Summary of Product Characteristics for Pharmaceutical Products

1. NAME OF THE MEDICINAL PRODUCT

TRAMAZAC

Tramadol Hydrochloride Capsules 50mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Capsule contains:

Tramadol Hydrochloride BP 50 mg

For full list excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule

Green cap/Green body size '2' locked hard gelatin capsules containing white to off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Management (treatment and prevention) of moderate to severe pain.

4.2 Posology and method of administration

Posology

The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The lowest effective dose for analgesia should generally be selected. The total daily dose of 400mg active substance should not be exceeded, except in special circumstances.

Unless otherwise prescribed Tramadol Capsules should be administered as follows:

Adults and adolescents aged 12 years and over:

Acute pain: An initial dose of 100mg is usually necessary. This can be followed by doses of 50 mg or 100 mg at 4- 6 hourly intervals, and duration of therapy should be matched to clinical need.

Pain associated with chronic conditions:

Use an initial dose of 50mg and then titrate dose according to pain severity. The need for continued treatment should be assessed at regular intervals as withdrawal symptoms and been reported, although rarely (See section 4.4).

Geriatric patients

A dose adjustment is not usually necessary in patients up to 75 years without clinically manifest hepatic or renal insufficiency. In elderly patients over 75 years elimination may be prolonged. Therefore, if necessary, the dosage interval is to be extended according to the patient's requirements.

Renal insufficiency/dialysis and hepatic impairment

In patients with renal and/or hepatic insufficiency the elimination of tramadol is delayed. In these patients' prolongation of the dosage intervals should be carefully considered according to the patient's requirements.

Children:

Tramadol Capsules are not suitable for children below the age of 12 years.

Method of administration

For oral administration.

The capsules are to be taken whole, not divided or chewed, with sufficient liquid, independent of meals.

Duration of administration

Tramadol Capsules should under no circumstances be administered for longer than absolutely necessary. If long-term pain treatment with Tramadol Capsules is necessary in view of the nature and severity of the illness, then careful and regular monitoring should be carried out (if necessary, with breaks in treatment) to establish whether and to what extent further treatment is necessary.

4.3 Contraindications

Tramadol should not be administered to patients who have previously demonstrated hypersensitivity to it, or to any of the ingredients, or in cases of acute intoxication with alcohol, hypnotics, analgesics, opioids or other psychotropic medicinal drugs. In common with other opioid analgesics, it should not be administered to patients who are receiving monoamine oxidase (MAO) inhibitors or within two weeks of their withdrawal (see section 4.5).

Tramadol should not be given to patients suffering from uncontrolled epilepsy. Tramadol must not be used for narcotic withdrawal treatment.

4.4 Special warnings and precautions for use

Tramadol may only be used with particular caution in opioid-dependent patients, patients with head injury, shock, a reduced level of consciousness of uncertain

origin, disorders of the respiratory Centre or function, increased intracranial pressure.

In patients sensitive to opiates the product should only be used with caution.

Concomitant use of Tramadol and sedating medicinal products such as benzodiazepines or related substances, may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedating medicinal products should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Tramadol concomitantly with sedating medicinal products, the lowest effective dose of Tramadol should be used, and the duration of the concomitant treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

Convulsions have been reported in patients receiving tramadol at the recommended dose levels. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg). In addition, tramadol may increase the seizure risk in patients taking other medicinal products that lowers the seizure threshold (see section 4.5). Patients with epilepsy or those susceptible to seizures should be only treated with tramadol if there are compelling circumstances.

Care should be taken when treating patients with respiratory depression, or if concomitant CNS depressant drugs are being administered (see section 4.5), or if the recommended dosage is significantly exceeded (see section 4.9) as the possibility of respiratory depression cannot be excluded in these situations.

Tolerance, psychic and physical dependence may develop, especially after long-term use. In patients with a tendency to drug abuse or dependence, treatment with tramadol should only be carried out for short periods under strict medical supervision.

When a patient no longer requires therapy with tramadol, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

Tramadol is not suitable as a substitute in opioid-dependent patients. Although it is an opioid agonist, tramadol cannot suppress morphine withdrawal symptoms.

CYP2D6 metabolism

Tramadol is metabolized by the liver enzyme CYP2D6. If a patient has a deficiency or is completely lacking this enzyme an adequate analgesic effect may not be

obtained. Estimates indicate that up to 7% of the Caucasian population may have this deficiency. However, if the patient is an ultra-rapid metabolizer there is a risk of developing <side effects> of opioid toxicity even at commonly pre- scribed doses. General symptoms of opioid toxicity include confusion, somnolence, shallow breathing, small pupils, nausea, vomiting, constipation and lack of appetite. In severe cases this may include symptoms of circulatory and respiratory depression, which may be life threatening and very rarely fatal.

