

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Omnopon Injection

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains Papaveretum BP 15.4 mg, equivalent to:

Anhydrous morphine (as Morphine Hydrochloride Ph. Eur.)	10	mg
Papaverine Hydrochloride Ph. Eur.	1.2	mg
Codeine Hydrochloride Ph. Eur.	1.04	mg

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Solution for injection

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Pre-operative medication. As an analgesic in the relief of moderate to severe pain.

##### 4.2 Posology and method of administration

For subcutaneous or intramuscular injection.

###### Adults

The usual dosage by sc or im injection is 7.7-15.4mg (0.5 to 1.0ml) repeated every 4 hours if necessary.

###### Elderly and debilitated patients

The elderly are more sensitive to the action of narcotic analgesics. The initial dose should not exceed 7.7mg (0.5ml).

###### Children 1-12 years

The usual dose by sc or im injection is 0.154-0.231mg/kg (0.01-0.015ml/kg) body weight.

###### Children 1-12 months

The usual dose by sc or im injection is 0.1155-0.154mg/kg (0.0075-0.01ml/kg) body weight.

###### Neonates aged up to 1 month

The usual dose by sc or im injection is 0.1155mg/kg (0.0075ml/kg) body weight.

### 4.3 Contraindications

- Coma.
- Hypersensitivity to any of the products ingredients.
- Acute respiratory depression or chronic obstructive airways disease.
- Asthma (during an attack).
- Acute alcoholism.
- Head injuries or increased intracranial pressure.
- Heart failure secondary to lung disease.
- Risk of paralytic ileus.
- Pheochromocytoma.
- Current use of monoamine oxidase inhibitors or within two weeks of their withdrawal.

### 4.4 Special warnings and precautions for use

Repeated administration of Omnopon may induce tolerance to the drug, with a tendency to increasing dosage requirements to obtain the desired effect, or to physical and psychological dependence of the morphine type, with the development of withdrawal symptoms after abrupt cessation of therapy. Cross-tolerance between narcotic analgesics can occur. Excessive dosage (relative or absolute) may induce convulsions.

Omnopon should only be given with caution to neonates and premature infants, elderly and debilitated patients, and in patients with:

- Adrenocortical insufficiency.
- Biliary tract disorders.
- Hypotension.
- Hypothyroidism or Hyperthyroidism.
- Depressed respiratory reserve.
- Prostatic hypertrophy.
- Shock.
- Supraventricular tachycardia.
- Convulsive disorders.
- Hepatic or renal impairment. (Avoid or reduce dose).

### 4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of Omnopon with phenothiazines may induce severe hypotension.

Patients should be instructed to avoid alcohol while under treatment, since the individual response cannot be foreseen.

Anxiolytics, Hypnotics and other CNS Depressions: Sedative effects may be enhanced by simultaneous use of morphine.

Ciprofloxacin: the manufacturer of ciprofloxacin advises that, if it used for surgical prophylaxis, that opiates should not be used for premedication as this may reduce the plasma concentration of ciprofloxacin.

### 4.6 Pregnancy and lactation

There is inadequate evidence of safety of Omnopon in human pregnancy, and therefore, the established medical principle of prescribing medicaments in early pregnancy only when absolutely indicated should be observed. Omnopon crosses the placenta and is also excreted in breast milk. This should be borne in mind when considering its use in patients during pregnancy or breast feeding. Administration in labour may cause respiratory depression in the newborn infant.

#### 4.7 Effects on ability to drive and use machines

Omnopon may modify patients' reactions (driving ability, operation of machinery, etc.) to a varying extent, depending on dosage, administration and individual susceptibility.

#### 4.8 Undesirable effects

- Hallucinations, confusion, mood changes, dysphoria and dependence.
- Headache, vertigo, dizziness and drowsiness.
- Sweating and postural hypotension.
- Miosis.
- Bradycardia, palpitations, tachycardia, and facial flushing.
- Constipation, nausea, vomiting and a dry mouth.
- Ureteric or biliary spasm.
- Rashes and pruritis.
- Decrease in libido or potency.
- Difficult with micturition.
- Hypothermia.

Late post-operative vomiting may be a problem in paediatrics. Very rarely, neonatal convulsions have been reported.

#### 4.9 Overdose

Signs of overdosage are similar to those seen with morphine; they include pin-point pupils, depressed respiration and coma. In severe poisoning there may be dilation of the pupils, shock severe respiratory depression and pulmonary oedema.

Intensive supportive therapy should be carried out. Naloxone is the preferred antidote.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

Omnopon, a potent analgesic, contains both the phenanthrene and isoquinoline groups of opium alkaloids. The former included codeine and morphine, which exert a marked narcotic action on the central nervous system. The second group is represented by papaverine, which acts mainly at the periphery as an antispasmodic.

#### 5.2 Pharmacokinetic properties

Pharmacokinetic data on Omnopon are not available.

#### 5.3 Preclinical safety data

Not applicable.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Ethanol 96 %  
 Glacial acetic acid  
 Sodium hydroxide  
 Water for injections

## **6.2 Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## **6.3 Shelf Life**

2 years.

## **6.4 Special precautions for storage**

Do not store above 25°C.  
Protect from light.

## **6.5 Nature and contents of container**

1 ml colourless Type I glass ampoules in packs of ten.

## **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**

Martindale Pharmaceuticals  
Bampton Road  
Romford  
RM3 8UG  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 361/9/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15 April 1992

Date of last renewal: 15 April 2003

## **10 DATE OF REVISION OF THE TEXT**

December 2005