

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fentium – Fentanyl 100micrograms in 2ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Fentanyl citrate 78.5 micrograms

Equivalent to Fentanyl50 micrograms

Excipient with known effect:

This medicine contains 7.1 mg (or 0.31 mmol) sodium per 2ml ampoule, essentially 'sodium-free'.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear, colorless solution

4. Clinical particulars

4.1 Therapeutic indications

Fentanyl is an opioid analgesic used:

- in low doses to provide analgesia during short surgical procedures
- in high doses as an analgesic/respiratory depressant in patients requiring assisted ventilation
- in combination with a neuroleptic drug as part of the technique of neuroleptanalgesia
- in the treatment of severe pain, such as the pain of myocardial infarction

4.2 Posology and method of administration

Prior to starting treatment with opioids, a discussion should be held with patients to put in place a strategy for ending treatment with fentanyl to minimise the risk of addiction and drug withdrawal syndrome (see section 4.4).

Route of administration

Intravenous administration either as a bolus or by infusion.

Intramuscular administration.

Fentanyl should be given only in an environment where the airway can be controlled and by personnel who can control the airway (see section 4.4 Special warnings and precautions for use).

To avoid bradycardia, it is recommended to administer a small intravenous dose of an anti-cholinergic just before anaesthetic induction.

It is recommended to wear gloves while opening the ampoule (see section 6.6).

Posology

Fentanyl, by the intravenous route, can be administered to both adults and children. The dose of fentanyl should be individualised according to age, body weight, physical status, underlying

pathological condition, use of other drugs and type of surgery and anaesthesia.

Adults

Usual dosage regimen in adults		
Usage	Initial (micrograms)	Supplemental (micrograms)
Spontaneous Respiration	50 - 200	50
Assisted Ventilation	300 - 3500	100 - 200

Doses more than 200micrograms are for use in anaesthesia only. As a premedicant, 1ml -2ml fentanyl may be given intramuscularly 45minutes before induction of anaesthesia.

After intravenous administration in un-premedicated adult patients, 2ml fentanyl may be expected to provide sufficient analgesia for 10-20minutes in surgical procedures involving low pain intensity. 10ml fentanyl injected as a bolus gives analgesia lasting about one hour. The analgesia produced is sufficient for surgery involving moderately painful procedures. Giving a dose of 50micrograms/kg fentanyl will provide intense analgesia for some four to six hours, for intensely stimulating surgery.

Fentanyl may also be given as an infusion. In ventilated patients, a loading dose of fentanyl may be given as a fast infusion of approximately 1microgram/kg/min for the first 10minutes followed by an infusion of approximately 0.1micrograms/kg/min. Alternatively the loading dose of fentanyl may be given as a bolus. Infusion rates should be titrated to individual patient response; lower infusion rates may be adequate. Unless it is planned to ventilate post-operatively, the infusion should be terminated at about 40 minutes before the end of surgery.

Lower infusion rates, e.g., 0.05-0.08micrograms/kg/minute are necessary if spontaneous ventilation is to be maintained. Higher infusion rates (up to 3micrograms/kg/minute) have been used in cardiac surgery.

Fentanyl is chemically incompatible with the induction agent's pentobarbital sodium, thiopentone and methohexitone because of wide differences in pH (see section 6.2 Incompatibilities).

Paediatric population

Children aged 12 to 17 years old:

Follow adult dosage.

Children aged 2 to 11 years old:

Usual dosage regimen in Children			
Usage	Age (years)	Initial (micrograms/Kg)	Supplemental (micrograms/Kg)
Spontaneous Respiration	2 - 11	1 - 3	1 - 1.25
Assisted Ventilation	2 - 11	1 - 3	1 - 1.25

Use in children:

Analgesia during operation, enhancement of anaesthesia with spontaneous respiration

Techniques that involve analgesia in a spontaneous breathing child should only be used as part of an anaesthetic technique or given as part of a sedation/ analgesia technique with experienced personnel in an environment that can manage sudden chest wall rigidity requiring intubation, or apnoea requiring airway support (see section 4.4).

Use in elderly and debilitated patients:

As with other opioids, the initial dose should be reduced in the elderly (>65 years of age) and in debilitated patients. The effect of the initial dose should be considered in determining supplemental doses.

Obese patients:

In obese patients there is a risk of overdosing if the dose is calculated based on body weight. Obese patients should have dosage calculated according to their estimated lean body mass.

