SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Swamlo 5 (Amlodipine Tablets 5mg)
Swamlo 10 (Amlodipine Tablets 10mg)

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

Swamlo 5 (Amlodipine Tablets 5mg)
Each uncoated tablet contains
Amlodipine Besilate BP equivalent to Amlodipine 5mg

Swamlo 10 (Amlodipine Tablets 10mg)
Each uncoated tablet contains
Amlodipine Besilate BP equivalent to Amlodipine 10mg

For a full list of excipients, see section 6.1.

3.PHARMACEUTICAL FORM

Uncoated Tablets.

Swamlo 5 (Amlodipine Tablets 5mg): White to off white colored, round shaped, biconvex, uncoated tablets with both sides plain.

Swamlo 10 (Amlodipine Tablets 10mg): White to off white colored, round shaped, biconvex, uncoated tablets with both sides plain.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hypertension

Amlodipine Tablets is indicated in the treatment of mild to moderate essential Hypertension Combination of Amlodipine Tablets with a diuretic, a beta-blocking agent, or an angiotensin converting enzyme inhibitor has been found to be compatible and showed additive antihypertensive effect.

Chronic Stable Angina

Amlodipine tablets are indicated for the management of chronic stable angina (effort-associated angina) in patients who remain symptomatic despite adequate doses of beta-blockers and/or organic nitrates or who cannot tolerate those agents.
Amlodipine tablets may be tried in combination with beta-blockers in chronic stable angina in patients with normal ventricular function. When such

concomitant therapy is introduced, care must be taken to monitor blood pressure closely since hypotension can occur from the combined effects of the drugs.

Vasospastic Angina (Prinzmetal's or Variant Angina)
Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy or in combination with other antianginal agents.

4.2 Posology and Method of

Administration Posology
Adults
For both hypertension and angina the usual initial dose is 5 mg Amlodipine tablets once daily which may be increased to a maximum dose of 10 mg depending on the individual patient's response.
In hypertensive patients, Amlodipine tablets has been used in combination with a thiazide diuretic, alpha blocker, beta blocker, or an angiotensin converting enzyme inhibitor. For angina, Amlodipine tablets may be used as monotherapy or in combination with other antianginal medicinal products in patients with angina that is refractory to nitrates and/or to adequate doses of beta blockers.
No dose adjustment of Amlodipine tablets is required upon concomitant administration of thiazide diuretics, beta blockers, and angiotensin-converting enzyme inhibitors.

Special populations
Elderly patients
Amlodipine tablets used at similar doses in elderly or younger patients is equally well tolerated. Normal dosage regimens are recommended in the elderly, but increase of the dosage should take place with care.

Patients with hepatic impairment
Dosage recommendations have not been established in patients with mild to moderate hepatic impairment; therefore dose selection should be cautious and should start at the lower end of the dosing range. The pharmacokinetics of amlodipine have not been studied in severe hepatic impairment. Amlodipine should be initiated at the lowest dose 2.5mg and titrated slowly in patients with severe hepatic impairment.

Patients with renal impairment
Changes in amlodipine plasma concentrations are not correlated with degree of renal impairment, therefore the normal dosage is recommended. Amlodipine is not dialysable.

Paediatric population
Children and adolescents with hypertension from 6 years to 17 years of age. The recommended antihypertensive oral dose in paediatric patient's ages 6-17 years is 2.5 mg once daily as a starting dose, up-titrated to 5 mg once daily if blood pressure goal is not achieved after 4 weeks. Doses in excess of 5 mg daily have not been studied in paediatric patients.

Children under 6 years old
No data are available.

Method of Administration:
Tablet for oral administration. The tablets should be taken with a glass of water independently from meals.

4.3 Contra-indications

Amlodipine is contraindicated in patients with:
- hypersensitivity to dihydropyridine derivatives, amlodipine or to any of the excipients
- severe hypotension (less than 90 mmHg systolic)
- shock (including cardiogenic shock).
- obstruction of the outflow tract of the left ventricle (e.g., high grade aortic stenosis).
- haemodynamically unstable heart failure after acute myocardial infarction.

4.4 Special Warnings and

Precautions for Use General
Beta-blocker withdrawal: Amlodipine tablets gives no protection against the dangers of abrupt beta-blocker withdrawal and such withdrawal should be done by the gradual reduction of the dose of beta-blocker.

Cardiovascular
Increased Angina and/or Myocardial Infarction: Rarely, patients, particularly those with Severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. The mechanism of this effect has not been elucidated

Outflow Obstruction (Aortic Stenosis): Amlodipine tablets should be used with caution in a presence of fixed left ventricular outflow obstruction (aortic

stenosis).

