SUMMARYOFPRODUCTCHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tramadol Hydrochloride 50mg Dispersible Tablets (T DOL RAPID)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg tramadol hydrochloride.

Excipients with known effect:Lactose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Uncoated dispersible tablets.

White, round shaped, flat face, beveled edge, uncoated tablets with plain on one side and break line on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of moderate to severe pain.

4.2 Posology and method of administration

Posology

The dose of tramadol 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.

Dose for adults and adolescents from 12 years of age

For oral use:

Acute pain:

An initial dose is 50 - 100 mg depending on the intensity of pain. This can be followed by doses of 50 or 100 mg not more frequently than 4 hourly, and duration of therapy should be matched to clinical need. A total daily dose of 400 mg should not be exceeded except in special clinical circumstances.

Pain associated with chronic conditions:

Use an initial dose of 50 mg and then titrate dose according to pain severity. The initial dose may be followed if necessary by 50 - 100 mg every 4 to 6 hours. The recommended doses are intended as a guideline. Patients should always receive the lowest dose that provides effective pain control. A total daily dose of 400 mg should not be exceeded except in special clinical circumstances. The need for continued treatment should be assessed at regular intervals.

Pediatric population:

Tramadol Hydrochloride 50 mg Tablets should not be used in children under 12 years of age since safety and efficacy have not been established.

Elderly people:

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

Patients with renal or 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.

In patients with severe renal and/or hepatic impairment, the use of Tramadol Hydrochloride 50mgtablets is not recommended.

As tramadol is only removed very slowly by haemodialysis or haemofiltration, post-dialysis administration to maintain analgesia is not usually necessary.

Method of administration

The tablet disperses rapidly in the mouth and is then swallowed. Alternatively, the tablet can be dispersed in half a glass of water, stirred and drunk immediately independently of meals.

4.3 Contraindications

Tramadol Hydrochloride 50mg tablets must not be administered to patients who have previously demonstrated hypersensitivity to the active substance or any of the excipients.

The product must not be administered to patients suffering from acute intoxication or overdose with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic drugs.

In common with other opioid analgesics it must not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal. It must not be administered concomitantly with nalbuphine, buprenorphine or pentazocine (see 4.5, interactions with other medicinal products and other forms of interaction).

Contraindicated in patients suffering from uncontrolled epilepsy.

Tramadol must not be administered during breast-feeding if long term treatment is necessary.

Tramadol Hydrochloride 50mg tablets are not suitable for children under 12 years of age.

4.4 Special warnings and precautions for use

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

Concomitant prescribing 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 Hydrochloride 50mg tablets 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).

Risk of tolerance, dependence and withdrawal symptoms:

At therapeutic doses, prescribe Tramadol Hydrochloride 50mg tablets has the potential to cause withdrawal symptoms. Rarely cases of dependence and abuse have been reported. However, Tramadol should only be used for short periods and under strict medical supervision in patients with a tendency of drug abuse or dependence.

Tolerance, psychic and physical dependence may develop, especially after long-term use.

At therapeutic doses withdrawal symptoms have been reported at a reporting frequency of 1 in 8,000. Reports of dependence and abuse have been less frequent. Because of this potential the clinical need for continued analgesic treatment should be reviewed regularly. In patients with a tendency to drug abuse or dependence, treatment should be for short periods and under strict medical supervision.

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

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

Serotonin syndrome

Serotonin syndrome, a potentially life-threatening condition, has been reported in patients receiving tramadol in combination with other serotonergic medicinal products or tramadol alone (see sections 4.5, 4.8 and 4.9).

If concomitant treatment with other serotonergic medicinal products is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose escalations.

Symptoms of serotonin syndrome may include mental status changes, autonomic instability, neuromuscular abnormalities and/or gastrointestinal symptoms.

If serotonin syndrome is suspected, a dose reduction or discontinuation of therapy should beconsidered depending on the severity of the symptoms. Withdrawal of the serotonergic drugsusually brings about a rapid improvement.

CYP2D6 metabolism

Tramadol is metabolised 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 metaboliser there is a risk of developing side effects of opioid toxicity even at commonly prescribed doses.

Symptoms of circulatory and respiratory depression, which may be life threatening and very rarely fatal. Estimates of prevalence of ultra-rapid metabolisers in different populations are summarised below:

Population	Prevalence %
African/Ethiopian	29%

Afro-American	3.4% - 6.5%
Asian	1.2% - 2%
Caucasian	3.6% - 6.5%
Greek	6.0%
Hungarian	1.9%
Northern European	1% - 2%

Sleep-Related Breathing Disorders

Opioids can cause sleep-related breathing disorders, including central sleep apnea (CSA) and sleep- related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.