Estimates of prevalence of ultra-rapid metabolizers in different populations are summarized below:

Population	**Prevalence %**
African/Ethiopian	29 %
African American	3.4 % to 6.5 %
Asian	1.2 % to 2 %
Caucasian	3.6 % to 6.5 %
Greek	6.0 %
Hungarian	1.9 %
Northern European	1 % to 2 %

Post-operative use in children

There have been reports in the published literature that tramadol given post-operatively in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnea, led to rare, but life-threatening adverse events. Extreme caution should be exercised when tramadol is administered to children for post-operative pain relief and should be accompanied by close monitoring for symptoms of opioid toxicity including respiratory depression.

Children with compromised respiratory function

Tramadol is not recommended for use in children in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma or extensive surgical procedures. These factors may worsen symptoms of opioid toxicity.

When a patient no longer requires therapy with tramadol, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

Precautions

Tramadol should be used with caution in opioid-dependent patients, patients with head injury, a reduced level of consciousness of uncertain origin, increased intracranial pressure, severe impairment of hepatic and renal function, disorders of the respiratory Centre or function and in patients prone to convulsive disorders or in shock.

In patients sensitive to opiates the product should only be used with caution.

Care should be taken when treating patients with respiratory depression, or if concomitant CNS depressant drugs are being administered (see section 4.5), or if the recommended dosage is significantly exceeded (see section 4.9) as the possibility of respiratory depression cannot be excluded in these situations. At therapeutic doses, respiratory depression has infrequently been reported.

Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs:

Concomitant use of Tramadol and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death.

Because of these risks, concomitant pre- scribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Tramadol concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Tramadol should not be combined with MAO inhibitors (see section 4.3).

In patients treated with MAO inhibitors in the 14 days prior to the use of the opioid pethidine, life- threatening interactions on the central nervous system, respiratory and cardiovascular function have been observed. The same interactions with MAO inhibitors cannot be ruled out during treatment with Tramadol.

Concomitant administration of Tramadol with other centrally depressant medicinal products including alcohol may potentiate the CNS effects (see section 4.8).

The concomitant use of opioids with sedating medicinal products such as

benzodiazepines or related substances increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose of Tramadol and the duration of the concomitant use should be limited (see section 4.4)

The results of pharmacokinetic studies have so far shown that on the concomitant or previous administration of cimetidine (enzyme inhibitor) clinically relevant interactions are unlikely to occur. Simultaneous or previous administration of carbamazepine (enzyme inducer) may reduce the analgesic effect and shorten the duration of action.

Tramadol can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, anti- psychotics and other seizure threshold-lowering medicinal product (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.

Concomitant therapeutic use of tramadol and serotonergic drugs, such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors (see section 4.3), tricyclic antidepressants and mirtazapine may cause serotonin toxicity. Serotonin syndrome is likely when one of the following is observed:

• Spontaneous clonus
• Inducible or ocular clonus with agitation or diaphoresis
• Tremor and hyperreflexia
• Hypertonia and body temperature > 38°C and inducible ocular clonus.

Withdrawal of the serotonergic drugs usually brings about a rapid improvement. Treatment depends on the type and severity of the symptoms.

Caution should be exercised during concomitant treatment with tramadol and coumarin derivatives (e.g. warfarin) due to reports of increased INR with major bleeding and ecchymoses in some pa- tients.

Other active substances known to inhibit CYP3A4, such as ketoconazole and erythromycin, might inhibit the metabolism of tramadol (N-demethylation) probably also the metabolism of the active

O-demethylated metabolite. The clinical importance of such an interaction has not been studied (see section 4.8).

In a limited number of studies, the pre- or postoperative application of the antiemetic 5-HT3 antago- nist ondansetron increased the requirement of tramadol

in patients with postoperative pain.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Animal studies with tramadol revealed at very high doses effects on organ development, ossifica- tion and neonatal mortality. Tramadol crosses the placenta. There is inadequate evidence available on the safety of tramadol in human pregnancy, therefore tramadol should not be used in pregnant women.

Tramadol - administered before or during birth - does not affect uterine contractility. In neonates it may induce changes in the respiratory rate which are usually not clinically relevant. Chronic use during pregnancy may lead to neonatal withdrawal symptoms.