Use in Patients With Congestive Heart Failure: Although generally calcium channel blockers should only be used with caution in patients with heart failure, it has been observed that Amlodipine tablets had no overall deleterious effect on survival and cardiovascular morbidity in both short-term and long-term clinical trials in these patients. While a significant proportion of the patients in these studies had a history of ischemic heart disease, angina or hypertension, the studies were not designed to evaluate the treatment of angina or hypertension in patients
with concomitant heart failure.
In a long-term, placebo controlled study in patients with severe heart failure (NYHA class III and IV) the reported incidence of pulmonary oedema was higher in the amlodipine treated group than in the placebo group. Hence patients with heart failure should be treated with caution.

Hypotension: Amlodipine tablets may occasionally precipitate symptomatic hypotension. Careful monitoring of blood pressure is recommended, especially in patients with a history of cerebrovascular insufficiency, and those taking medications known to lower blood pressure.

Peripheral Edema: Mild to moderate peripheral edema was the most common adverse event in the clinical trials. The incidence of peripheral edema was dose dependent and ranged in frequency from 3.0 to 10.8% in 5 to 10 mg dose range. Care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Hepatic/Biliary/Pancreatic
Use in Patients with Impaired Hepatic Function: There are no adequate studies in patients with liver dysfunction and dosage recommendations have not been established.
In a small number of patients with mild to moderate hepatic impairment given single dose of 5 mg, amlodipine half-life has been prolonged. Amlodipine should therefore be initiated at the lower end of the dosing range and caution should be used in these patients, both on initial treatment and when increasing the dose.

Patients with severe hepatic impairment or hepatic failure:
Because Amlodipine tablets is extensively metabolized by the liver and the plasma elimination half-life (t 1/2) is 56 hours in patients with impaired hepatic function, it should be administered cautiously and at reduced dosages in patients with severely impaired hepatic function. Slow dose titration and careful monitoring are required in patients with severe hepatic impairment.

Concomitant Use with Strong Inhibitors of CYP 3A4:
Use of Amlodipine tablets with drugs that result in strong inhibition of CYP 3A4, such as ketoconazole, clarithromycin, ritonavir, may lead to increased plasma levels of amlodipine and associated serious events. Such concomitant use should be avoided.
An observational study demonstrated an increased risk of hospitalization with acute kidney injury when amlodipine was used concomitantly with clarithromycin in elderly patients (>65 years of age) compared to when it was used concomitantly with azithromycin, odds ratio[amlodipine: 1.61 (95% C.I. 1.29-2.02)].

Special Populations
Pregnant Women: Although amlodipine was not teratogenic in the rat and rabbit some dihydropyridine compounds have been found to be teratogenic in animals. In rats, Amlodipine has been shown to prolong both the gestation period and the duration of labor. There was no effect on the fertility of rats treated with amlodipine. There is no clinical experience with Amlodipine tablets in pregnant women. Amlodipine tablets should be used during

pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus. **Nursing Women:** It is not known whether amlodipine is excreted in human milk. Since amlodipine safety in newborns has not been established, Amlodipine tablets should not be given to nursing mothers.

Pediatrics (< 6 years of age): The use of Amlodipine tablets is not recommended in patients less than 6 years of age since safety and efficacy have not been established in that population. Pediatric safety and efficacy studies beyond 8 weeks of duration have not been conducted.
The effect of Amlodipine tablets on blood pressure in patients less than 6 years of age is not known. The pediatric administration should be based on a careful risk/benefit assessment of the limited available information. The risk/benefit assessment should be conducted by a qualified physician.

Geriatrics: In elderly patients (≥65 years) clearance of amlodipine is decreased with a resulting increase in AUC. In clinical trials the incidence of adverse reactions in elderly patients was approximately 6% higher than that of younger population (<65 years). Adverse reactions include edema, muscle cramps and dizziness. Amlodipine tablets should be used cautiously in elderly patients. Dosage adjustment is advisable.

Patients with renal impairment
Amlodipine may be used in such patients at normal doses. Changes in amlodipine plasma concentrations are not correlated with degree of renal

impairment. Amlodipine is not dialysable.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction Effects of other medicinal products on amlodipine

CYP3A4 inhibitors

Concomitant use of amlodipine with strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides like erythromycin or clarithromycin, verapamil or diltiazem) may give rise to significant increase in amlodipine exposure resulting in an increased risk of hypotension. The clinical translation of these PK variations may be more pronounced in the elderly. Clinical monitoring and dose adjustment may thus be required.