Adrenal insufficiency

Opioid analgesics may occasionally cause reversible adrenal insufficiency requiring monitoring and glucocorticoid replacement therapy. Symptoms of acute or chronic adrenal insufficiency may include e.g. severe abdominal pain, nausea and vomiting, low blood pressure, extreme fatigue, decreased appetite, and weight loss.

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 apnoea, 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 impairment

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.

Alcohol intake and concomitant use of carbamazepine are not recommended during treatment.

Precautions:

Tramadol should be used with caution in patients with head injury, increased intracranial pressure, impairment of hepatic and renal function, decreased level of consciousness and in patients prone to convulsive disorders or in shock.

Susceptible to seizures should only be treated with tramadol if there are compelling reasons. The risk of convulsions may increase in patients taking tramadol and concomitant medication that can lower the seizure threshold (see section 4.5 Interaction with other medicinal products and other forms of interaction).

At the recommended doses Tramadol is unlikely to produce clinically relevant respiratory depression. However, care should be taken when treating patients with existing respiratory depression, or excessive bronchial secretion and in those patients taking concomitant CNS depressant drugs.

Excipients

T DOL Rapid contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of the following is contraindicated:

Patients treated with monoamine oxidase inhibitors within 14 days prior to the administration of the opioid pethidine have experienced life-threatening interactions affecting the central nervous system as well as the respiratory and circulatory centres (risk of serotonergic syndrome – see below). The possibility of similar interactions occurring between monoamine oxidase inhibitors (including the selective MAO-A and -B inhibitors and linezolid) and tramadol cannot be ruled out.

The combination of mixed agonists/antagonists (e.g. buprenorphine, nalbuphine, pentazocine) and tramadol is not recommended because it is theoretically possible that the analgesic effect of a pure agonist is attenuated under these circumstances and that a withdrawal syndrome may occur.

Sedatives such as benzodiazepines or related drugs:

The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

Concomitant therapeutic use of tramadol and serotonergic agents 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 syndrome, a potentially life-threatening condition (see sections 4.4 and 4.8).

Concomitant administration of Tramadol with other centrally acting drugs (including other opioid derivatives, benzodiazepines, barbiturates, other anxiolytics, hypnotics, sedative anti-depressants,sedative anti-histamines, neuroleptics, centrally acting anti-hypotensive drugs, baclofen and alcohol) may potentiate CNS depressant effects including respiratory depression.

Simultaneous administration of carbamazepine markedly decreases serum concentrations of tramadol to an extent that a decrease in analgesic effectiveness and a shorter duration of action may occur.

Tramadol can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), antipsychotics and other seizure-threshold lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions (see sections 4.4 Special warnings and special precautions for use and 5.2 Pharmacokinetic properties).

There have been isolated reports of interaction with coumarin anticoagulants resulting in an increased international normalised ratio (INR) and so care should be taken when commencing treatment with tramadol in patients on anticoagulants.

In a limited number of studies the pre- or postoperative application of the antiemetic 5-HT3 antagonist ondansetron increased the requirement of tramadol in patients with postoperative pain.

4.6 Fertility, pregnancy and lactation

Pregnancy:

In humans, there are no sufficient data to assess malformative effect of tramadol when given during the first trimester of pregnancy. Animal studies have not shown any teratogenic effects, but at high doses, foetotoxicity due to maternotoxicity appeared (See 5.3 Preclinical data).

Tramadol crosses the placenta, therefore as with other opioid analgesics, chronic use of tramadol during the third trimester may induce a withdrawal syndrome in new-born. At the end of pregnancy, high dosages, even for short term treatment, may induce respiratory depression in new-born. There is inadequate evidence available on the safety of tramadol in human pregnancy, therefore Tramadol should not be used in pregnant woman.

Breastfeeding:

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.

4.7 Effects on ability to drive and use machines

Tramadol Hydrochloride may cause drowsiness and this effect may be potentiated by alcohol and other CNS depressants. 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 table below presents possible adverse drug reactions in system organ class order and sorted by frequency.

OrganSystem	**Frequency**	**Adversedrugreaction**
Immunesystemdisorders	***Rare (>1/10.000, <1/1.000)***	- allergic reactions (e.g. dyspnoea,bronchospasm,wh

		eezing,angioneuroticoedema) and anaphylaxis.
Metabolism and Nutritional disorders	***Rare*** ***(>1/10.000, <1/1.000)***	- changes in appetite.
	Frequency not known *(cannot be estimated from the available data)*	-hypoglycaemia, hyponatremia
Psychiatric disorders	***Rare*** ***(>1/10.000, <1/1.000)***	The following may vary in nature and intensity depending on the individual (see below): - changes in mood (e.g. elation, dysphoria) - changes in activity (e.g. suppression, increase) - change in cognitive and sensorial capacity (e.g. decision behaviour, perception disorders) - hallucinations - confusion - sleep disturbances - nightmares - dependency (see below)
Nervous system disorders	***Very Common*** ***(>1/10)***	- dizziness
	Common ***(>1/100, <1/10)***	- headache - drowsiness
	Rare ***(>1/10.000, <1/1.000)***	- epileptiform convulsions (see below) - paraesthesia - tremor.
	Very rare (including isolated cases) ***(<1/10.000)***	- vertigo
	Frequency not known *(cannot be estimated from the available data)*	serotonin syndrome

