REGISTRATION DOSSIER		
Name of the Product	Clonazepam Tablets USP 2 mg	**Module-1 – Administrative Information**
Brand Name	Coclam Tablets 2 mg	

1.5 Product information

1.5.1 Prescribing information (Summary of product characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg)

Each uncoated tablet contains:
Clonazepam USP……2 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) has been found useful when used alone or as an adjunct in the management of myoclonic and akinetic seizures and petit mal variant (Lennox-Gastaut syndrome).

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) may be of some value in patients with absence spells (petit mal) who have failed to respond to succinimides.

Up to nearly one-third of the patients in some studies have shown a loss of anticonvulsant activity, often within the first three months of administration of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg). In some cases dosage adjustment may re-establish efficacy.

Geriatrics (>65 years of age)
In general elderly patients should be started on lowest possible dose of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) and observed closely.

Pediatrics (<18 years of age)
For a brief description see WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics (<5

years of age) and DOSAGE AND ADMINISTRATION, Recommended Dose and Dosage Adjustment, Children.

4.2 Posology and method of administration

Clonazepam is available as a tablet. The tablets should be administered with water by swallowing the tablet whole.

Seizure Disorders:

Adults:

The initial dose for adults with seizure disorders should not exceed 1.5 mg/day divided into three doses. Dosage may be increased in increments of 0.5 to 1 mg every 3 days until seizures are adequately controlled or until side effects preclude any further increase. Maintenance dosage must be individualized for each patient depending upon response. Maximum recommended daily dose is 20 mg.

The use of multiple anticonvulsants may result in an increase of depressant adverse effects. This should be considered before adding clonazepam to an existing anticonvulsant regimen.

Pediatric Patients:
Clonazepam is administered orally. In order to minimize drowsiness, the initial dose for infants and children (up to 10 years of age or 30 kg of body weight) should be between 0.01 and 0.03 mg/kg/day but not to exceed 0.05 mg/kg/day given in two or three divided doses. Dosage should be increased by no more than 0.25 to 0.5 mg every third day until a daily maintenance dose of 0.1 to 0.2 mg/kg of body weight has been reached, unless seizures are controlled or side effects preclude further increase. Whenever possible, the daily dose should be divided into three equal doses. If doses are not equally divided, the largest dose should be given before retiring.

Geriatric Patients:
There is no clinical trial experience with clonazepam in seizure disorder patients 65 years of age and older. In general, elderly patients should be started on low doses of clonazepam and observed closely.

Panic Disorder:

Adults:
The initial dose for adults with panic disorder is 0.25 mg bid. An increase to the target dose for most patients of 1 mg/day may be made after 3 days. The recommended dose of 1 mg/day is based on the results from a fixed dose study in which the optimal effect was seen at 1 mg/day. Higher doses of 2, 3 and 4 mg/day in that study were less effective than the 1 mg/day dose and were associated with more adverse effects. Nevertheless, it is possible that some individual patients may benefit from doses of up to a maximum dose of 4 mg/day, and in those instances, the dose may be increased in increments of

0.125 to 0.25 mg bid every 3 days until panic disorder is controlled or until side effects make further increases undesired. To reduce the inconvenience of somnolence, administration of one dose at bedtime may be desirable.

Treatment should be discontinued gradually, with a decrease of 0.125 mg bid every 3 days, until the drug is completely withdrawn.

There is no body of evidence available to answer the question of how long the patient treated with clonazepam should remain on it. Therefore, the physician who elects to use clonazepam for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Pediatric Patients:
There is no clinical trial experience with clonazepam in panic disorder patients under 18 years of age.

Geriatric Patients:
There is no clinical trial experience with clonazepam in panic disorder patients 65 years of age and older. In general, elderly patients should be started on low doses of clonazepam and observed closely.

4.3 Contraindications

- Patients who are hypersensitive to other benzodiazepines, this drug or to any ingredient in the formulation or component of the container.
- Severe respiratory insufficiency
- Severe hepatic impairment as benzodiazepines may precipitate hepatic encephalopathy.
- Sleep apnea syndrome
- Myasthenia gravis
- Narrow angle glaucoma

4.4 Special warnings and precautions for use

RISKS FROM CONCOMITANT USE WITH OPIOIDS
Concomitant use of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) and opioids may result in profound sedation, respiratory depression,coma, and death.

- Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

General
A paradoxical increase in seizure activity or the appearance of new seizure types has occurred in a very few patients during treatment with Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg). When used in patients in whom several different types of seizures coexist, Clonazepam Tablets USP 2 mg

(Coclam Tablets 2 mg) may increase the incidence or precipitate the onset of generalized tonic-clonic seizures (grand mal). These phenomena may require the addition of appropriate anticonvulsants or an increase in their dosage. The concomitant use of valproic acid and clonazepam may produce absence status.

The abrupt withdrawal of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg), particularly in those patients on long-term, high dose therapy, may precipitate status epilepticus. Therefore, as with any other anticonvulsant, gradual withdrawal is essential when discontinuing Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg). While Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) is being gradually withdrawn, the simultaneous substitution of incremental doses of another anticonvulsant may be indicated.

Risks from concomitant use of opioids and benzodiazepines
Concomitant use of benzodiazepines, including Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg), and opioids may result in profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioid analgesics alone. Because of similar pharmacological properties, it is reasonable to expect similar risk with the concomitant use of other CNS depressant drugs with opioid analgesics.

If a decision is made to prescribe Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use. In patients already receiving an opioid analgesic, prescribe a lower initial dose of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) than indicated in the absence of an opioid, and titrate based on clinical response. If an opioid analgesic is initiated in a patient already taking Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg), prescribe a lower initial dose of the opioid analgesic, and titrate based on clinical response. Follow patients closely for signs and symptoms of respiratory depression and sedation.

Advise both patients and caregivers about the risks of respiratory depression and sedation when Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) is used with opioids.
Advise patients not to drive or operate heavy machinery until the effects of concomitant use of the opioid have been determined. Some loss of effect may occur during the course of clonazepam treatment.

Hepatic impairment

Benzodiazepines may have a contributory role in precipitating episodes of hepatic encephalopathy in severe hepatic impairment. Special caution should be exercised when administering Rivotril to patients with mild to moderate hepatic impairment.

CNS, psychosis and depression

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) should be used with particular caution in patients with ataxia.

Benzodiazepines are not recommended for the primary treatment of psychotic illness.

Patients with a history of depression and/or suicide attempts should be kept under close supervision.

Concomitant use of alcohol/CNS depressants

The concomitant use of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) with alcohol and/or CNS depressants should be avoided. Such concomitant use has the potential to increase the clinical effects of RIVOTRIL possibly including severe sedation that could result in coma or death, clinically relevant respiratory and/or cardiovascular depression.

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) should be used only with particular caution in patients with ataxia, and in the event of acute intoxication with alcohol or drugs.

Patients should be advised against the concurrent use of alcohol and other CNS depressant drugs.

Psychiatric and 'paradoxical' reactions

Paradoxical reactions such as restlessness, agitation, irritability, aggressiveness, anxiety, delusion, anger, nightmares, hallucinations, psychoses, inappropriate behavior and other adverse behavioral effects are known to occur when using benzodiazepines. Should this occur, the use of the drug should be discontinued. Paradoxical reactions are more likely to occur in children and in the elderly.

Psychiatric

Suicidal Ideation and Behaviour:
Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications.
Patients with a history of depression and/or suicide attempts should be kept under close supervision.

All patients treated with antiepileptic drugs (AEDs), irrespective of indication, should be monitored for signs of suicidal ideation and behaviour and appropriate treatment should be considered.

Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

An FDA meta-analysis of randomized placebo controlled trials, in which AEDs were used for various indications, has shown a small increased risk of suicidal ideation and behaviour in patients treated with

these drugs. The mechanism of this risk is not known. There were 43,892 patients treated in the placebo controlled clinical trials that were included in the meta-analysis. Approximately 75% of patients in these clinical trials were treated for indications other than epilepsy and, for the majority of non-epilepsy indications the treatment (AED or placebo) was administered as monotherapy. Patients with epilepsy represented approximately 25% of the total number of patients treated in the placebo controlled clinical trials and, for the majority of epilepsy patients, treatment (AED or placebo) was administered as adjunct to other antiepileptic agents (i.e., patients in both treatment arms were being treated with one or more AEDs). Therefore, the small increased risk of suicidal ideation and behavior reported from the meta-analysis (0.43% for patients on AEDs compared to 0.24% for patients on placebo) is based largely on patients that received monotherapy treatment (AED or placebo) for nonepilepsy indications. The study design does not allow an estimation of the risk of suicidal ideation and behaviour for patients with epilepsy that are taking AEDs, due both to this population being the minority in the study, and the drug-placebo comparison in this population being confounded by the presence of adjunct AED treatment in both arms.

Amnesia

Anterograde amnesia may occur using benzodiazepines at therapeutic dosages, the risk increasing at higher dosages.

Lactose intolerance

Lactose is a non-medicinal ingredient in Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg). Therefore, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Porphyria

In patients with porphyria, clonazepam has to be used with care because it may have a porphyrogenic effect.

Medical history of alcohol or drug abuse

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) should be used with extreme caution in patients with a history of alcohol or drug abuse.

Benzodiazepines have produced habituation, dependence and withdrawal symptoms similar to those noted with barbiturates and alcohol. The risk of dependence increases with dose and duration, and is greater in patients with a medical history of alcohol and drug abuse.

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Dependence and Tolerance

With long-term Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) treatment at the therapeutic doses, development of physical and psychologicaldependence may occur. The risk of dependence increases with dose and duration of treatment; it is also greater in patients with a medical history of alcohol and/or drug abuse. Abuse has been reported in poly-drug abusers.

Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. The possibility that such effects may also occur following short-term use, especially at high doses, or if the daily dose is reduced rapidly or abruptly discontinued, should be considered. Symptoms of withdrawal include tremor, sweating, agitation, sleep disturbances and anxiety, headaches, diarrhea, muscle pain, extreme anxiety, tension, restlessness, mood changes, confusion, and irritability. In severe cases the following symptoms may occur: derealization, depersonalization, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact or hallucinations. Since the risk of withdrawal symptoms is greater after abrupt discontinuation of treatment, abrupt withdrawal of the drug should be avoided and treatment - even if only of short duration - should be terminated by gradually reducing the daily dose.

Renal

The safety and efficacy of clonazepam in patients with renal impairment has not been studied.

Clonazepam metabolites are excreted by the kidneys; to avoid excessive accumulation, caution should be exercised in the administration of the drug to patients with impaired renal function.

Respiratory

Respiratory depression may occur following administration of Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg). This effect may be aggravated by pre-existing airway obstruction or brain damage or if other medications which depress respiration have been given. As a rule, this effect can be avoided by careful adjustment of the dose to individual requirements.

Treatment with Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) should be instituted with caution in patients with chronic respiratory diseases.
Hypersecretion in the upper respiratory passages has at times been a troublesome adverse reaction during Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) therapy, especially in small mentally retarded children who ordinarily have difficultly handling secretions. Therefore special attention must be paid to maintaining patency of the
airways.

Falls and fractures

There have been reports of falls and fractures among benzodiazepine users. The risk is increased in those taking concomitant sedatives (including alcoholic beverages) and in the elderly.

Hypersalivation

Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) may produce an increase in salivation. This should be considered before giving the drug to patients who have difficulty handling secretions. Because of this and the possibility of respiratory depression, Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) should be used with caution in patients with chronic respiratory diseases.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of Clonazepam on the Pharmacokinetics of Other Drugs:

Clonazepam does not appear to alter the pharmacokinetics of phenytoin, carbamazepine or phenobarbital. The effect of clonazepam on the metabolism of other drugs has not been investigated.

Effect of Other Drugs on the Pharmacokinetics of Clonazepam:

Literature reports suggest that ranitidine, an agent that decreases stomach acidity, does not greatly alter clonazepam pharmacokinetics.