Breast-feeding

Approximately 0.1% of the maternal dose of tramadol is excreted in breast milk. In the immediate post-partum period, for maternal oral daily dosage up to 400 mg, this corresponds to a mean amount of tramadol ingested by breast-fed infants of 3% of the maternal weight-adjusted dosage. For this reason, tramadol should not be used during lactation or alternatively, breast-feeding should be discontinued during treatment with tramadol. Discontinuation of breast-feeding is generally not necessary following a single dose of tramadol.

Fertility

Post marketing surveillance does not suggest an effect of tramadol on fertility.

Animal studies did not show an effect of tramadol on fertility.

4.7 Effects on ability to drive and use machines

Even when taken according to instructions, Tramadol may cause drowsiness and dizziness and this effect may be potentiated by alcohol and other central nervous system (CNS) depressants or psychotropic substances. Ambulant patients should be warned not to drive or operate machinery if affected.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine

• However, you would not be committing an offence (called 'statutory defence') if:
- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
- It was not affecting your ability to drive safely.

4.8 Undesirable effects

The most commonly reported adverse reactions are nausea and dizziness, both occurring in more than 10% of patients. The frequencies are defined as follows:
Very common: ≥1/10
Common: ≥1/100, <1/10
Uncommon: ≥1/1000, <1/100
Rare: ≥1/10 000, <1/1000
Very rare: <1/10 000
Not known: cannot be estimated from the available data

Blood and lymphatic system disorders
There have also been cases of blood dyscrasias observed with tramadol treatment, but direct causality has not been confirmed.

Immune system disorders
Rare: hypersensitivity/allergic reactions (e.g. dyspnea, bronchospasm, wheezing, angioneurotic oedema) and anaphylaxis.

Psychiatric disorders:
Rare: sleep disturbance, delirium, anxiety, confusion, nightmares and hallucinations, have been re- ported. Psychic adverse reactions may occur following administration of tramadol which vary individually in intensity and nature (depending on personality and duration of treatment). These include changes in mood (usually elation, occasionally dysphoria), changes in activity (usually suppression, occasionally increase) and changes in cognitive and sensorial capacity (e.g. decision behavior, perception disorders). Dependence may occur.

Dependence: Prolonged administration of tramadol may lead to dependence.
Withdrawal reactions: Symptoms of withdrawal reactions, similar to those occurring during opiate withdrawal, may occur as follows: agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms. Other symptoms that have very rarely been seen with tramadol dis- continuation include: panic attacks, severe anxiety, hallucinations, paranesthesia's, tinnitus

and unusual CNS symptoms (i.e. confusion, delusions, personalization, derealization, paranoia).

Nervous system disorders:

Very common: dizziness

Common: headache and drowsiness (somnolence)

Rare: changes in appetite, paranesthesia, tremor, respiratory depression, involuntary muscle contractions , abnormal coordination. Epileptiform convulsions have been reported occurring mainly after administration of high doses of tramadol or after treatment with drugs which can lower the seizure threshold or themselves induce cerebral convulsions (e.g. anti-depressants or anti-psychotics) (see sections 4.4 and 4.5), syncope.

If the recommended doses are considerably exceeded and other centrally depressant substances are administered concomitantly (see section 4.5), respiratory depression may occur.

Not known: speech disorders

Eye disorders:

Rare: blurred vision, mydriasis, blurred vision.

Cardiac disorders:

Uncommon: cardiovascular regulation (palpitations, tachycardia). These adverse reactions may oc- cur especially on intravenous administration and in patients who are physically stressed.

Rare: bradycardia, hypertension (increase in blood pressure).

Vascular disorders:

Uncommon: cardiovascular regulation (postural hypotension or cardiovascular collapse). These ad- verse reactions may occur especially on intravenous administration and in patients who are physically stressed.

Respiratory, thoracic and mediastinal disorders:

Rare: respiratory depression, dyspnea

If the recommended doses are considerably exceeded and other centrally depressant substances are administered concomitantly (see section 4.5), respiratory depression may occur.

Worsening of asthma has been reported, though a causal relationship has not been established.

Gastrointestinal disorders:

Very common: nausea

Common: vomiting, constipation and dry mouth.

Uncommon: retching; gastrointestinal discomfort (a feeling of pressure in the stomach, bloating), diarrhea

Skin and subcutaneous tissue disorders:

Common: sweating

Uncommon: dermal reactions (e.g. pruritus, rash, urticaria)

Musculoskeletal and connective tissue disorders:

Rare: motorial weakness

Hepatobiliary disorders:

In a few isolated cases an increase in liver enzyme values has been reported in a temporal connection with the therapeutic use of tramadol.