Eye disorders	***Rare*** ***(>1/10.000, <1/1.000***	- blurred vision
Cardiac disorders	***Uncommon*** ***(>1/1000, <1/100)***	- cardiovascular regulation (e.g. palpitation, tachycardia, postural hypotension, cardiovascular collapse). These effects may occur especially on intravenous administration and in patients who are physically stressed.
	Rare ***(>1/10.000, <1/1.000)***	- bradycardia, increase in blood pressure
Vascular disorders	***Very rare (including isolated cases)***	- flushing
	(<1/10.000)	
Respiratory, thoracic and mediastinal disorders	***Very rare (including isolated cases)*** ***(<1/10.000)***	- worsening of asthma, respiratory depression (see below)
	Not known	- hiccups
Gastrointestinal disorders	***Very Common*** ***(>1/10)***	- vomiting, nausea
	Common ***(>1/100, <1/10)***	- constipation, dry mouth
	Uncommon ***(>1/1000, <1/100)***	- retching, gastrointestinal irritation (a feeling of pressure in the stomach, bloating)
Hepato-biliary disorders	***Very rare (including isolated cases)*** ***(<1/10.000)***	- increase in liver enzyme values (a few isolated cases have been reported)
Skin and subcutaneous tissue disorders	***Common*** ***(>1/100 <1/10)***	- sweating
	Uncommon ***(>1/1000, <1/100)***	- dermal reactions (e.g. pruritus, rash, urticaria)
Musculoskeletal, connective tissue and bone disorders	***Rare*** ***(>1/10.000, <1/1.000)***	- motorial weakness
Renal and urinary system disorders	***Rare*** ***(>1/10.000, <1/1.000)***	- micturition disorders (difficulty in passing urine and urinary retention)
General disorders	***Common*** ***(>1/100, <1/10)***	- fatigue

Psychic side-effects may occur following administration of tramadol which vary individually in intensity and nature (depending on personality and duration of medication). 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 behaviour, perception disorders), hallucinations, confusion, sleep disturbances and nightmares.

Prolonged administration of Tramadol may lead to dependence (see section 4.4). Symptoms of withdrawal reactions, similar to those occurring during opiate withdrawal, may occur as follows: agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms.

Epileptiform convulsions are rare and occur mainly after administration of high doses of tramadol or after concomitant treatment with drugs which can lower the seizure threshold or themselves induce cerebral convulsions (e.g. antidepressants or anti-psychotics, see section 4.5 "Interaction with other medicinal products and other forms of interaction".

Worsening of asthma has also been reported, though a causal relationship has not been established. Respiratory depression has been reported. If the recommended doses are considerably exceeded and other centrally depressant substances are administered concomitantly (see section 4.5 "Interaction with other medicinal products and other forms of interaction") respiratory depression may occur.

4.9 Overdose

Symptoms of overdose are typical of other opioid analgesics, and include miosis, vomiting, hypotension, cardiovascular collapse, sedation and coma, epileptic seizures and respiratory depression. Respiratory failure may also occur. Serotonin syndrome has also been reported.

Supportive measures such as maintaining the patency of the airway and maintaining cardiovascular function should be instituted; naloxone should be used to reverse respiratory depression; fits can be controlled with diazepam. Naloxone administration may increase the risk of seizures. The use of benzodiazepines (intravenously) should be considered for patients with seizures.

Tramadol is minimally eliminated from the serum by haemodialysis or haemofiltration. Therefore treatment of acute intoxication with Tramadol with haemodialysis or haemofiltration alone is not suitable for detoxification.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Analgesics, other opioids, ATC code: N02AX02

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

Tramadol has antitussive properties. Unlike morphine, tramadol does not depress breathing over a wide range of analgesic doses. The effects of tramadol on the cardiovascular system are comparatively small. The potency of tramadol is 1/10 to 1/6 that of morphine.

Pediatric Population
Effects of enteral and parenteral administration of tramadol have been investigated in clinical trials involving more than 2000 paediatric 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 2mg/kg or multiple doses of up to 8mg/kg per day (to a maximum of 400mg per day) efficacy of tramadol hydrochloride 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 paediatric patients older that 1 year (see section 4.2).