Renal Impairment:

In patients with renal impairment reduced dosing of fentanyl should be considered and these patients should be observed carefully for signs of fentanyl toxicity (see section 5.2 Pharmacokinetic properties).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or other opioids.

- Respiratory depression, obstructive airways disease.
- Concurrent administration with monoamine oxidase inhibitors or within 2 weeks of their discontinuation.

4.4 Special warnings and precautions for use

Warnings:

Following intravenous administration of fentanyl, a transient fall in blood pressure may occur, especially in hypovolaemic patients. Appropriate measures to maintain a stable arterial pressure should be taken.

Tolerance and Opioid use disorder (abuse and dependence)

For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses.

Repeated use of opioids may lead to Opioid use disorder (OUD). Abuse or intentional misuse of opioids may result in overdose and/or death. The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g., major depression, anxiety and personality disorders).

Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.

A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.

Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of pain control as initially experienced. Patients may also supplement their treatment with additional pain relievers. These could be signs that the patient is developing tolerance.

The risks of developing tolerance should be explained to the patient.

Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.

Patients should be closely monitored for signs of misuse, abuse, or addiction. The clinical need for analgesic treatment should be reviewed regularly.

Drug withdrawal syndrome

Prior to starting treatment with any opioids, a discussion should be held with patients to put in place a withdrawal strategy for ending treatment with fentanyl.

Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months.

The opioid drug withdrawal syndrome is characterised by some or all the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis, and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.

If women receive this drug during pregnancy, there is a risk that their new-born infants will experience neonatal withdrawal syndrome.

Respiratory Depression

As with all potent opioids, profound analgesia is accompanied by marked respiratory depression, which may persist into or recur in the early postoperative period. Care should be taken after large doses or infusions of fentanyl to ensure that adequate spontaneous breathing has been established and maintained before discharging the patient from the recovery area.

Significant respiratory depression will occur following the administration of fentanyl in doses more than 200micrograms. This, and the other pharmacological effects of fentanyl, can be reversed by specific opioid antagonists, but additional doses may be necessary because the respiratory depression may last longer than the duration of action of the opioid antagonist.

Resuscitation equipment and opioid antagonists should be readily available.

Hyperventilation during anaesthesia may alter the patient's response to CO₂, thus affecting respiration postoperatively.

Administration in labour may cause respiratory depression in the new-born infant.

Hyperalgesia

Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain. This might be qualitatively and anatomically distinct from pain related to disease progression or to breakthrough pain resulting from development of opioid tolerance. Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose.

Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs
Concomitant use of fentanyl and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma, and death. Because of these risks, 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 fentanyl 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).

Cardiac disease

Bradycardia, and possibly cardiac arrest, can occur if the patient has received an insufficient amount of anticholinergic, or when fentanyl is combined with non-vagolytic muscle relaxants. Bradycardia can be antagonised by atropine.

Muscle rigidity

Muscular rigidity (morphine-like effect) may occur.

Rigidity, which may also involve the thoracic muscles, can be avoided by the following measures:

- slow IV injection (usually sufficient for lower doses).
- premedication with benzodiazepines.
- use of muscle relaxants.

Non-epileptic (myo)clonic movements can occur.

Precautions:

Fentanyl should be given only in an environment where the airway can be controlled and by personnel who can control the airway.

Special dosing conditions

The use of rapid bolus injections of opioids should be avoided in patients with compromised intracerebral compliance; in such patients the transient decrease in the mean arterial pressure has occasionally been accompanied by a transient reduction of the cerebral perfusion pressure.

It is recommended to reduce dosage in the elderly and debilitated patients. In uncontrolled hypothyroidism, pulmonary disease, decreased respiratory reserve, alcoholism and hepatic or renal impairment the dosage should be titrated with care and prolonged post-operative monitoring is required.

Patients on chronic opioid therapy or with a history of opioid abuse may require higher doses.

Myasthenia gravis

In patients with myasthenia gravis, careful consideration should be applied in the use of certain anticholinergic agents and neuromuscular-blocking pharmaceutical agents prior to, and during, the administration of a general anaesthetic regimen which includes administering intravenous fentanyl.

Interaction with neuroleptics

If fentanyl is administered with a neuroleptic, the user should be familiar with the special properties of each drug, particularly the difference in duration of action. When such a combination is used, there is a higher incidence of hypotension. Neuroleptics can induce extrapyramidal symptoms that can be controlled with anti-Parkinson agents.

