SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Oxycod 10 - Oxycodone Hydrochloride 10mg in 1ml solution for injection or infusion.
Oxycod 20 - Oxycodone Hydrochloride 20mg in 2ml solution for injection or infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml ampoule contains
Oxycodone hydrochloride.....10mg
Eq to 9mg oxycodone.

Each 2ml ampoule contains:
Oxycodone hydrochloride.....20mg
Eq to 18mg oxycodone).

Excipients with known effect:
contains less than 1 mmol sodium (23mg) per 1ml - essentially "sodium-free".

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection or infusion. Clear colourless solution, practically free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oxycodone is indicated in adults for the treatment of moderate to severe pain in patients with cancer and post-operative pain, and for the treatment of severe pain requiring the use of a strong opioid.

4.2 Posology and method of administration

Prior to starting opioid treatment, a discussion should be held with patients about an ending strategy to minimise addiction/withdrawal risk. Dose should be adjusted according to pain severity, patient condition, and prior analgesic use.

Intravenous - Bolus

Dilute to 1mg/ml; administer 1mg-10mg slowly over 1-2 minutes. Not more frequently than every 4 hours.

Intravenous - Infusion

Dilute to 1mg/ml; starting dose 2mg/hour recommended.

Intravenous - PCA

Dilute to 1mg/ml; bolus doses of 0.03mg/kg with minimum lock-out time of 5 minutes.

Subcutaneous - Bolus

Use 10mg/ml concentration; starting dose 5mg, repeated at 4-hourly intervals as required.

Subcutaneous - Infusion

Dilute if required; starting dose 7.5mg/day in opioid naïve patients, titrated gradually.

Conversion from morphine / oral-parenteral switching

Parenteral morphine to parenteral oxycodone: 1:1 dose ratio. Oral to parenteral oxycodone: 2mg oral oxycodone equivalent to 1mg parenteral oxycodone. Inter-patient variability requires careful titration.

Special populations

Elderly: treat with caution, lowest dose with careful titration. Renal/hepatic impairment: reduce recommended starting dose by 50%, titrate to adequate pain control. Paediatric population: no data available for patients under 18 years.

Method of administration

Subcutaneous or intravenous injection or infusion. Oxycodone should not be used longer than necessary; taper gradually when discontinuing.

4.3 Contraindications

Hypersensitivity to oxycodone or any excipient. Must not be used where opioids are contraindicated: severe respiratory depression with hypoxia, paralytic ileus, acute abdomen, severe chronic obstructive lung disease, cor-pulmonale, severe bronchial asthma, elevated blood CO_2, chronic constipation.

4.4 Special warnings and precautions for use

Caution when administering to debilitated elderly, patients with impaired pulmonary/hepatic/renal function, myxoedema, hypothyroidism, Addison's disease, toxic psychosis, prostate hypertrophy, adrenocortical insufficiency, alcoholism, delirium tremens, biliary tract disease, pancreatitis, inflammatory bowel disorders, hypotension, hypovolaemia, raised intracranial pressure, head injury, sleep apnoea, or patients on benzodiazepines/other CNS depressants/MAO inhibitors.

Sleep related breathing disorders

Opioids may cause central sleep apnoea and sleep-related hypoxemia, and worsen pre-existing sleep apnoea. Consider decreasing total opioid dosage in patients presenting with CSA.

Concomitant use with sedatives

Concomitant use with benzodiazepines or related drugs may result in sedation, respiratory depression, coma, and death; reserve for patients without alternative options, use lowest effective doses and shortest duration, and monitor closely.

Drug dependence, tolerance and potential for abuse

Repeated use may lead to Opioid Use Disorder (OUD); risk increased with personal/family history of substance use disorders, current tobacco use, or other mental health disorders. Monitor for drug-seeking behaviour; consult addiction specialist if OUD signs present.

Drug withdrawal syndrome / Hyperalgesia

May occur upon abrupt cessation; taper gradually (may take weeks to months). Hyperalgesia may present as increased, more diffuse pain and may resolve with dose reduction.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use with sedatives (benzodiazepines etc.) increases risk of sedation, respiratory depression, coma and death - limit dosage/duration. CNS-affecting drugs (other opioids, gabapentinoids, anxiolytics, hypnotics, antipsychotics, antidepressants, muscle relaxants, antihypertensives, alcohol) may have additive effects.

