1. NAME OF THE MEDICINAL PRODUCT

Morphia 10mg/ml solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 10 mg morphine sulphate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear colourless to pale yellow solution.

pH 2.5 to 6.5.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Morphine in indicated for the management of severe post-operative and post-traumatic pain as well assevere opioid sensitive pain such as cancer pain.

4.2 Posology and method of administration

Posology

Administration and dosage should be individualized taking into account the nature and severity of painand the patient's general condition.

Individual criteria for the dose depend on the patient's age, weight, pain severity, and medical andanalgesic history.

Adults:
Intravenous: 2.5 – 15 mg administered during 4-5 minutes.

Epidural: Initially up to 5 mg, if necessary 1-2 mg after one hour. To be repeated as

needed.Epidural infusion: Initially 3.5-7.5 mg daily, if necessary increased by 1-2

mg daily.

Children and youth:
Intravenous: Only when a particularly fast response is required: 0.05-0.1 mg/kg body weight administered very slowly (dilution with isotonic sodium chloride solution is recommended).

Epidural: 0.03-0.05 mg/kg 1-2 times daily.

Subcutaneous, intramuscular: 0.05-0.2 mg/kg body weight, up to every 4 hours if needed.

New born
Intravenous: Only when a particularly fast response is required: 0.025-0.05 mg/kg body weight,administered very slowly (dilution with isotonic sodium chloride solution is recommended).

Epidural: 0.03-0.05 mg/kg 1-2 times daily.
Subcutaneous, intramuscular: 0.025-0.05 mg/kg body weight, up to every 4 hours if needed.
For doses corresponding to very small volumes Morphine is recommended to be diluted with isotonic sodium chloride solution to ensure correct dosing.

In severe cancer related pain dose adjustments can be made as long as the effect of the morphine givesa true pharmacological analgesia, i.e. it does not give a sedative effect.

Respiratory depression is uncommon with repeated dosing of epidural morphine to treat pain in cancerpatients.

The equianalgesic dose of intrathecal morphine is about 5 times lower than that of epidural morphine,but data from clinical trials are lacking.

Treatment control.
Respiratory supportive therapy and naloxone may be required at respiratory depression.
As the respiratory depressant effect may be sustained, repeat doses of naloxone may be required in somecases.
Due to the risk of respiratory depression, patients given epidural morphine for the treatment of postoperative or traumatic pain should be carefully monitored for 8-12 hours after the last injection.The need for monitoring must be assessed for each individual case.
Urinary retention caused by morphine could if necessary be reversed by naloxone.

Special populations
Caution should be exercised and the dosage initially reduced in morphine treatment of elderly patientsand in patients with hepatic and renal impairment. See also section 4.3 and 4.4.

Paediatric population
Paediatric regional anaesthetic procedures should be performed by qualified clinicians who arefamiliar with this population and the technique.

Method of administration
Before subcutaneous and intramuscular doses corresponding to very small volumes are administeredto a new born child Morphine should be diluted to avoid dosing errors. Isotonic sodium chloride solution should be used. Dilution corresponding to an administration volume above 2 ml should be avoided.

For epidural use it is appropriate, with customary techniques, to ensure that the administration ofmorphine occurs in the epidural space. Both the effect and the risk of undesirable effects are significantly strengthened if Morphine accidentally is administered intrathecally.

Treatment goals and discontinuation
Before initiating treatment with Morphine, a treatment strategy including treatment duration and treatment goals, and a plan for end of the treatment, should be agreed together with the

patient, in accordance with pain management guidelines. During treatment, there should be frequent contact between the physician and the patient to evaluate the need for continued treatment, consider discontinuation and to adjust dosages if needed. When a patient no longer requires therapy with Morphine, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. In absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered (see section 4.4).

Duration of treatment
Morphine should not be used longer than necessary.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Secretion stagnation
- Respiratory depression
- Acute liver disease
- Agitation states during effect of alcohol or hypnotics
- General contraindications related to epidural administration shall be taken into consideration.