Renal and urinary disorders:

Rare: micturition disorders (difficulty in passing urine, dysuria and urinary retention)

Metabolism and nutrition disorders:

Not known: hypoglycemia

General disorders and administration site conditions:

Common: fatigue

Reporting of suspected adverse reactions.
Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org '

4.9 Overdose

Symptoms

In principle, on intoxication with tramadol symptoms similar to those of other centrally acting analgesics (opioids), are to be expected. These include in particular miosis, vomiting, cardiovascular collapse, sedation and consciousness disorders up to coma, seizures and respiratory depression up to respiratory arrest.

Treatment

The general emergency measures apply. Keep open the respiratory tract (aspiration), maintain respiration and circulation depending on the symptoms. The antidote for respiratory depression is naloxone. In animal experiments naloxone had no effect on convulsions. In such cases diazepam should be given intravenously.

In case of intoxication orally, gastrointestinal decontamination with activated charcoal or by gastric lavage is only recommended within 2 hours after tramadol intake. Gastrointestinal decontamination at a later time point may be useful in case of intoxication with exceptionally large quantities.

Tramadol is minimally eliminated from the serum by hemodialysis or haemo filtration. Therefore, treatment of acute intoxication with Tramadol with hemodialysis or hemofiltration alone is not suitable for detoxification.

Drug dependence

Repeated use of Tramadol can lead to drug dependence, even at therapeutic doses. The risk of drug dependence may vary depending on a patient's individual risk factors, dosage, and duration of opioid treatment (see section 4.4).

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other opioids, ATC code: N02AX02

Tramadol, a cyclohexanol derivative, is a centrally acting opioid analgesic. It is a non-selective pure agonist at μ, δ and κ opioid receptors with a higher affinity for the μ receptor. Other mechanisms which contribute to its analgesic effect are inhibition of neuronal reuptake of noradrenaline and enhancement of serotonin release.

Tramadol also has an antitussive effect. In contrast to morphine, analgesic doses of tramadol over a wide range have no respiratory depressant effect. Also, gastrointestinal motility is less affected.

Effects on the cardiovascular system tend to be slight. The potency of tramadol is reported to be 1/10 (one tenth) to 1/6 (one sixth) that of morphine.

Pediatric population

Effects of enteral and parenteral administration of tramadol have been investigated in clinical trials involving more than 2000 pediatric patients ranging in age from neonate to 17 years of age. The indications for pain treatment studied in those trials included pain after surgery (mainly abdominal), after surgical tooth extractions, due to fractures, burns and traumas as well as other painful conditions likely to require analgesic treatment for at least 7 days.

At single doses of up to 2 mg/kg or multiple doses of up to 8 mg/kg per day (to a maximum of 400 mg per day) efficacy of tramadol was found to be superior to placebo, and superior or equal to paracetamol, nalbuphine, pethidine or low dose

morphine. The conducted trials confirmed the efficacy of tramadol. The safety profile of tramadol was similar in adult and pediatric patients older than 1 year (see section 4.2).

5.2 Pharmacokinetic properties

More than 90% of Tramadol is absorbed after oral administration. The mean absolute bioavailability is approximately 70%, irrespective of the concomitant intake of food. The difference between absorbed and non-metabolized available tramadol is probably due to the low first-pass effect. The first-pass effect after oral administration is a maximum of 30%.

Tramadol has a high tissue affinity (V d,ß = 203 ± 40 l). It has a plasma protein binding of about 20

%.

Following a single oral dose administration of tramadol 100 mg as capsules or tablets to young healthy volunteers, plasma concentrations were detectable within approximately 15 to 45 minutes within a mean C_{max} of 280 to 208 mcg/L and T_{max} of 1.6 to 2h.

Tramadol passes the blood-brain and placental barriers. Very small amounts of the substance and its O-desmethyl derivative are found in the breast-milk (0.1 % and 0.02 % respectively of the applied dose).

Elimination half-life t1/2,ß is approximately 6 h, irrespective of the mode of administration. In patients above 75 years of age it may be prolonged by a factor of approximately 1.4.