CYP3A4 inducers

There is no data available regarding the effect of CYP3A4 inducers on amlodipine. The concomitant use of CYP3A4 inducers (e.g., rifampicin, hypericum perforatum) may give a lower plasma concentration of amlodipine. Amlodipine should be used with caution together with CYP3A4 inducers.

Administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects.

Dantrolene (infusion)

In animals, lethal ventricular fibrillation and cardiovascular collapse are observed in association with hyperkalemia after administration of verapamil and intravenous dantrolene. Due to risk of hyperkalemia, it is recommended that the co-administration of calcium channel blockers such as amlodipine be avoided in patients susceptible to malignant hyperthermia and in the management of malignant hyperthermia.

Effects of amlodipine on other medicinal products

The blood pressure lowering effects of amlodipine adds to the blood pressure-lowering effects of other medicinal products with antihypertensive properties.

Tacrolimus

There is a risk of increased tacrolimus blood levels when co-administered with amlodipine but the pharmacokinetic mechanism of this interaction is not fully understood. In order to avoid toxicity of tacrolimus, administration of amlodipine in a patient treated with tacrolimus requires monitoring of tacrolimus blood levels and dose adjustment of tacrolimus when appropriate.

Mechanistic Target of Rapamycin (mTOR) Inhibitors
mTOR inhibitors such as sirolimus, temsirolimus, and everolimus are CYP3A substrates. Amlodipine is a weak CYP3A inhibitor. With concomitant use of mTOR inhibitors, amlodipine may increase exposure of mTOR inhibitors.

Cyclosporine
No drug interaction studies have been conducted with cyclosporine and amlodipine in healthy volunteers or other populations with the exception of renal transplant patients, where variable trough concentration increases (average 0% - 40%) of cyclosporine were observed. Consideration should be given for monitoring cyclosporine levels in renal transplant patients on amlodipine, and cyclosporine dose reductions should be made as necessary.

Simvastatin
Co-administration of multiple doses of 10 mg of amlodipine with 80 mg simvastatin resulted in a 77% increase in exposure to simvastatin compared to simvastatin alone. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.
In clinical interaction studies, amlodipine did not affect the pharmacokinetics of atorvastatin, digoxin or warfarin.

4.6 Fertility, Pregnancy and Lactation Pregnancy
The safety of amlodipine in human pregnancy has not been established. In animal studies, reproductive toxicity was observed at high doses. Use in pregnancy is only recommended when there is no safer alternative and when the disease itself carries greater risk for the mother and foetus.

Breast-feeding
It is not known whether amlodipine is excreted in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with amlodipine should be made taking into account the benefit of breast-feeding to the child and the benefit of amlodipine therapy to the mother.

Fertility
Reversible biochemical changes in the head of spermatozoa have been reported in some patients treated by calcium channel blockers. Clinical data are insufficient regarding the potential effect of amlodipine on fertility. In one rat study, adverse effects were found on male fertility.

4.7 Effects on Ability to Drive and Use Machines

Amlodipine can have minor or moderate influence on the ability to drive and use

machines. If patients taking Amlodipine suffer from dizziness, headache, fatigue or nausea the ability to react may be impaired. Caution is recommended especially at the start of treatment.

4.8 Undesirable Effects

The following adverse reactions have been observed and reported during treatment with amlodipine with the following frequencies: 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) ; not known (cannot be estimated from the available data).
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Blood and lymphatic system disorders
Very rare: Leukocytopenia, thrombocytopenia

Immune system disorders
Very rare: Allergic reactions

Metabolism and nutrition disorders
Very rare: Hyperglycaemia

Psychiatric disorders
Uncommon: Depression, mood changes (including anxiety),
insomnia Rare: Confusion

Nervous system disorders
Common: Somnolence, dizziness, headache (especially at the beginning of the treatment) Uncommon: Tremor, dysgeusia, syncope, hypoaesthesia, paraesthesia
Very rare: Hypertonia, peripheral neuropathy

Eye disorders
Common: Visual disturbance (including diplopia)

Ear and labyrinth disorders
Uncommon: Tinnitus

Cardiac disorders
Common: Palpitations
Uncommon: Arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation) Very rare: Myocardial infarction

Vascular disorders
Common: Flushing

Uncommon:
Hypotension Very
rare: Vasculitis

Respiratory, thoracic and mediastinal disorders
Common: Dyspnoea
Uncommon: Cough,
rhinitis

Gastrointestinal disorders
Common: Abdominal pain, nausea, dyspepsia, altered bowel habits (including diarrhoea and constipation)
Uncommon: Vomiting, dry mouth
Very rare: Pancreatitis, gastritis, gingival hyperplasia