4.4 Special warnings and precautions for use

Addictive agent. Take extreme caution when prescribing this drug.
The patient may develop tolerance to morphine with prolonged use and require progressively higherdoses to achieve the desired analgesic effect. There may also be cross-tolerance with other opioids.

The dose may need to be reduced in bronchial asthma, head injuries, hypotension associated with hypovolaemia, hypothyroidism, impaired hepatic and renal function, inflammatory bowel diseases,pancreatitis, bile duct spasm, urinary tract spasm and in the treatment of elderly patients.

Morphine should not be used in idiopathic or psychopathological pain conditions.

Treatment with MAO inhibitors, see 4.5 Interaction with other medicinal products and other forms ofinteraction.

There is an increased risk for respiratory depression in the treatment of elderly patients.

Hyperalgesia that does not respond to a further dose increase of morphine may occur in particular inhigh doses. A morphine dose reduction or change in opioid may be required.

Plasma concentrations of morphine may be reduced by rifampicin. The analgesic effect of morphineshould be monitored and doses of morphine adjusted during and after treatment with rifampicin.

Oral P2Y12 inhibitor antiplatelet therapy
Within the first day of concomitant P2Y12 inhibitor and morphine treatment, reduced efficacy ofP2Y12 inhibitor treatment has been observed (see section 4.5).

Constipation
Constipation is a common side effect of morphine. The use of laxatives should be considered duringthe use of Morphine.

Acute chest syndrome (ACS) in patients with sickle cell disease (SCD)
Due to a possible association between ACS and morphine use in SCD patients treated with morphineduring a vaso-occlusive crisis, close monitoring for ACS symptoms is warranted.

Adrenal insufficiency
Opioid analgesics may cause reversible adrenal insufficiency requiring monitoring and glucocorticoidreplacement therapy. Symptoms of adrenal insufficiency may include e.g. nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure.

Decreased Sex Hormones and increased prolactin
Long-term use of opioid analgesics may be associated with decreased sex hormone levels andincreased prolactin. Symptoms include decreased libido, impotence or amenorrhea.

Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs:
Concomitant use of Morphine 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 Morphineconcomitantly with sedative medicines, the lowest effective dose should be used, and the duration oftreatment 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 awareof these symptoms (see section 4.5).

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

Severe cutaneous adverse reactions (SCARs)
Acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, has been reported in association with morphine treatment. Most of these reactions occurred within the first 10 days of treatment. Patients should be informed about the signs and symptoms of AGEP and advised toseek medical care if they experience such symptoms.
If signs and symptoms suggestive of these skin reactions appear, morphine should be withdrawn andan alternative treatment considered.

Hepatobiliary disorders
Morphine may cause dysfunction and spasm of the sphincter of Oddi, thus raising intrabiliary pressureand increasing the risk of biliary tract symptoms and pancreatitis.

Opioid Use Disorder (abuse and dependence)
Tolerance and physical and/or psychological dependence may develop upon repeated administrationof opioids such as Morphine.

Repeated use of Morphine can lead to Opioid Use Disorder (OUD). A higher dose and longer duration of opioid treatment, can increase the risk of developing OUD. Abuse or intentional misuse of Morphine 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 othermental health disorders (e.g. major depression, anxiety and personality disorders).

Before initiating treatment with Morphine and during the treatment, treatment goals and a discontinuation plan should be agreed with the patient (see section 4.2). Before and during treatmentthe patient should also be informed about the risks and signs of OUD. If these signs occur, patients should be advised to contact their physician.
Patients will require monitoring for signs of drug-seeking behaviour (e.g. too early requests for refills).This includes the review of concomitant opioids and psycho-active drugs (like benzodiazepines). For patients with signs and symptoms of OUD, consultation with an addiction specialist should be considered.

Withdrawal (abstinence)
The risk of withdrawal (abstinence) increases with the time the drug is used, and with higher doses.Symptoms can be minimized with adjustments of dose or dosage form, and gradual withdrawal of morphine. For individual symptoms, see section 4.8.

