

Introducing Ayendi® Nasal Spray (Diamorphine Hydrochloride) -Licensed, effective, accurate, simple

Ayendi® Nasal Spray is licensed for the 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.

Licensed
For relief of acute severe nociceptive pain in patients aged 2-15 years^{1,2}

Rapid
Highly effective at 5 minutes post dose³

Reliable
Onset of action of oral morphine delayed and unpredictable⁴

Avoids off-label use
Assessed for efficiency, safety and quality

Metered dose
Precise volume and dose in every spray^{1,2}

Consistent droplets
Optimal absorption and minimal run-off⁵



Minimal distress
Rated as acceptable by 98% of children³

Disposable tips
Multi-patient use from one bottle, for easy, fast administration^{1,2}

Simple to use
Easy reconstitution procedure for multiple patients^{1,2}

Simple to store
No need for refrigeration^{1,2}

Simple dosing
Helps minimise risk of error

Easy recognition
Available in two clearly labelled strengths

The ONLY licensed intranasal diamorphine

Now available in a smaller pack size (5ml diluent)

Ayendi® Product Range

Presentation	Total diamorphine dose in bottle (as supplied)	Volume when reconstituted	Single dose (dose per spray)	Single spray liquid volume
Diamorphine 720mcg /actuation nasal spray bottle ¹	72mg	5ml (14.4mg/ml)	0.72mg	0.05ml
	144mg	10ml (14.4mg/ml)		
Diamorphine 1600mcg /actuation nasal spray bottle ²	160mg	5ml (32mg/ml)	1.6mg	0.05ml
	320mg	10ml (32mg/ml)		

720mcg/spray for children 12kg to <30kg¹

Weight of child	Approx age	Total No. Sprays*	Total dose delivered
12kg to <18kg	2-5 years	2	1.44mg
18kg to <24kg	5-8 years	3	2.16mg
24kg to <30kg	8-10 years	4	2.88mg (max dose)



1600mcg/spray for children and adolescents 30kg to 50kg²

Weight of child	Approx age	Total No. Sprays*	Total dose delivered
30kg to <40kg	10-14 years	2	3.20mg
40kg to 50kg	14-15 years	3	4.80mg (max dose)



*Must be administered into alternating nostrils

Patients should be monitored for at least 30 minutes following administration for signs of respiratory depression^{1,2}

Ayendi® Nasal Spray is available to order from your nearest AAH wholesaler. Order codes:
Ayendi® Nasal Spray 72mg/5ml 720mcg/spray AYE0004K, Ayendi® Nasal Spray 144mg/10ml 720mcg/spray AYE0001W,
Ayendi® Nasal Spray 160mg/5ml 1600mcg/spray AYE0005G, Ayendi® Nasal Spray 320mg/10ml 1600mcg/spray AYE0003Y.

For further information please email: ayendi@wockhardt.co.uk or call 01978 661261 or visit www.wockhardt.co.uk/ayendi.html
Prescribing information can be found overleaf.



The ONLY licensed intranasal diamorphine

Ayendi® is available in two strengths and two bottle sizes: 5ml and 10ml



Prescribing Information for Ayendi®

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

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 (5ml diluent) or 320mg (10ml diluent). For 720 microgram/actuation bottles contain 72mg (5ml diluent) or 144 mg (10ml diluent).

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 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, 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 (72mg in 5ml), £112.50 (144mg in 10ml) 1600microgram/actuation - £113.52 (160mg in 5ml), £123.75 (320mg in 10ml) **MARKETING AUTHORISATION HOLDER** Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK. No PL 29831/0465 and PL 29831/0466 **DATE** Sept 2016

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Wockhardt UK Ltd (01978 661261)

References

1. Ayendi® 720mcg Summary of Product Characteristics.
2. Ayendi® 1600mcg Summary of Product Characteristics.
3. Data on File Wockhardt.
4. Maurice SC, O'Donnell JJ, Beattie TF. Emergency analgesia in the paediatric population. Part II: pharmacological methods of pain relief. Emerg Med J 2002; 19(2): 101-105
5. Wolfe TR, Braude DA. Intranasal Medication Delivery for Children: A brief Review and Update. Pediatrics. 2010; September Vol 126(3): 532-537

IND01/17 May 2017