Anticholinergics/anticholinergic-activity drugs may increase anticholinergic adverse effects. MAO inhibitors may cause CNS excitation/depression with hypertensive/hypotensive crisis - avoid co-administration or within 2 weeks of discontinuation. Serotonergic agents (SSRIs, SNRIs) may cause serotonin toxicity. Alcohol may enhance pharmacodynamic effects - avoid.

Oxycodone is metabolised mainly by CYP3A4 with contribution from CYP2D6. CYP3A4 inhibitors (macrolides, azole-antifungals, protease inhibitors, cimetidine, grapefruit juice) may increase oxycodone plasma concentrations - e.g. itraconazole increased AUC ~2.4-fold, voriconazole ~3.6-fold, telithromycin ~1.8-fold, grapefruit juice ~1.7-fold. CYP3A4 inducers (rifampicin, carbamazepine, phenytoin, St John's Wort) may reduce plasma concentrations - e.g. St John's Wort reduced AUC ~50%, rifampicin ~86%. CYP2D6 inhibitors (paroxetine, quinidine) may decrease clearance.

4.6 Fertility, pregnancy, and lactation

Use should be avoided to the extent possible in pregnant or lactating patients.

Pregnancy

Limited data; infants born to mothers receiving opioids during the last 3-4 weeks before delivery should be monitored for respiratory depression. Regular use may cause foetal drug dependence, leading to neonatal withdrawal symptoms. Administration during labour may depress neonatal respiration; an antidote should be readily available.

Breastfeeding

Oxycodone may be secreted in breast milk and cause infant respiratory depression; should not be used in breast-feeding mothers.

Fertility

Nonclinical toxicity studies in rats have not shown any effect on fertility.

4.7 Effects on ability to drive and use machines

Oxycodone may impair ability to drive and use machines depending on dosage and individual susceptibility; patients should not drive or operate machinery if affected.

4.8 Undesirable effects

Adverse drug reactions are typical of full opioid agonists. Tolerance and dependence may occur. The most serious adverse reaction is respiratory depression, most likely in elderly, debilitated or opioid-intolerant patients.

Very common: Somnolence, dizziness, headache, constipation, nausea, vomiting, pruritus. Common: Decreased appetite, anxiety, confusional state, depression, insomnia, tremor, lethargy, sedation, dyspnoea, bronchospasm, abdominal pain, diarrhoea, dry mouth, dyspepsia, rash, hyperhidrosis, asthenia, fatigue. Uncommon: Hypersensitivity, dehydration, agitation, hallucinations, amnesia, convulsion, respiratory depression, hiccups, dysphagia, increased hepatic enzymes, urinary retention, erectile dysfunction, drug withdrawal syndrome, oedema, drug tolerance. Rare: Hypotension, orthostatic hypotension. Not known: Anaphylactic/anaphylactoid reaction, aggression, drug dependence, hyperalgesia, central sleep apnoea syndrome, dental caries, cholestasis, urticaria, amenorrhoea, drug withdrawal syndrome neonatal.

4.9 Overdose

Symptoms

Acute overdose can manifest as miosis, respiratory depression, hypotension, and hallucinations; nausea/vomiting common in less severe cases. Non-cardiac pulmonary oedema and rhabdomyolysis particularly common after IV injection. Circulatory failure, somnolence progressing to stupor/coma, hypotonia, bradycardia, pulmonary oedema and death may occur in severe cases; effects potentiated by concomitant alcohol/psychotropic drugs.

Treatment

Establish patent airway and assisted/controlled ventilation. Naloxone is the specific antidote. For massive overdosage: naloxone IV 0.4-2mg (adult) or 0.01mg/kg (children), repeated at 2-minute intervals; infusion at 60% of initial dose/hour if repeated doses needed. Intramuscular naloxone is an alternative if IV access unavailable. For less severe overdosage: naloxone 0.2mg IV followed by 0.1mg increments every 2 minutes. Observe patient for at least 6 hours after last naloxone dose. Naloxone should be administered cautiously in physically dependent patients to avoid precipitating acute withdrawal.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the

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

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Natural opium alkaloids. ATC code: N02AA05.

