

# Ayendi® Nasal Spray

Diamorphine HCL Nasal Spray

## Priming/Administration of Solution

1. Remove green safety clip and prime twice into a sink wall or sharps bin

2. Administer the necessary dose, alternating nostrils for each spray. Hold bottle upright ensuring dip tube remains in the solution



3. Replace green safety clip and change the nasal tip



4. Discard used nasal tip in sharps bin

5. Monitor the patient for 30 minutes following administration



Prescribing Information is located on reverse

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Replacement nasal tips are available free of charge from Wockhardt UK Ltd.  
Tel: 01978 661261 or Email: [ayendi@wockhardt.co.uk](mailto:ayendi@wockhardt.co.uk)

### Ayendi® (diamorphine hydrochloride) 720 and 1600 microgram/actuation Nasal Spray Prescribing Information

Please read the Summary of Product Characteristics before prescribing

**PRESENTATION** Freeze dried powder and diluent (0.5%w/v preserved saline) for reconstitution. For 1600 microgram/actuation bottles contain 160mg (8ml bottle) or 320mg (17 ml bottle). For 720 microgram/actuation bottles contain 72mg (8ml bottle) or 144 mg (17 ml bottle).

**INDICATION** Treatment of acute severe nociceptive pain in children and adolescents 2 to 15 years of age in a hospital setting. Ayendi Nasal Spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring.

#### **DOSAGE AND ADMINISTRATION**

Single dose only. Direct spray towards lateral nasal wall with patient in semi-recumbent position. Dose according to weight approximately 0.1 mg/kg (refer to dosage chart in SmPC for details). Patients should be monitored for at least 30 minutes following administration.

#### **CONTRAINDICATIONS**

Known hypersensitivity to diamorphine, morphine or any excipients. Respiratory depression, obstructive airways disease, acute asthma exacerbations, phaeochromocytoma, biliary colic, coma, raised intracranial pressure, head injuries, acute alcoholism, where there is a risk of paralytic ileus, diarrhoea due to antibiotic induced pseudomembranous colitis or poisoning.

#### **SPECIAL WARNINGS/PRECAUTIONS**

For intranasal administration only. Risk of transmission of infectious agents if nasal tips are not changed between patients. Repeated administration may lead to tolerance and dependence. Exercise caution in patients with history of drug abuse. Avoid or use with an anti-spasmodic in biliary tract disorders. Use with caution in patients with asthma or decreased respiratory reserve, toxic psychosis, CNS depression, myxoedema, prostatic hypertrophy or urethral stricture, severe inflammatory or obstructive bowel disorders, hypotension, shock, convulsive disorders and adrenal insufficiency. Avoid concomitant use with MAOIs and for two weeks after stopping. Consider dose reduction in renal and hepatic impairment.

#### **INTERACTIONS**

Enhanced sedative and hypotensive effect with alcohol, tricyclic antidepressants, anxiolytics, antipsychotics and hypnotics. Enhanced depressive effects with anaesthetics. Diamorphine may delay the absorption of mexiletine. Plasma levels may be increased by ritonavir.

May potentiate effects of CNS depressants. Concomitant use of anti-diarrhoeal and anti-peristaltic agents may increase risk of severe constipation. Risk of severe constipation and/or urinary retention increased with antimuscarinics. Potential additive CNS depression with nitrous oxide – consider depression of protective reflexes. Gastrointestinal effects of domperidone and metoclopramide may be antagonized. Cimetidine inhibits metabolism of opioids.

#### **PREGNANCY AND LACTATION**

Safety has not been established in pregnancy. Avoid in breast-feeding women. Use during labour carries risk of respiratory depression in the neonate and gastric stasis during labour (increasing risk of inhalational pneumonia).

**SIDE EFFECTS Common:** sedation, nausea and vomiting, constipation, sweating, dizziness, dysgeusia, nasal discomfort, sneezing, epistaxis, laryngitis, pruritus. **Uncommon/serious:** respiratory depression, depressed level of consciousness, hypoxia, anaphylaxis (following IV administration), abdominal pain, haematemesis, psychiatric disorders including psychological dependence, confusion, hallucinations, rash and urticaria, mood changes, changes in vision, palpitations, orthostatic hypotension, biliary spasm, and urinary retention. Please consult SmPC for other side effects.

#### **LEGAL CATEGORY POM**

#### **PACKAGE QUANTITY AND PRICE**

720microgram/actuation - £107.90 per 8ml bottle, £112.50 per 17ml bottle. 1600microgram/actuation - £113.52 per 8ml bottle, £123.75 per 17ml bottle

#### **MARKETING AUTHORISATION HOLDER**

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK  
No PL 29831/0465 and PL 29831/0466

DATE March 2016

**Adverse events should be reported.**  
Reporting forms and information can be found at  
[www.mhra.gov/yellowcard](http://www.mhra.gov/yellowcard)  
Adverse events should also be reported to the Drug Safety and  
Information Department at Wockhardt UK (Tel: 01978 661261)

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