Hepatobiliary disorders
Very rare: Hepatitis, jaundice, hepatic enzyme increased*

Skin and subcutaneous tissue disorders
Uncommon: Alopecia, purpura, skin discolouration, hyperhidrosis, pruritus, rash, exanthema, urticaria
Very rare: Angioedema, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, Quincke oedema, photosensitivity
Not known: Toxic epidermal necrolysis

Musculoskeletal and connective tissue disorders Common: Ankle swelling, muscle cramps Uncommon: Arthralgia, myalgia, back pain

Renal and urinary disorders
Uncommon: Micturition disorder, nocturia, increased urinary frequency

Reproductive system and breast disorders
Uncommon: Impotence, gynaecomastia

General disorders and administration site conditions
Very common: Oedema
Common: Fatigue,
asthenia
Uncommon: Chest pain, pain, malaise

Investigations
Uncommon: Weight increased, weight decreased

***mostly consistent with cholestasis**

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective national regulatory authorities

4.9. Overdose

In humans experience with intentional overdose is limited.

Symptoms

Available data suggest that gross overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported.

Treatment

Clinically significant hypotension due to amlodipine overdosage calls for active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevation of extremities and attention to circulating fluid volume and urine output.

A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Gastric lavage may be worthwhile in some cases. In healthy volunteers the use of charcoal up to 2 hours after administration of amlodipine 10 mg has been shown to reduce the absorption rate of amlodipine.

Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

5.PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamics Properties

Pharmacotherapeutic group: Calcium channel blockers, selective calcium channel blockers with mainly vascular effects.

ATC Code: C08CA01.

Mechanism of Action

Amlodipine is a calcium ion influx inhibitor (calcium entry blocker or calcium ion antagonist). Amlodipine is a member of the dihydropyridine class of calcium antagonists. The therapeutic effect of this group of drugs is believed to be related to their specific cellular

action of selectively inhibiting transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The contractile processes of these tissues are dependent upon the movement of extracellular calcium ions into

these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Serum calcium concentration is not affected by amlodipine. Within the physiologic pH range, amlodipine is an ionized compound and its kinetic interaction with the calcium channel receptor is characterized by the gradual association and dissociation with the receptor binding site. Experimental data suggest that amlodipine binds to both dihydropyridine and nondihydropyridine binding sites.

A. **Hypertension** The mechanism by which amlodipine reduces arterial blood pressure involves
   -direct peripheral arterial vasodilation and reduction in peripheral vascular resistance.

B. **Angina** The precise mechanism by which amlodipine relieves angina has not been fully delineated. Amlodipine is a dilator of peripheral arteries and arterioles which reduces the total peripheral resistance and, therefore, reduces the workload of the heart (afterload). The unloading of the heart is thought to decrease ischemia and relieve effort angina by reducing myocardial energy oxygen consumption and oxygen requirements.

Pharmacodynamics
Hemodynamics: Following administration of recommended doses to patients with hypertension, amlodipine produces vasodilation resulting in a reduction of supine and standing blood pressures.

These decreases in blood pressure are not accompanied by any significant change in heart rate or plasma catecholamine levels with chronic dosing. With chronic once daily oral administration (5 and 10 mg once daily), antihypertensive effectiveness is maintained throughout the 24 hours dose interval with minimal peak to trough differences in plasma concentration. Since the vasodilation induced by amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration of amlodipine. In normotensive patients with angina amlodipine has not been associated with any clinically significant reductions in blood pressure or changes in heart rate.

Negative inotropic effects have not been observed when amlodipine was administered at the recommended doses to man, but has been demonstrated in animal models. Hemodynamic measurements of cardiac function at rest and during exercise (or pacing) in angina patients with normal ventricular function have generally demonstrated a small increase in cardiac index without significant influence on dP/dt or on left ventricular end diastolic pressure or volume.

In hypertensive patients with normal renal function, therapeutic doses of amlodipine resulted in a decrease in renal vascular resistance and an increase in glomerular filtration rate and effective renal plasma flow without change in filtration fraction.

Electrophysiologic Effects: Amlodipine does not change sinoatrial nodal function or atrioventricular conduction in intact animals, or man. In patients with chronic stable angina, intravenous administration of 10 mg of amlodipine and a further 10 mg of amlodipine after a 30 min. interval produced peripheral vasodilation and afterload reduction, but did not significantly alter A-H and H-V conduction and sinus node recovery time after pacing.