Paediatric population
Respiratory depression poses a risk to all children. Neonates (especially if they breath spontaneously)may have an increased sensitivity. Use intravenous morphine with special care in children below 1 year of age.

4.5 Interaction with other medicinal products and other forms of interaction

The combination should be avoided
Morphine should be used with caution in patients who are concurrently receiving other central nervoussystem depressants including other opioids, sedatives or hypnotics, general anaesthetics, phenothiazines, other tranquilisers, muscle relaxants, antihypertensives, gabapentin or pregabalin.
Interactive effects resulting in respiratory depression, hypotension, profound sedation, or coma mayresult if these drugs are taken in combination with the usual doses of morphine.

Small amounts of alcohol
Small amounts of alcohol can dramatically potentiate the weak respiratory depressant effect ofmorphine. The combination should therefore be avoided.

MAO-inhibitors
MAO inhibitors may potentiate the effect of morphine (respiratory depression and hypotension). Serotonergic syndrome has been reported with concomitant use of pethidine and MAO inhibitors, andcan therefore not be excluded in the combination of morphine and MAO inhibitors.

P2Y12 inhibitor
A delayed and decreased exposure to oral P2Y12 inhibitor antiplatelet therapy has been observed in patients with acute coronary syndrome treated with morphine. This interaction may be related to reduced gastrointestinal motility and apply to other opioids. The clinical relevance is unknown, but data indicate the potential for reduced P2Y12 inhibitor efficacy in

patients co-administered morphine and a P2Y12 inhibitor (see section 4.4). In patients with acute coronary syndrome, in whom morphinecannot be withheld and fast P2Y12 inhibition is deemed crucial, the use of a parenteral P2Y12 inhibitor may be considered.

The following combinations may require dose adjustment

Rifampicin
Rifampicin decreases the plasma concentration of orally administered morphine to such an extent, thathigher doses than normal are required for analgesic effect.

Diclofenac
Diclofenac may increase the analgesic effect of morphine, shown in a study of 120 women whoreceived epidural morphine.

Amitriptyline, clomipramine and nortriptyline
Amitriptyline, clomipramine and nortriptyline enhance the analgesic effect of morphine. Doseadjustment may be required.

Combined morphine agonists/antagonists
Combined morphine agonists/antagonists (buprenorphine, nalbuphine, pentazocine) reduce theanalgesic effect by competitive blocking of receptors, thereby increasing the risk of withdrawalsymptoms.

For the following combinations, the clinical significance is unclear.

Baclofen
The combination of morphine and intrathecal baclofen caused decreased blood pressure in a patient.The risk that this combination can cause apnoea or other CNS symptoms cannot be excluded.

Hydroxyzine
Due to an additive effect, concomitant administration of hydroxyzine and morphine may increase CNSdepression and drowsiness. Consider changing to non-sedating antihistamine.

Methylphenidate
Methylphenidate may increase the analgesic effect of morphine. Consider reducing the dose ofmorphine when used concomitantly.

Nimodipine
Nimodipine may increase the analgesic effect of morphine. Consider reducing the dose of morphinewhen used concomitantly.

Ritonavir
Morphine levels may be decreased due to induction of glucuronidation by concomitant administrationof ritonavir, when used as an antiretroviral agent or as a pharmacokinetic enhancer (boost) of other protease inhibitors.

4.6 Fertility, pregnancy and lactation

Men and women of childbearing potential
Due to the mutagenic properties of morphine, it should not be administered to men and women ofchild-producing/child bearing potential unless effective contraception is

assured (see section 5.3).

Pregnancy
There are limited amounts of data from the use of morphine in pregnant women. Morphine crosses theplacenta. Studies in animals have shown reproductive toxicity (see section 5.3). For this reason, morphine must only be used during pregnancy in cases where the maternal benefitclearly outweighs the risk for the child.