Bile duct

As with other opioids, due to the anticholinergic effects administration of fentanyl may lead to increases of bile duct pressure and in isolated cases spasms of the Sphincter of Oddi might be observed.

Intestinal motility

As with other opioids, fentanyl can have an inhibitory effect on intestinal motility. This should be considered in the pain management of intensive care patients with inflammatory or obstructive intestinal diseases.

Serotonin Syndrome

Caution is advised when fentanyl is co-administered with drugs that affect the serotonergic neurotransmitter systems.

The development of a potentially life-threatening serotonin syndrome may occur with the concomitant use of serotonergic drugs such as Selective Serotonin Re-uptake Inhibitors (SSRIs) and Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs), and with drugs which impair metabolism of serotonin (including Monoamine Oxidase Inhibitors [MAOIs]). This may occur within the recommended dose.

Serotonin syndrome may include mental-status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular abnormalities (e.g., hyperreflexia, incoordination, rigidity), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea).

If serotonin syndrome is suspected, rapid discontinuation of fentanyl should be considered.

Paediatric population

Techniques that involve analgesia in a spontaneously breathing child should only be used as part of an anaesthetic technique or given as part of a sedation / analgesia technique, with experienced personnel in an environment that can manage sudden chest wall rigidity requiring intubation, or apnoea requiring airway support.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of other drugs on fentanyl

Sedative medicines 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).

Other Central Nervous System (CNS) depressants

The use of other CNS depressants such as opioid premedication, barbiturates, neuroleptics, general anaesthetics, gabapentinoids (gabapentin and pregabalin), and other non-selective CNS depressants (e.g., alcohol) may enhance or prolong the respiratory depression of fentanyl. When patients have received other CNS-depressants, the dose of fentanyl required may be less than usual. Concomitant use with fentanyl in spontaneously breathing patients may increase the risk of respiratory depression, profound sedation, coma, and death.

The pharmacological effects of fentanyl citrate can be reversed by naloxone.

Antipsychotics

Droperidol: The concomitant use of droperidol can result in a higher incidence of hypotension.

Antihypertensive

Clonidine: Co-administration of clonidine may enhance fentanyl effects and especially prolong fentanyl-induced respiratory depression.

Cytochrome P450 3A4 (CYP3A4) inhibitors

Fentanyl, a high clearance drug, is rapidly and extensively metabolised mainly by CYP3A4. When IV fentanyl is used, the concomitant use of a CYP3A4 inhibitor may result in a decrease in fentanyl clearance. With single-dose IV fentanyl administration, the period of risk for respiratory depression may be prolonged, which may require special patient care and longer observation. With multiple-dose fentanyl administration, the risk for acute and/or delayed respiratory depression may be increased, and a dose reduction of fentanyl may be required to avoid accumulation of fentanyl.

Oral ritonavir (a potent CYP3A4 inhibitor) reduced the clearance of a single IV fentanyl dose by two thirds, although peak plasma concentrations of IV fentanyl were not affected. However, itraconazole (another potent CYP3A4 inhibitor) at 200mg/day given orally for 4 days had no significant effect on the pharmacokinetics of a single dose of IV fentanyl.

Co-administration of fluconazole or voriconazole (moderate CYP3A4 inhibitors) and fentanyl may result in an increased exposure and/or prolonged exposure to fentanyl.

Bradycardia and possibly cardiac arrest can occur when fentanyl is combined with non-vagolytic muscle relaxants (e.g., vecuronium).

Serotonergic Drugs

Coadministration of fentanyl with a serotonergic agent, such as a Selective Serotonin Re-uptake Inhibitor (SSRI) or a Serotonin Norepinephrine Re-uptake Inhibitor (SNRI) or a Monoamine Oxidase Inhibitor (MAOI), may increase the risk of serotonin syndrome, a potentially life-threatening condition (see section 4.3 Contraindications)

Effect of fentanyl on other drugs

Following the administration of fentanyl, the dose of other CNS depressant drugs should be

reduced. This is particularly important after surgery, because profound analgesia is accompanied by marked respiratory depression, which can persist or recur in the postoperative period. Administration of a CNS depressant, such as a benzodiazepine, during this period may disproportionally increase the risk for respiratory depression (see above).

