PRODUCT INFORMATION
PROLADONE®

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NAME OF THE DRUG

Oxycodone Pectinate

DESCRIPTION

PROLADONE® suppositories contain 30mg oxycodone (as the pectinate) as the active ingredient. The inactive ingredients are lactose, maize starch, pectin, povidone, magnesium stearate and hard fat.

PROLADONE® consists of an oval, 22 mm x 10 mm compressed cone, which will dissolve in use and which is covered by a wax coating to aid insertion, presented as a smooth, mottled, off-white product.

PHARMACOLOGY

The effects of oxycodone pectinate are of longer duration than those of oxycodone hydrochloride. The suppository has been found to reduce the severity of intractable pain due to carcinomatosis for up to 8 hours.

INDICATIONS

PROLADONE® is indicated for:

- Semi-synthetic narcotic analgesic.
- Relief of post-operative pain following a wide range of major operative procedures such as major orthopaedic, abdominal, gynaecological and thoracic surgery and for the relief of pain in malignant disease.

CONTRAINDICATIONS

PROLADONE® is contraindicated in:

- Hypersensitivity to opiate narcotics
- Acute respiratory depression
- Cor pulmonale
- Cardiac arrhythmias
- Bronchial asthma
- Acute alcoholism
- Brain tumour
- Head injuries
- Increased cerebrospinal or intracranial pressure
- Severe CNS depression
- Convulsive disorders
- Delirium tremens
- Suspected surgical abdomen
- Concomitant MAOIs or within 14 days of such therapy

WARNINGS AND PRECAUTIONS

Oxycodone can produce drug dependence and therefore has the potential of being abused. Psychological dependence, physical dependence and tolerance may develop upon repeated administration. Abrupt withdrawal of oxycodone in those physically dependent may precipitate withdrawal symptoms. Therefore, patients on prolonged therapy should be withdrawn gradually from the drug if it is no longer required for pain control.

Oxycodone should be used with extreme caution in patients with head injuries and raised intracranial pressure as respiratory depression and ability to increase CSF pressure may be exaggerated, thereby complicating the clinical course.

Therapeutic doses of oxycodone may decrease respiratory drive and increase airways resistance in patients with acute asthma, chronic obstructive airways disease or those with substantially decreased pulmonary reserve or respiratory depression.
Oxycodone should be used only with caution and in reduced dosage during concomitant administration of other narcotic analgesics, general anaesthetics, phenothiazines and other tranquillisers, sedative/hypnotics, some tricyclic antidepressants and other CNS depressants (including alcohol). Respiratory depression, hypotension and profound sedation or coma may result.

Administration of oxycodone may result in severe hypotension in patients whose ability to maintain adequate blood pressure is compromised by reduced blood volume, or concurrent administration of such drugs as phenothiazines or certain anaesthetics. Oxycodone may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Oxycodone may impair the mental and/or physical abilities needed for certain potentially hazardous activities, such as driving a car or operating machinery. Patients should be cautioned accordingly.

Opioid analgesics should be used with caution in patients with myasthenia gravis. The euphoric activity of opioid compounds has led to their abuse. It should be given with caution or in reduced doses to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, prostatic hypertrophy or shock. It should be used with caution in patients with obstructive bowel disorders.

Oxycodone should be administered with caution, and in reduced dosages, to elderly or debilitated patients.

**Use in Pregnancy**

(Category C)

The only concern with this drug in pregnancy is with its use during labour when narcotic analgesics may cause respiratory depression in the newborn infant.

**Use in Lactation**

It is not known whether it is excreted in breast milk nor whether it has a harmful effect on the newborn. Therefore, it is not recommended for nursing mothers unless the expected benefits outweigh the potential risk.

**Use in Children**

Oxycodone should not be administered to children.

**Interactions with Other Drugs**

Generally, the effects of oxycodone may be antagonised by acidifying agents and potentiated by alkalising agents.

The analgesic effect of oxycodone is potentiated by amphetamines, chlorpromazine and methocarbamol. CNS depressants, such as other opioids, anaesthetics, sedatives, hypnotics, barbiturates, phenothiazines, chloral hydrate and glutethimide may enhance the depressant effects of oxycodone. MAOIs (including procarbazine hydrochloride), pyrazolidone antihistamines, β-blockers and alcohol may also enhance the depressant effect of oxycodone.

Oxycodone may increase the anticoagulant activity of coumarin derivatives.

**ADVERSE REACTIONS**

In normal doses, the most common side effects of opioid analgesics are nausea, vomiting, constipation, drowsiness and confusion. Micturition may be difficult and there may be ureteric or biliary spasm; there is also an antidiuretic effect. Dry mouth, sweating, facial flushing, anorexia, faintness, vertigo, bradycardia, supraventricular tachycardia, syncope, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and miosis also occur. Raised intracranial pressure occurs in some patients. Due to the histamine-releasing effect, reactions such as urticaria and pruritus occur in some individuals. Muscle rigidity has been reported following the administration of opioids. Larger doses produce respiratory depression and hypotension, with circulatory failure and deepening coma. Convulsions may occur in infants and children. Death may occur from respiratory failure. Toxic doses vary considerably with the individual and regular users may tolerate large doses.

In long term use, physical dependence and tolerance may develop.

The following withdrawal symptoms may be observed after narcotics are discontinued:

Body aches, diarrhoea, gooseflesh, loss of appetite, nervousness, restlessness, runny nose, sneezing, tremors or shivering, stomach cramps, nausea, trouble with sleeping, unusual increase in sweating and yawning, weakness, tachycardia and unexplained fever. With appropriate medical use of narcotics and gradual withdrawal from the drug, these symptoms are usually mild.
DOSAGE AND ADMINISTRATION

One suppository every six to eight hours; in case of terminal disease, one suppository as required to control pain.

OVERDOSAGE

Symptoms:
Serious overdosage with oxycodone is characterised by respiratory depression and somnolence progressing to coma and skeletal muscle flaccidity. Cardiac arrest and death may occur.

Treatment:
Primary attention should be given to the re-establishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including oxycodone. Therefore, an appropriate dose of naloxone (usual adult dose: 0.4 mg) should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression.

Oxygen, intravenous fluids, vasopressors and other supportive measures should be used as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

In an individual physically dependent on narcotics, the administration of the usual dose of a narcotic antagonist will precipitate an acute withdrawal syndrome. The severity of this syndrome will depend on the degree of physical dependence and the dose of antagonist administered. The use of narcotic antagonists in such individuals should be avoided if possible. If a narcotic antagonist must be used to treat serious respiratory depression in the physically dependent patient, only 10 to 20% of the usual initial dose of the antagonist should be administered.

In severe toxicity, the cardiovascular system is usually depressed and requires supportive treatment. If hypotension is due to vasodilatation, plasma expansion, or even vasopressors may be required. Additional measures include support of electrolyte balance, maintenance of normal temperature, catheterisation of the bladder to avoid distension and symptomatic treatment of itching, nausea, vomiting, headache and confusion during the recovery period.

PRESENTATION

PROLADONE® contains oxycodone 30mg per suppository as the active ingredient.

It is presented as a pack of 12 suppositories.

AUST R 14965. Catalogue Number : TAB007

POISON SCHEDULE- Schedule 8 (S8) Controlled drug.

NAME AND ADDRESS OF THE SPONSOR

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