5.2 Pharmacokinetic properties

Absorption
After oral administration, tramadol is almost completely absorbed. Mean absolute bioavailability is approximately 70% following a single dose and increases to approximately 90% at steady state.

Following a single oral dose administration of tramadol hydrochloride 100 mg to young healthy volunteers, plasma concentrations were detectable within approximately 15-45 minutes with a mean Cmax of 280 to 308 ng/ml and T_{max} of 1.6 to 2 hours.

In a specific study of comparing the dispersible tablets with Immediate Release capsules, the administration of a single dose of 50 mg Tramadol dispersible in healthy volunteers produced a mean AUC 1102 ± 357 ng.h/ml, a mean C_{max} 141± 39 ng/ml; and a mean T_{max} 1.5 hours. This demonstrated bioequivalence to 50 mg immediate release capsules (AUC 1008 ± 285 ng.h/ml; C_{max} 139 ± 37 ng/ml; T_{max} 1.5 hours).

Distribution
Plasma protein binding of tramadol is approximately 20%. It is independent of the plasma concentration of the drug within the therapeutic range.

Tramadol crosses the blood-brain barrier and the placental barrier. Tramadol and its metabolite O-desmethyltramadol are detectable in breast milk in very small amounts (0.1% and 0.02% of the administered doses, respectively).

Tramadol has a high tissue affinity, with an apparent volume of distribution of 3 to 4 l/kg.

Metabolism
Tramadol is metabolised by cytochrome P450 isoenzyme CYP2D6. It undergoes biotransformation to a number of metabolites mainly by means of N- and O-demethylation. O-desmethyl tramadol appears to be the most pharmacologically active metabolite, showing analgesic activity in rodents. It is 2 to 4 times more active than tramadol.

As humans excrete a higher percentage of unchanged tramadol than animals it is believed that the contribution made by this metabolite to analgesic activity is likely to be less in humans than animals. In humans the plasma concentration of this metabolite is about 25% that of unchanged tramadol.

The inhibition of one or both types of the isoenzymes CYP3A4 and CYP2D6 involved in the biotransformation of tramadol may affect the plasma concentration of tramadol or its active metabolite

Elimination
For tramadol, the terminal elimination half-life (t½β) was 6.0 ± 1.5 hours in young volunteers. For O-desmethyltramadol, t½β (6 healthy volunteers) was 7.9 hours (range 5.4 – 9.6 hours).

When C14 labelled tramadol was administered to humans, approximately 90% was excreted via the kidneys with the remaining 10% appearing in the faeces.

Tramadol pharmacokinetics show little age dependence in volunteers up to the age of 75 years. In volunteers aged over 75 years, t½β was 7.0 ± 1.6 hours on oral administration.

Since tramadol is eliminated both metabolically and renally, the terminal half-life t½β may be prolonged in impaired hepatic or renal function. However, the increase in the t½β values is relatively low if at least one of these organs is functioning normally. In patients with liver cirrhosis t½β tramadol was a mean of 13.3 ± 4.9 hours; in patients with renal insufficiency (creatinine clearance ≤ 5 ml/min) it was 11.0 ± 3.2 hours.

PK/PD
Tramadol has a linear pharmacokinetic profile within the therapeutic dosage range.

The PK/PD relation is dose-dependent, but varies within a wide range. Generally, a serum concentration between 100 and 300 ng/ml is 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

In single and repeat-dose toxicity studies (rodents and dogs) exposure to tramadol 10 times that expected in man is required before toxicity (hepatotoxicity) is observed. Symptoms of toxicity are typical of opioids and include restlessness, ataxia, vomiting, tremor, dyspnoea and convulsions.

Exposure to tramadol (> that expected in man), in lifetime toxicity studies in rodents did not reveal any evidence of carcinogenic hazard, and a battery of in-vitro and in-vivo mutagenicity tests were negative.

No teratogenic effects have been observed in animal tests (rat and rabbit: the dosage of Tramadol given has been up to seven times higher than the dosage given to humans). Minimal embryo toxic effects (delayed ossification) were observed in the tests. No effect was observed on the fertility or the development of the offspring in the tests.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (Spray Dried Mannitol))
Lactose (Directly Compressible)
Crospovidone(Type-A)
Sucralose
Aniseed Flavour TP-130 Powder
Flavour Spearmint Powder
Colloidal Silicone Dioxide
Sodium StearylFumarate

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30^{o}C.

6.5 Nature and contents of container

Alu Alu Strip pack

6.6 Special precautions for disposal

NoSpecial Requirement

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

TRO/IND/006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

- Date of first authorization : 17 April 2017
- Date of renewal : NA

10. DATE OF REVISION OF THE TEXT

28 July 2023