Long term use of morphine during pregnancy may result in a neonatal opioid withdrawal state. Morphine can prolong or shorten the duration of labour. Morphine can produce respiratory depression in the neonate, if it is administered during labour. Newborns whose mothers received opioid analgesicsduring pregnancy should be monitored for signs of neonatal withdrawal (abstinence) syndrome and respiratory depression. Treatment may include an opioid (withdrawal), an opioid antagonist (respiratory depression) and supportive care.
Especially during the 2 to 3 hours before expected partum morphine should only be administered onstrict indication and following a mother benefit versus baby risk analysis.

Breast-feeding:
Morphine is excreted into breast milk, where it reaches higher concentrations than in maternal plasma. Since clinically relevant concentrations of morphine may be reached in nursing infants, breast-feedingis not recommended (see section 5.2).

Fertility
There are no clinical data on the effects of morphine on male or female fertility.
Animal studies have shown that morphine may reduce fertility (see 5.3. preclinical safety data).

4.7 Effects on ability to drive and use machines

Morphine has major influence on the ability to drive and use machines. Treatment with Morphine may impair reaction ability.

4.8 Undesirable effects

Approximately 20% of the patients experience nausea and vomiting. Most side effects are dosedependent.

Adverse reactions listed below are classified according to frequency and system organ class. Frequency groupings are defined according to the following convention: Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1000 to < 1/100), rare (≥ 1/10000 to < l/ 1000), veryrare (<1/10000), not known (cannot be estimated from the available data).

Immune system disorders:
Not known: anaphylactoid reactions

Endocrine disorders:
Common: increased ADH release.

Psychiatric disorders:
Uncommon: dysphoria.
Not known: euphoria, sleep, memory and concentration difficulties, hallucinations,

confusion,dependence

Nervous system disorders:
Common: increased $PaCO_2$ levels, sedation.
Uncommon: respiratory depression, disorientation, drowsiness, dizziness, headache, dazed,dysphoria
Not known: convulsions, allodynia, hyperalgesia (see section 4.4), hyperhidrosis

Eye disorders:
Common: miosis.

Cardiac disorders
Rare: palpitations, tachycardia

Vascular disorders:
Rare: orthostatic hypotension., hypertension, hypotension, peripheral oedema, syncope

Respiratory, thoracic and mediastinal disorders:
Uncommon: bronchoconstriction
Not known: central sleep apnoea syndrome

Gastrointestinal disorders:
Common: nausea, vomiting, constipation
Not known: dry mouth, pancreatitis

Hepatobiliary disorders:
Uncommon: bile duct spasm
Not known: spasm of sphincter of Oddi

Skin and subcutaneous tissue disorders:
Common: pruritus
Not known: acute generalised exanthematous pustulosis (AGEP), urticaria

Musculoskeletal, connective tissue and bone disorderNot known: myoclonus

Renal and urinary disorders:
Common: urinary retention.
Uncommon: urinary tract spasm

General disorders and administration site conditions:
Uncommon: light-headedness.
Not known: drug withdrawal (abstinence) syndrome

Drug dependence and withdrawal (abstinence) syndrome
Use of opioid analgesics may be associated with the development of physical and/or psychological dependence or tolerance. An abstinence syndrome may be precipitated when opioid administration is suddenly discontinued or opioid antagonists administered, or can sometimes be experienced betweendoses. For management, see 4.4.
Physiological withdrawal symptoms include: Body aches, tremors, restless legs syndrome, diarrhoea, abdominal colic, nausea, flu-like symptoms, tachycardia and mydriasis. Psychological symptoms include dysphoric mood, anxiety and irritability. In drug dependence,

“drug craving” is often involved.

Drug dependence
Repeated use of Morphine 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 ofopioid treatment (see section 4.4).

Respiratory depression has a slow onset and is most evident 5-8 hours after injection. Co-administration of parenteral narcotics may increase the frequency of side effects and can enhancethe depressant effects. The risk of late respiratory depression should be specially monitored at post- operative use. The risk of respiratory depression is very small in the treatment of cancer patients previously treated with morphine.