Oxycodone is a full opioid agonist with no antagonist properties, with affinity for kappa, mu and delta opioid receptors in the brain and spinal cord. The therapeutic effect is mainly analgesic, anxiolytic and sedative. Opioids may induce spasm of the sphincter of Oddi. Whether oxycodone has immunological effects similar to morphine is unknown.

5.2 Pharmacokinetic properties

Pharmacokinetic studies demonstrated equivalent availability of oxycodone via intravenous and subcutaneous routes, as single bolus or continuous 8-hour infusion.

Distribution

Distributed throughout the body; approximately 45% bound to plasma protein.

Metabolism

Metabolised in the liver via CYP3A4 and CYP2D6 to noroxycodone, oxymorphone and noroxymorphone, subsequently glucuronidated. Noroxycodone and noroxymorphone are the major circulating metabolites; none are thought to contribute significantly to analgesic effect.

Elimination

Plasma elimination half-life approximately 3-5 hours; excreted in urine and faeces. Plasma concentrations minimally affected by age (15% greater in elderly). Females have up to 25% higher plasma concentrations than males. Crosses the placenta and is found in breast milk. Hepatic or renal dysfunction may increase plasma concentrations and elimination half-life, with increased drug effects.

5.3 Preclinical safety data

No effect on fertility or early embryonic development in rats at doses up to 8mg/kg/day; no deformities induced in rats (up to 8mg/kg/day) or rabbits (up to 125mg/kg/day), though dose-related developmental variations were observed at the highest rabbit dose, likely secondary to severe maternal toxicity. Peri/postnatal studies showed no effects on F1/F2 generation behavioural/reproductive indices apart from body weight effects at higher maternal doses.

Genotoxic risk considered minimal/absent at therapeutic systemic concentrations; not genotoxic in bacterial mutagenicity or in vivo micronucleus assays, with mixed results in in vitro mouse lymphoma/chromosomal aberration assays. Carcinogenicity evaluated in a 2-year rat study; no increased tumour incidence at doses up to 6mg/kg/day (limited by opioid-related pharmacological effects).

6 Pharmaceutical particulars

6.1 List of excipients

- Citric acid
- Sodium citrate dihydrate
- Sodium chloride
- Hydrochloric acid (for pH adjustment)
- Sodium hydroxide (for pH adjustment)
- Water for injections

6.2 Incompatibilities

Must not be mixed with other medicinal products except those mentioned in section 6.6. Cyclizine at concentrations ≤3mg/ml shows no precipitation for 24 hours at 25°C when mixed undiluted or diluted with water for injections; precipitation occurs above 3mg/ml or when diluted with 0.9% saline - water for injections recommended as diluent. Prochlorperazine is chemically incompatible.

6.3 Shelf life

Unopened ampoules: 24 months. Opened ampoules: use immediately after opening. Prepared infusion solutions: chemical/physical in-use stability demonstrated for 24 hours at 25°C; from a microbiological standpoint, use immediately unless diluted under controlled aseptic conditions.

6.4 Special precautions for storage

Do not store above 30°C. Do not use if particulate matter is present.

6.5 Nature and contents of container

Clear glass ampoules, glass type I, Ph. Eur., nominal volume 1ml or 2ml. Pack size: 5 ampoules, 10 ampoules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Each ampoule is for single use in a single patient; use immediately after opening and discard any unused portion. Compatible with hyoscine butylbromide, hyoscine hydrobromide, dexamethasone sodium phosphate, haloperidol, midazolam hydrochloride, metoclopramide hydrochloride, and levomepromazine hydrochloride. Physically/chemically stable in common syringe/tubing/infusion bag materials over 24 hours at 25°C without light protection required. 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 authorisation number(s)

vH2025/CTD11494/25119

9. Date of first authorisation/renewal of the authorisation

24-11-2025

10. Date of revision of the text

Not Applicable.