Plasma concentrations of etomidate increased considerably (by a factor 2-3) when combined with fentanyl. The total plasma clearance and volume of distribution of etomidate is decreased by a factor of 2 to 3 without a change in half-life when administered with fentanyl.

Simultaneous administration of fentanyl and intravenous midazolam results in an increase in the terminal plasma half-life and a reduction in the plasma clearance of midazolam. When these drugs are co-administered with fentanyl their dose may need to be reduced.

4.6 Fertility, pregnancy, and lactation

Pregnancy

Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.

If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

There are no adequate data from the use of fentanyl in pregnant women. Fentanyl can cross the placenta in early pregnancy. Studies in animals have shown some reproductive toxicity (see Section 5.3, Preclinical safety data). The potential risk for humans is unknown.

Administration during labour may depress respiration in the neonate and an antidote for the child should be readily available.

Breast-feeding

Administration to nursing women is not recommended as fentanyl may be secreted in breast milk and may cause respiratory depression in the infant. Therefore, breast-feeding or use of expressed breast milk is not recommended within 24 hours of treatment. The risk/benefit of breast-feeding following fentanyl administration should be considered.

Fertility

There are no clinical data on the effects of fentanyl on male or female fertility. In animal studies, some tests on rats showed reduced female fertility at maternal toxic doses (see section 5.3 Preclinical safety data).

4.7 Effects on ability to drive and use machines

Where early discharge is envisaged, patients should be advised not to drive or to operate machinery for at least 24 hours following administration.

4.8 Undesirable effects

The safety of fentanyl IV was evaluated in 376 subjects who participated in 20 clinical trials evaluating fentanyl IV as an anaesthetic. These subjects took at least 1 dose of fentanyl IV and provided safety data. Based on pooled safety data from these clinical trials, the most reported ($\geq 5\%$ incidence) Adverse Drug Reactions (ADRs) were (with % incidence): nausea (26.1); vomiting (18.6); muscle rigidity (10.4); hypotension (8.8); hypertension (8.8); bradycardia (6.1); and sedation (5.3).

Including the above-mentioned ADRs, Table 1 displays ADRs that have been reported with the use of fentanyl IV from either clinical trials or post marketing experience.

Tabulated summary of adverse reactions

Adverse events are listed below by system organ class and frequency.

Term	Frequency of occurrence
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)

System Organ Class	Frequency	Undesirable effects
Immune System Disorders	Not Known	Hypersensitivity (such as anaphylactic shock, anaphylactic reaction, urticaria)
Psychiatric Disorders	Common	Agitation
	Uncommon	Euphoric mood
	Not Known	Delirium, Drug dependence (see section 4.4)
Nervous System Disorders	Very Common	Muscle rigidity (which may also involve the thoracic muscles)
	Common	Dyskinesia; Sedation; Dizziness
	Uncommon	Headache
	Not Known	Convulsions; Loss of consciousness; Myoclonus
Eye Disorders	Common	Visual disturbance
Cardiac Disorders	Common	Bradycardia; Tachycardia; Arrhythmia
	Not Known	Cardiac arrest
Vascular Disorders	Common	Hypotension; Hypertension; Venous pain
	Uncommon	Phlebitis; Blood pressure fluctuation
Respiratory, Thoracic and Mediastinal Disorders	Common	Laryngospasm; Bronchospasm; Apnoea
	Uncommon	Hyperventilation; Hiccups
	Not Known	Respiratory depression
Gastrointestinal Disorders	Very common	Nausea; Vomiting
Skin and Subcutaneous Tissue Disorders	Common	Allergic dermatitis
	Not Known	Pruritus
General Disorders and Administration Site Conditions	Uncommon	Chills; Hypothermia; Drug withdrawal syndrome
	Not Known	Drug withdrawal syndrome (see section 4.4)
Injury, Poisoning and Procedural Complications	Common	Postoperative confusion
	Uncommon	Airway complication of anaesthesia

When a neuroleptic is used with fentanyl, the following adverse reactions may be observed: chills and/or shivering, restlessness, postoperative hallucinatory episodes, and extrapyramidal symptoms (see Section 4.4).

Reporting of adverse Effects

Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdose

Patients should be informed of the signs and symptoms of overdose and to ensure that family and friends are also aware of these signs and to seek immediate medical help if they occur.

