

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Palfium Tablets 5mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains dextromoramide tartrate equivalent to 5mg of dextromoramide.

For excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

White, circular, flat, beveled-edged tablets with a single score line on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Management of moderate to severe pain.

4.2 Posology and method of administration

Palfium tablets are for oral administration.

Adults: The usual dose is 5 to 20mg. An initial dose of 5mg is recommended.

Elderly: As with all opioid analgesics, a reduction in dosage is advisable in the elderly.

Children: Not recommended.

4.3 Contraindications

Use in patients with hypersensitivity or idiosyncratic response to dextromoramide.

Use in patients with respiratory depression.

Use in patients after operative interventions in the biliary tract.

Use in patients with acute alcoholism, increased intracranial pressure, or in coma, or with convulsive disorders.

Use in patients who are receiving, or have within 2 weeks received, monoamine oxidase inhibitors.

Use in infants.

4.4 Special warnings and precautions for use

Palfium tablets should only be used with extreme caution and in reduced dosage in the elderly, the debilitated, or in patients with hypothyroidism, adrenocortical insufficiency, shock, liver dysfunction, prostatic hypertrophy, hepatic or

renal insufficiency, biliary tract disorders.

Repeated use will induce physical and psychological dependence, with a withdrawal syndrome on cessation of therapy.

Repeated use will also result in the development of tolerance requiring increases in dosage to achieve the required effect.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration with other central nervous system depressants (including alcohol and anaesthetics) will induce an increased depressant effect.

4.6 Pregnancy and lactation

Palfium can induce respiratory depression, particularly in neonates; therefore it should not be used in obstetric delivery. All the narcotic analgesics are able to traverse the placenta and also are excreted in milk.

This should be borne in mind when considering their use in patients during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Palfium may induce drowsiness. Patients receiving Palfium should not drive or operate machinery unless its effects on physical and mental ability have gone.

4.8 Undesirable effects

Possible side-effects include nausea, vomiting, drowsiness, dizziness, sweating, difficulty in micturition, bradycardia and postural hypotension. Side-effects tend to occur more commonly in ambulant patients than in those at rest in bed.

4.9 Overdose

Signs of opioid overdosage may include respiratory depression and hypotension, with circulatory failure and deepening coma. The triad of coma, pinpoint pupils and respiratory depression is indicative of opioid overdosage.

In acute overdosage, the stomach should be emptied by aspiration and lavage.

Intensive supportive therapy may be required to manage respiratory failure and shock. The specific antagonist naloxone hydrochloride is used to counteract respiratory depression and coma resulting from excessive doses of opioids. A dose of 0.4 to 2.0mg is given by intravenous injection, repeated every 2 to 3 minutes if necessary, up to a total of 10mg. The circulation should be maintained with intravenous fluids if required; a patent airway should be maintained and assisted respiration may be necessary until spontaneous breathing is restored.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dextromoramide is a narcotic analgesic. In common with other opioid analgesics, dextromoramide produces its major effects on the central nervous system by interacting with opioid receptors.

5.2 Pharmacokinetic properties

Following oral administration, absorption from the gut is variable and the drug is metabolised in the liver and is excreted through urine and bile. Dextromoramide crosses the placenta and enters the foetal circulation.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Acacia
Magnesium Stearate
Colloidal Anhydrous Silica
Talc
Maize Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container.

6.5 Nature and contents of container

Polypropylene ‘securitainer’ tablets containers with tamper evident polypropylene caps.
Pack sizes: 50 and 250 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Ltd.
Roscrea
Co. Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 73/19/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

January 2006