four pharmacologically inactive metabolites. The major metabolite, 5'-carboxy meloxicam (60% of dose), from P-450 mediated metabolism was formed by oxidation of an intermediate metabolite 5'-hydroxymethyl meloxicam which is also excreted to a lesser extent (9% of dose). In vitro studies indicate that cytochrome P-450 2C9 plays an important role in this metabolic pathway with a minor contribution of the CYP 3A4 isozyme. Patients' peroxidase activity is probably responsible for the other two metabolites which account for 16% and 4% of the administered dose, respectively.

Excretion
Meloxicam excretion is predominantly in the form of metabolites, and occurs to equal extents in the urine and feces. Only traces of the unchanged parent compound are excreted in the urine (0.2%) and feces (1.6%). The extent of the urinary excretion was confirmed for unlabeled multiple 7.5 mg doses: 0.5%, 6% and 13% of the dose were found in urine in the form of meloxicam, and the 5'-hydroxymethyl and 5'-carboxy metabolites, respectively. There is significant biliary and/or enteral secretion of the drug. This was demonstrated when oral administration of cholestyramine following a single IV dose of meloxicam decreased the AUC of meloxicam by 50%

The mean elimination half-life (t1/2) ranges from 15 hours to 20 hours. The elimination half-life is constant across dose levels indicating linear metabolism within the therapeutic dose range. Plasma clearance ranges from 7 to 9 mL/min.

5.3Preclinical safety Data

The toxicological profile of meloxicam has been found in preclinical studies to be identical to that of NSAID: Gastrointestinal ulcers and erosions, renal papillary necrosis at high doses during chronic administration in two animal species.
Oral reproductive studies in the rat have shown a decrease of ovulations and inhibition of implantations and embryotoxic effects (increase of resorptions) at maternotoxic dose levels at 1 mg/kg and higher. Studies of toxicity on reproduction in rats and rabbits did not reveal teratogenicity up to oral doses of 4 mg/kg in rats and 80 mg/kg in rabbits.
The affected dose levels exceeded the clinical dose (7.5-15 mg) by a factor of 10 to 5-fold on a mg/kg dose basis (75 kg person). Foetotoxic effects at the end of gestation, shared by all prostaglandin synthesis inhibitors, have been described.

No evidence has been found of any mutagenic effect, either in vitro or in vivo. No carcinogenic risk has been found in the rat and mouse at doses far higher than those used clinically.

6. Pharmaceutical Particulars:

6.1 List of excipients
Base Granules (Starch+Lactose+Ccs), Magnesium Stearate, Sodium starch Glycollate, colloidal silicon Dioxide, Talcum, Sodium lauryl sulphate

6.2 Incompatibilities

Summary of Product Characteristic

None known

6.3Shelf life
36 months

6.4Special precautions for storage
Store below 25°C, in a dry place and away from children Keep out of reach of children.

6.5 Nature and contents of container
10 tablets packed in Alu-PVC blister and such 1blisters are packed in a printed carton with insert.

7. Marketing Authorization Holder:
NAME: NOVOPHARM FORMULATIONS (P) LTD.
ADDRESS: 105.Rajmandir , 62- Alkapuri Society,
R.C Dutt Road, Vadodara – 390007,
GUJARAT, INDIA.
COUNTRY: INDIA
TELEPHONE: +91– 265–2342033
E-MAIL:novopharm.export@gmail.com

8. Marketed By:
Mexzen Nigeria Limited.,
43 Ifoshi Road, Pipeline Bus Stop,
Ejigbo, Lagos, Nigeria.
Phone: +234 8035369184
Email: mexzen123@gmail.com

9. Product license / registration Number (s)
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10. Manufacturer Name:
Name: BAROQUE PHARMACEUTICALS PRIVATE LIMITED
Address: 192/2, Sokhda-388620,
Khambhat, Anand, Gujarat, India.

11. Date of first authorization/renewal of the authorization:
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12. Date of revision of the text:
Sep 2022