Symptoms and signs:

The manifestations of fentanyl overdosage are generally an extension of its pharmacological action. Depending on the individual sensitivity, the clinical picture is determined primarily by the degree of respiratory depression which varies from bradypnea to apnoea.

Treatment

Hypoventilation or apnoea	O2 administration, assisted or controlled respiration.
Respiratory depression	Specific opioid antagonist. This does not preclude the use of immediate countermeasures. The respiratory depression may last longer than the effect of the antagonist; additional doses of the latter may therefore be required.
Muscular rigidity	Intravenous neuromuscular blocking agent to facilitate assisted or controlled respiration.

The patient should be carefully observed; body warmth and adequate fluid intake should be maintained. If hypotension is severe or if it persists, the possibility of hypovolaemia should be considered and, if present, it should be controlled with appropriate parenteral fluid administration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetic general, opioid
anaesthetic ATC code: N01AH01

Fentanyl is a synthetic opiate with a clinical potency of 50 to 100 times that of morphine. Its onset of action is

rapid, and its duration of action is short. In man, a single IV dose of 0.5-1 mg/70 kg body weight immediately produces a pronounced state of surgical analgesia, respiratory depression, bradycardia, and other typical morphine-like effects. The duration of action of the peak effects is about 30 minutes. All potent morphine-like drugs produce relief from pain, ventilatory depression, emesis, constipation, physical dependence, certain vagal effects, and varying degrees of sedation. Fentanyl, however, differs from morphine not only by its short duration of action but also by its lack of emetic effect and minimal hypotensive activity in animals.

5.2 Pharmacokinetic properties

Pharmacokinetic parameters for fentanyl	
Urinary excretion	8%
Bound in plasma	80%

Clearance (ml/min/kg)	13 ± 2
Volume of distribution (litres/kg)	4.0 ± 0.4
Estimates of terminal half-life range from	141 to 853 minutes

Renal impairment

Data obtained from a study administering IV fentanyl in patients undergoing renal transplantation suggest that the clearance of fentanyl may be reduced in this patient population. If patients with renal impairment receive fentanyl, they should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary (see section 4.2 Posology and method of administration).

Obese Patients

An increase in clearance of fentanyl is observed with increased body weight. In patients with a BMI>30, clearance of fentanyl increases by approximately 10% per 10 kg increase of the fat free mass (lean body mass).

5.3 Preclinical safety data

In vitro fentanyl showed, like other opioid analgesics, mutagenic effects in a mammalian cell culture assay, only at cytotoxic concentrations and along with metabolic activation. Fentanyl showed no evidence of mutagenicity when tested in in vivo rodent studies and bacterial assays. In a two-year rat bioassay, fentanyl was not carcinogenic.

Some tests on female rats showed reduced fertility as well as embryo mortality. These findings were related to maternal toxicity and not a direct effect of the drug on the developing embryo. There was no evidence of teratogenic effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

water for injections

hydrochloric acid, or sodium hydroxide for pH adjustment.

6.2 Incompatibilities

Fentanyl citrate is reportedly physically incompatible with pentobarbital sodium, methohexital sodium and thiopental sodium.

6.3 Shelf life

24 Months

From a microbiological point of view, the product should be used immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Any unused portion of the product should be discarded immediately after use.

6.4 Special precautions for storage

Do not store above 30°C.

Keep the ampoules in the outer carton to protect from light.

6.5 Nature and contents of container

Clear glass ampoules, glass type I, Ph. Eur. Pack sizes: 5x 2ml or 10 x 2ml
Not all packs may be marketed

6.6 Special precautions for disposal and other handling

Use finger protection when opening an ampoule.

The injection is for single patient use and should be used immediately after opening. The injection should not be used if particles are present. Any unused portion should be discarded.

The product can be used either undiluted or diluted. Dilution ranges tested with 0.9 % sodium chloride and 5 % glucose solutions are 1:1 and 1:25. Hence the maximal dilution must not exceed 1 part fentanyl with 25 parts

0.9 % sodium chloride or 5 % glucose solutions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Tasa Pharma Limited
Unit C1-C3
Kay complex Nairobi
Kenya.

8. MARKETING AUTHORIZATION NUMBER

H2025/12046/26276

9. DATE OF FIRST REGISTRATION/ RENEWAL OF THE REGISTRATION

27/08/2025

10. DATE OF REVISION OF THE TEXT

27/08/2025