With regards to undesirable effects, in epidural morphine treatment the occurrence of pruritus is observed, whereas epidurally administered morphine does not appear to give the same tendency to nausea and vomiting, bile duct and urinary tract spasm and sedation, as when given intramuscularlywith equianalgesic doses. However, epidural morphine gives an increased frequency of urinary retention by relaxing the detrusor muscle with subsequent increased bladder capacity.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. Itallows continued monitoring of the benefit/risk balance of the medicinal product. 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 of overdose:
Signs of overdose include pin-point pupils, respiratory depression and hypotension. Circulatory disorders and coma may occur in severe cases. Death may occur from respiratory failure. Pneumoniaaspiration.

Typical triad symptoms: low level of consciousness, severe respiratory depression, maximum mioticpupils. Hypotension. Pale, clammy skin. At high doses, cyanosis, areflexia, respiratory arrest, unconsciousness, circulatory failure, pulmonary oedema. Acidosis, convulsions (especially in children), possibly hypokalaemia and hypocalcaemia. Nausea, vomiting, constipation. Risk of myocardial injury, rhabdomyolysis and renal failure in severe intoxication.

Treatment of overdose:
Respiratory depression at morphine intoxication can be reversed with naloxone, initially 0.4 mg foradults (children 0.01 mg/kg) slowly intravenously, the dose is gradually increased if necessary.
Continuous infusion of naloxone can sometimes be a practical option.
Respiratory treatment on the indication (with PEEP in pulmonary oedema). Naloxone cannot replace respiratory therapy in serious intoxication. Intravenous fluids (electrolyte, glucose), blood gas control,acidosis correction. Symptomatic therapy.

Toxicity:
Toxic dose for adults (no onset of tolerance) is usually in the range of 40-60 mg orally and 30 mgparenterally. Scopolamine, hypnotics and alcohol potentiate toxic effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Natural opium alkaloids, ATC code: N02AA01

Latency and duration
The latency to achieve analgesic effect is about 10 minutes and the time for full effect is about 45-60 minutes after injection. Epidural administration of morphine is a long-acting analgesic method intended for epidural, lumbar or thoracic, administration. A more effective pain relief with longer duration on pain from the thorax, abdomen and lower extremities is obtained compared with morphineadministered parenterally. The mean duration of effect at a dose of 4 mg epidural morphine is about 10-12 hours in post-operative pain. The treatment effect and analgesic duration varies with type of surgery. In the treatment of severe opioid sensitive pain, e.g., in cancer, the analgesic effect of the above dose may be lower and of shorter duration.

Mode of action
Morphine has an agonistic effect on opioid receptors. The strong analgesic effect is due to an alteredpain perception and partly to an increase in pain threshold.
Epidurally administered morphine probably exerts its main effect directly on the opiate receptors inthe spinal cord and causes a selective inhibition of the pain impulse to the central nervous system (CNS). The analgesic effect is segmental, however, not completely, and free of motor, sensory or sympathetic blockade.

Metabolites
Morphine is metabolised by conjugation to the 2 major metabolites morphine-6-glucuronide (M6G) and morphine-3-glucuronide (M3G). Small amounts of morphine-3,6-diglucuronide may also be formed. M3G has low affinity for opioid receptors, i.e. no documented analgesic effect, but can contribute to excitatory effect. M6G is twice as potent as morphine in systemic administration, and thepharmacological effects of M6G cannot be distinguished from morphine. In chronic administration, it stands for a significant proportion of morphine analgesic effects.

Respiratory depression
The respiratory depressant effect of morphine is due to an inhibition of the carbon dioxide stimulatingeffect on the respiratory centre in the medulla oblongata, but also due to the fact that respiratory response to low oxygen tension is inhibited. The respiratory depressant effects of epidural morphine isconditioned mainly by cranial CSF transportation from the site of injection. The medical product can then reach the vital centres in the medulla oblongata. In patients with normal ventilation abilities an epidural dose of 2-5 mg of morphine have little importance in this regard. There is an increased risk ofrespiratory depression in the treatment of elderly patients, particularly when used with other narcotic analgesics and in repeated epidural doses. Risk of respiratory depression is also present in patients with chronic respiratory disease and patients with high intracranial pressure.
The effects of morphine can be enhanced after encephalitis.