In humans' tramadol is mainly metabolized by means of N- and O-demethylation and conjugation of the O-demethylation products with glucuronic acid. Only O-desmethyltramadol is pharmacologically active. There are considerable interindividual quantitative differences between the other metabolites. So far, eleven metabolites have been found in the urine. Animal experiments have shown that O-desmethyltramadol is more potent than the parent substance by the factor 2 - 4. Its half-life t1/2,ß (6 healthy volunteers) is 7.9 h (range 5.4 - 9.6 h) and is approximately that of tramadol.

The inhibition of one or both types of the isoenzymes CYP3A4 and CYP2D6 involved in the bio- transformation of tramadol may affect the plasma concentration of tramadol or its active metabolite. Tramadol and its metabolites are almost completely excreted via the kidneys. Cumulative urinary excretion is 90 % of the total radioactivity of the administered dose. In cases of impaired hepatic

and renal function the half-life may be slightly prolonged. In patients with cirrhosis of the liver, elimination half-lives of 13.3 ± 4.9 h (tramadol) and 18.5 ± 9.4 h (Desmethyltramadol), in an extreme case 22.3 h and 36 h respectively, have been determined. In patients with renal insufficiency (creatinine clearance < 5 ml/min) the values were 11 ± 3.2 h and 16.9 ± 3 h, in an extreme case 19.5 h and 43.2 h respectively.

Tramadol has a linear pharmacokinetic profile within the therapeutic dosage range. The relationship between serum concentrations and the analgesic effect is dose-dependent, but varies considerably in isolated cases. A serum concentration of 100 - 300 ng/ml is usually effective.

Pediatric population

The pharmacokinetics of tramadol and O-desmethyltramadol after single-dose and multiple-dose oral administration to subjects aged 1 year to 16 years were found to be generally similar to those in adults when adjusting for dose by body weight, but with a higher between-subject variability in children aged 8 years and below.

In children below 1 year of age, the pharmacokinetics of tramadol and O-desmethyltramadol have been investigated, but have not been fully characterized. Information from studies including this age group indicates that the formation rate of O-desmethyltramadol via CYP2D6 increases continuously in neonates, and adult levels of CYP2D6 activity are assumed to be reached at about 1 year of age. In addition, immature glucuronidation systems and immature renal function may result in slow elimination and accumulation of O-desmethyltramadol in children under 1 year of age.

5.3 Preclinical safety data

On repeated oral and parenteral administration of tramadol for 6 - 26 weeks in rats and dogs and oral administration for 12 months in dogs hematological, clinic-chemical and histological investigation showed no evidence of any substance-related changes. Central nervous manifestations only occurred after high doses considerably above the therapeutic range: restlessness, salivation, convulsions, and reduced weight gain. Rats and dogs tolerated oral doses of 20 mg/kg and 10 mg/kg body weight respectively, and dogs rectal doses of 20 mg/kg body weight without any reactions.

In rats' tramadol dosages from 50 mg/kg/day upwards caused toxic effects in dams and raised neonate mortality. In the offspring retardation occurred in the form of

ossification disorders and delayed vaginal and eye opening. Male fertility was not affected. After higher doses (from 50 mg/kg/day upwards) females exhibited a reduced pregnancy rate. In rabbits there were toxic effects in dams from 125 mg/kg upwards and skeletal anomalies in the offspring.

In some in-vitro test systems there was evidence of mutagenic effects. In-vivo studies showed no such effects. According to knowledge gained so far, tramadol can be classified as non-mutagenic.

Studies on the tumorigenic potential of tramadol hydrochloride have been carried out in rats and mice. The study in rats showed no evidence of any substance-related increase in the incidence of tumors. In the study in mice there was an increased incidence of liver cell adenomas in male animals (a dose-dependent, non-significant increase from 15 mg/kg upwards) and an increase in pulmonary tumors in females of all dosage groups (significant, but not dose-dependent).

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

The following excipients are contained in each capsule as

indicated: Dibasic calcium phosphate
Magnesium stearate
Microcrystalline cellulose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25^0C.

6.5 Nature and contents of container

Alu-PVC blister pack of 10‘s

Pack Size: 10x10 Capsules

6.6 Special precautions for disposal and other handling

No special requirements.

7.0. Marketing Authorization Holder.

Cadila Healthcare Limited
Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Ahmedabad, Gujarat, India

8.0 Marketing authorization number(s)

H2008/18848/103

9.0 Date of first authorization/renewal of the authorization

20/01/2026

10.0 Date of revision of the text

20/01/2026

8.0 MANUFACTURER

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9.0 DATE OF REVISION OF THE TEXT

To be stated at the time of printing once a change to the SPC has been approved.