Fluoxetine does not affect the pharmacokinetics of clonazepam. Cytochrome P-450 inducers, such as phenytoin, carbamazepine and phenobarbital, induce clonazepam metabolism, causing an approximately 30% decrease in plasma clonazepam levels. Although clinical studies have not been performed, based on the involvement of the cytochrome P-450 3A family in clonazepam metabolism, inhibitors of this enzyme system, notably oral antifungal agents, should be used cautiously in patients receiving clonazepam.

Pharmacodynamic Interactions:

The CNS-depressant action of the benzodiazepine class of drugs may be potentiated by alcohol, narcotics, barbiturates, nonbarbiturate hypnotics, antianxiety agents, the phenothiazines, thioxanthene and butyrophenone classes of antipsychotic agents, monoamine oxidase inhibitors and the tricyclic antidepressants, and by other anticonvulsant drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenicity studies have not been conducted with clonazepam.

The data currently available are not sufficient to determine the genotoxic potential of clonazepam.

In a two-generation fertility study in which clonazepam was given orally to rats at 10 and 100 mg/kg/day (low dose approximately 5 times and 24 times the maximum recommended human dose of 20 mg/day for seizure disorder and 4 mg/day for panic disorder, respectively, on a mg/m2 basis), there was a decrease in the number of pregnancies and in the number of offspring surviving until weaning.

4.6 Pregnancy and lactation

Teratogenic Effects:
Pregnancy Category D.

Nursing Mothers:
Mothers receiving clonazepam should not breastfeed their infants.

Pediatric Use:
Because of the possibility that adverse effects on physical or mental development could become apparent only after many years, a benefit-risk consideration of the long-term use of clonazepam is important in pediatric patients being treated for seizure disorder.

Safety and effectiveness in pediatric patients with panic disorder below the age of 18 have not been established.

Geriatric Use:
Clinical studies of clonazepam did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Because clonazepam undergoes hepatic metabolism, it is possible that liver disease will impair clonazepam elimination. Metabolites of clonazepam are excreted by the kidneys; to avoid their excess accumulation, caution should be exercised in the administration of the drug to patients with impaired renal function. Because elderly patients are more likely to have decreased hepatic and/or renal function, care should be taken in dose selection, and it may be useful to assess hepatic and/or renal function at the time of dose selection.

Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of clonazepam and observed closely.

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4.7 Effects on ability to drive and use machines

Patients receiving Clonazepam Tablets USP 2 mg (Coclam Tablets 2 mg) should be cautioned against engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle. Sedation, amnesia and impaired muscular function are effects of benzodiazpines that can adversely affect the ability to drive or operate machinery. This effect is increased if the patient has had alcohol.

Driving, operating machinery and other hazardous activities should be avoided altogether or at least during the first few days of treatment. The decision on this question rests with the patient's physician and should be based on the patient's response to treatment and the dosage involved. They also should be warned against the concomitant use of alcohol and other CNS depressant drugs.

4.8 Undesirable effects

The adverse experiences for clonazepam are provided separately for patients with seizure disorders and with panic disorder.

Seizure Disorders: The most frequently occurring side effects of clonazepam are referable to CNS depression. Experience in treatment of seizures has shown that drowsiness has occurred in approximately 50% of patients and ataxia in approximately 30%. In some cases, these may diminish with time; behavior problems have been noted in approximately 25% of patients. Others, listed by system, are:

Neurologic:
Abnormal eye movements, aphonia, choreiform movements, coma, diplopia, dysarthria, dysdiadochokinesis, 'glassy-eyed' appearance, headache, hemiparesis, hypotonia, nystagmus, respiratory depression, slurred speech, tremor, vertigo

Psychiatric:
Confusion, depression, amnesia, hallucinations, hysteria, increased libido, insomnia, psychosis (the behavior effects are more likely to occur in patients with a history of psychiatric disturbances). The following paradoxical reactions have been observed: excitability, irritability, aggressive behavior, agitation, nervousness, hostility, anxiety, sleep disturbances, nightmares and vivid dreams

Respiratory:
Chest congestion, rhinorrhea, shortness of breath, hypersecretion in upper respiratory passages

Cardiovascular:
Palpitations

Dermatologic:

Hair loss, hirsutism, skin rash, ankle and facial edema
Gastrointestinal:
Anorexia, coated tongue, constipation, diarrhea, dry mouth, encopresis, gastritis, increased appetite, nausea, sore gums

Genitourinary:
Dysuria, enuresis, nocturia, urinary retention

Musculoskeletal:
Muscle weakness, pains

Miscellaneous:
Dehydration, general deterioration, fever, lymphadenopathy, weight loss or gain

Hematopoietic:
Anemia, leukopenia, thrombocytopenia, eosinophilia

Hepatic:
Hepatomegaly, transient elevations of serum transaminases and alkaline phosphatase

4.9 Overdose

Human Experience:
Symptoms of clonazepam overdosage, like those produced by other CNS depressants, include somnolence, confusion, coma and diminished reflexes.

Overdose Management:
Treatment includes monitoring of respiration, pulse and blood pressure, general supportive measures and immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. Hypotension may be combated by the use of levarterenol or metaraminol. Dialysis is of no known value.

Flumazenil, a specific benzodiazepine-receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines and may be used in situations when an overdose with a benzodiazepine is known or suspected. Prior to the administration of flumazenil, necessary measures should be instituted to secure airway, ventilation and intravenous access. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for resedation, respiratory depression and other residual benzodiazepine effects for an appropriate period after treatment.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The precise mechanism by which clonazepam exerts its antiseizure and antipanic effects is unknown, although it is believed to be related to its ability to enhance the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. Convulsions produced in rodents by pentylenetetrazol or, to a lesser extent, electrical stimulation are antagonized, as are convulsions produced by photic stimulation in susceptible baboons. A taming effect in aggressive primates, muscle weakness and hypnosis are also produced. In humans, clonazepam is capable of suppressing the spike and wave discharge in absence seizures (petit mal) and decreasing the frequency, amplitude, duration and spread of discharge in minor motor seizures.

5.2 Pharmacokinetic properties

Clonazepam is rapidly and completely absorbed after oral administration. The absolute bioavailability of clonazepam is about 90%. Maximum plasma concentrations of clonazepam are reached within 1 to 4 hours after oral administration. Clonazepam is approximately 85% bound to plasma proteins. Clonazepam is highly metabolized, with less than 2% unchanged clonazepam being excreted in the urine. Biotransformation occurs mainly by reduction of the 7-nitro group to the 4-amino derivative. This derivative can be acetylated, hydroxylated and glucuronidated. Cytochrome P-450 including CYP3A, may play an important role in clonazepam reduction and oxidation. The elimination half-life of clonazepam is typically 30 to 40 hours. Clonazepam pharmacokinetics are dose-independent throughout the dosing range. There is no evidence that clonazepam induces its own metabolism or that of other drugs in humans.

5.3 Preclinical safety data

Carcinogenicity:

No 2-year carcinogenicity studies have been conducted with clonazepam. However, in an 18-month chronic study in rats no treatment-related histopathological changes were seen up to the highest tested dose of 300 mg/kg/day.

Mutagenicity:

Genotoxicity tests using bacterial systems with *in vitro* or host mediated metabolic activation did not indicate a genotoxic liability for clonazepam.

Impairment of Fertility:

Studies assessing fertility and general reproductive performance in rats showed a reduced pregnancy rate and impaired pup survival at doses of 10 and 100 mg/kg/day.

Teratogenicity:

No adverse maternal or embryo-fetal effects were observed in either mice or rats following administration of oral clonazepam during organogenesis, at doses of up to 20 or 40 mg/kg/day, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate BP, Microcrystalline cellulose BP, Pregelatinised starch USP, Magnesium Stearate BP, Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

10 Tablets are packed in Alu-PVDC Amber blister. Such 3 blisters are then packed in well printed carton alongwith a pack insert

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Centaur Pharmaceuticals Pvt. Ltd.
Plant: I, Plot No 3, 5B,2C, Tivim Industrial Estate, Karaswada, Mapusa, Goa-403526, India

8. MARKETING AUTHORISATION NUMBER(S)

158(380)/MFG/DFDA/2009/6999

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02.07.2009

10. DATE OF REVISION OF THE TEXT

Dec 2020.