Similar results were obtained in patients receiving amlodipine and concomitant betablockers. In clinical studies in which amlodipine was administered in combination with beta-blockers to patients with either hypertension or angina, no adverse effects on electrocardiographic arameters were observed. In clinical trials with angina patients, amlodipine as monotherapy did not alter electrocardiographic intervals.

Effects in Hypertension:

Pediatric Patients

Two hundred sixty-eight hypertensive patients aged 6 to 17 years were randomized first to Amlodipine Tablets 2.5 or 5 mg once daily for 4 weeks and then randomized again to the same dose or to placebo for another 4 weeks. Patients receiving 5 mg at the end of 8 weeks had lower blood pressure than those secondarily randomized to placebo. The magnitude of the treatment effect is difficult to interpret, but it is probably less than 5 mmHg systolic on the 5 mg dose. Adverse events were similar to those seen in adults.

Pediatric safety and efficacy studies beyond 8 weeks of duration have not been conducted. In addition, the long-term effect of amlodipine on growth and development, myocardial growth and vascular smooth muscles has not been studied.

5.2 Pharmacokinetic properties:

Absorption, distribution, plasma protein binding*:* After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. The volume of distribution is approximately 21 l/kg. *In vitro* studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins. The bioavailability of amlodipine is not affected by food intake.

Biotransformation/elimination

The terminal plasma elimination half-life is about 35-50 hours and is consistent with once daily dosing. Amlodipine is extensively metabolised by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine.

Hepatic impairment
Very limited clinical data are available regarding amlodipine administration in patients with hepatic impairment. Patients with hepatic insufficiency have decreased clearance of amlodipine resulting in a longer half-life and an increase in AUC of approximately 40- 60%.
Elderly population

The time to reach peak plasma concentrations of amlodipine is similar in elderly and younger subjects. Amlodipine clearance tends to be decreased with resulting increases in AUC and elimination half-life in elderly patients. Increases in AUC and elimination half-life in patients with congestive heart failure were as expected for the patient age group studied.

Paediatric population
A population PK study has been conducted in 74 hypertensive children aged from 1 to 17 years (with 34 patients aged 6 to 12 years and 28 patients aged 13 to 17 years) receiving amlodipine between 1.25 and 20 mg given either once or twice daily. In children 6 to 12 years and in adolescents 13-17 years of age the typical oral clearance (CL/F) was 22.5 and 27.4 L/hr respectively in males and 16.4 and 21.3 L/hr respectively in females. Large variability in exposure between individuals was observed. Data reported in children below 6 years is limited.

5.3 Preclinical Safety

Data Reproductive

toxicology
Reproductive studies in rats and mice have shown delayed date of delivery, prolonged duration of labour and decreased pup survival at dosages approximately 50 times greater than the maximum recommended dosage for humans based on mg/kg.

Impairment of fertility
There was no effect on the fertility of rats treated with amlodipine (males for 64 days and females 14 days prior to mating) at doses up to 10 mg/kg/day (8 times* the maximum recommended human dose of 10 mg on a mg/m2 basis). In another rat study in which male rats were treated with amlodipine besilate for 30 days at a dose comparable with the human dose based on mg/kg, decreased plasma follicle-stimulating hormone and testosterone were found as well as decreases in sperm density and in the number of mature spermatids and Sertoli

cells.

Carcinogenesis, mutagenesis
Rats and mice treated with amlodipine in the diet for two years, at concentrations calculated to provide daily dosage levels of 0.5, 1.25, and 2.5 mg/kg/day showed no evidence of carcinogenicity. The highest dose (for mice, similar to, and for rats twice* the maximum recommended clinical dose of 10 mg on a mg/m2 basis) was close to the maximum tolerated dose for mice but not for rats.
Mutagenicity studies revealed no drug related effects at either the gene or chromosome levels.
*Based on patient weight of 50 kg

6.PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Microcrystalline
Cellulose Sodium
Starch Glycolate
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light & moisture.

6.5 Nature and Contents of Container

Available in Blister pack.
Blister pack of Rigid PVC Film, coated with PVdC Pharma Grade (White Opaque, 90gsm) and Aluminium Foil of Hot form Blister.
Such two blisters of 14 tablets each are packed in a carton
along with insert. or
Such two blisters of 10 tablets each are packed in a carton
along with insert. or
Such ten blisters of 10 tablets each are packed in a carton along with insert.

6.6 Special precautions for disposal

No special requirements

Administrative Data

7. MARKETING AUTHORISATION HOLDER
Ind Swift Limited, India

8. MARKETING AUTHORISATION NUMBER
SWAMLO 5 -21469
SWAMLO 10 - H2014/CTD887/507

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10. DATE OF (PARTIAL) REVISION OF THE TEXT