If breathing is affected, respiratory supportive therapy and administration of naloxone may be required. As the depressant effects can be prolonged, repeat doses of naloxone is required in somecases.

Tolerance
Repeated dose of epidural morphine in animals noted reduced efficacy in experimental systems for theevaluation of analgesia. Experience from the development of tolerance in human is still limited but tolerance may occur. However, this usually does not cause any problems in the treatment of severe pain associated with cancer.
The equianalgesic dose of intrathecal morphine is about 5 times lower than that of epidural morphine,but clinical trials are not available.

5.2 Pharmacokinetic properties

Morphine does not have dose-dependent

kinetics.Absorption
Maximum concentration in blood is reached within 10-20 minutes. Epidurally administered morphineis significantly absorbed to the systemic circulation. The bioavailability of morphine may increase in patients with liver cancer.

Neonates have a reduced capacity to metabolise morphine. Older children probably have significantlylower morphine and metabolite concentrations in plasma compared to adults given a comparable dose/kg.

Distribution
The volume of distribution is about 3 L/ kg with a plasma protein binding of approximately 35%. Theclearance is approx. 24 ml/min * kg and half-life in plasma and cerebrospinal fluid (CSF) is 2-4 hoursafter epidural administration.

Metabolism, Elimination
Morphine is metabolized in the liver to the two major metabolites morphine-3-glucuronide (lack analgesic effect but can contribute with excitatory effects) and morphine-6-glucuronide (M6G) (morepotent than morphine itself). Small amounts of morphine-3,6-diglucuronide may also be formed.
Morphine and its metabolites undergo enterohepatic circulation. The elimination of morphine occurs primarily by glucuronidation and excretion of unchanged morphine in urine is <0.1%. M6G is excreted through the urine, accordingly M6G may accumulate in renal impairment. Hepatic and renalimpairment affects the elimination of the substance.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and repeated dose toxicity. There have been no long-term animal studies on the tumorigenic potential of morphine. Effects in non-clinical studies were observed for genotoxicity, andtoxicity to reproduction and development.

Mutagenic and tumorigenic potential
There are clearly positive findings available with regards to mutagenicity, which indicate that morphine has a clastogenic effect and that, furthermore, this effect exerts an influence on gametes. Thus, morphine is to be regarded as a mutagenic substance and such an effect may also be assumed inhumans.

Reproductive toxicity
Animal studies showed a potential for damage in offspring throughout the entire duration of gestation(CNS malformations, growth retardation, testicular atrophy, changes in neurotransmitter systems and behavioural patterns, dependence). In addition, morphine had an effect on male sexual behaviour and fertility in various animal species. In male rats, reduced fertility and chromosomal damage in gameteshave been reported.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulfite
Hydrochloric acid
Sodium hydroxide
Water for injection

6.2 Incompatibilities

Physicochemical incompatibility (formation of precipitates) has been demonstrated between solutionsof morphine sulphate and 5- fluorouracil.

6.3 Shelf life

24 months.

The product should be used immediately after first opening.

6.4 Special precautions for storage

Store below 30℃.
Keep the ampoules in the outer carton to protect from light.

6.5 Nature and contents of container

Ten clear glass ampoules of 1ml packed in a carton.

6.6 Special precautions for disposal and other handling

Splashes on the skin and in the eyes can cause pain, redness and itching. Avoid direct contact with the medical product. For method of administration refer to section 4.2. Do not use if particulate matter is present.

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

7. MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder/ Manufacturing Site Address:
Tasa Pharma Limited
Unit C1-C3
Kay complex
Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER

CTD10126

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/02/24

10. DATE OF REVISION OF THE TEXT

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