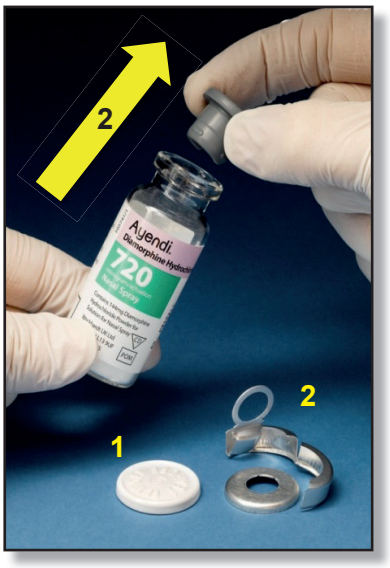
Ayendi® Nasal Spray

Diamorphine HCL Nasal Spray

Reconstitution/Preparation of Solution

1. **Flip off** protective cap

2. **Tear off aluminium seal** and **pull out rubber bung**

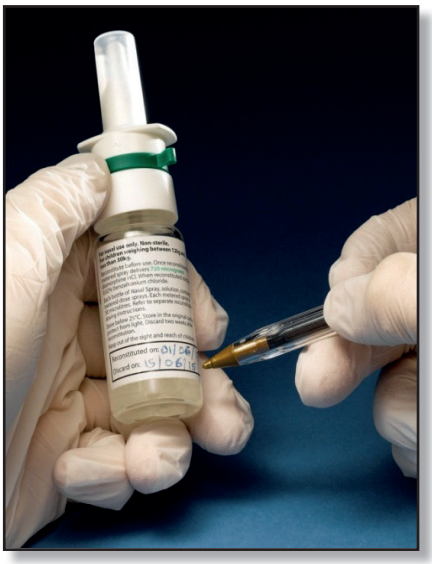


3. **Twist off seal** from plastic tube containing diluent and **squeeze contents** into bottle

4. Holding the bottle tightly **push nasal pump** with tip attached **onto glass bottle** so it **snaps in place**

5. **Swirl** bottle gently until powder is dissolved. **Do NOT vigorously shake** the bottle

6. Write **date of reconstitution** and **date for discarding** (14 days after reconstitution) on the label of the bottle



Prescribing Information is located on reverse

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7. **Remove green safety clip** and **prime nasal spray** by holding upright and **actuating 8 times**. Ensure dip tube remains in solution. **Replace safety clip**.

NB: Each time the tip is changed the pump must be primed a further **2** times

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 to15 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 intra-cranial 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 ritinovir. 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, dysguesia, 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
Adverse events should also be reported to the Drug Safety and Information Department at Wockhardt UK (Tel: 01978 661261)

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