PATIENT GROUP DIRECTION TEMPLATE

for the supply and/or administration of

AYENDI® NASAL SPRAY
(DIAMORPHINE HYDROCHLORIDE 720 AND 1600 MICROGRAM PER ACTUATION)

by registered health professional group(s) for the

TREATMENT OF ACUTE SEVERE NOCICEPTIVE PAIN
IN CHILDREN AND ADOLESCENTS (2 TO 15 YEARS OF AGE)
IN A HOSPITAL EMERGENCY SETTING

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it.

The most recent and in-date, final, signed version of the PGD should be used.

Prescribing Information can be found on page 5

1. CLINICAL CONDITION	
Clinical condition or situation to which this PGD applies	Treatment of acute severe nociceptive pain in children and adolescents 2 to 15 years of age in the hospital emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring.
Inclusion criteria	Children or adolescents 2 to 15 years of age presenting to the Emergency Department with acute severe nociceptive pain.
Exclusion criteria	Individuals under the age of 2 years or aged 16 years or over should not receive Ayendi Nasal Spray. Known hypersensitivity to diamorphine or morphine; respiratory depression; obstructive airways disease; acute asthma exacerbations; phaeochromocytoma; biliary colic; coma; raised intracranial pressure; head injury; acute alcoholism; where there is risk of paralytic ileus; diarrhoea due to antibiotic induced pseudomembranous colitis or poisoning.
Cautions/need for further advice	Ayendi Nasal Spray is for intranasal use only. There is a risk of transmission of infectious agents if nasal tips are not changed between patients. Repeated administration may lead to tolerance and dependence. Caution should be exercised in patients with a history of drug abuse. Should be used 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, adrenal insufficiency. Concomitant use with MAO inhibitors should be avoided and for 2 weeks after stopping. In patients with renal and hepatic impairment consider a reduction in dose.
Arrangements for referral for medical advice	All concerns or queries about the suitability of Ayendi Nasal Spray for a given patient should be referred to the on-duty consultant.
Action to be taken if patient excluded	If a patient is not considered suitable to receive Ayendi Nasal Spray, alternative analgesic options should be considered (e.g. oral or intravenous morphine) depending on the severity of pain, the compliance of the patient and the speed of onset required.
Action to be taken if patient declines treatment	Advise patient/parent/guardian/carer about the benefits of intranasal administration (e.g. convenience, comfort, speed of administration, speed of onset) including potential side effects. If the patient continues to decline treatment they should be offered alternative analgesia (e.g. oral or intravenous morphine). Document advice given and the decision reached.
2. DETAILS OF THE MEDICINE	
Name, form and strength of medicine	Ayendi (diamorphine hydrochloride) 720 and 1600 microgram/actuation nasal spray. As a multi-patient device, Ayendi Nasal Spray needs to be reconstituted one-time only.
Legal category	Prescription only medicine (POM).
Indicate any off-label use (if relevant)	Off-label use is not expected to occur.
Route/method of administration	Intranasal administration via a metered nasal spray pump.
Dose and frequency	Patients are administered a single dose according to their weight (approximately 0.1 mg/kg): Use **720 mcg/actuation nasal spray** for children **12 kg to <30 kg:** • 12 kg to <18 kg: 2 sprays in total (administered into alternating nostrils) • 18 kg to <24 kg: 3 sprays in total (administered into alternating nostrils) • 24 kg to <30 kg: 4 sprays in total (administered into alternating nostrils) Use **1600 mcg/actuation nasal spray** for children **30 kg to 50 kg:** • 30 kg to <40 kg: 2 sprays in total (administered into alternating nostrils) • 40 kg to 50 kg: 3 sprays in total (administered into alternating nostrils)
Quantity to be administered and/or supplied	Ayendi Nasal spray is for the administration of a single dose of diamorphine only (approximately 0.1mg/kg).

Maximum or minimum treatment period	Ayendi Nasal Spray is for single dose only. It is not licensed for repeat dosing. Each patient should undergo monitored observation (e.g. respiratory rate, pulse oximetry) for 30 minutes following administration.
Adverse events/side effects	*Common:* sedation, nausea and vomiting, constipation, sweating, dizziness, dysguesia, nasal discomfort, sneezing, epistaxis, laryngitis, pruritis. *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 urticarial, mood changes, changes in vision, palpitations, orthostatic hypotension, biliary spasm, and urinary retention. In addition, please refer to Ayendi's SmPCs.
Reference to clinical guidelines	The *College of Emergency Medicine* Best Practice Guidelines on the Management of Pain in Children recommend intranasal diamorphine (or/followed by intravenous morphine) as first-line treatment of severe pain in children (see Appendix).
Records to be kept	• Patient's name, hospital number, address, date of birth and consent given • Contact details of GP (if registered) • Diagnosis • Dose administered • Batch number and expiry date • Advice given to patient (including side effects) • Signature/name of staff who administered or supplied Ayendi Nasal Spray • Details of any adverse drug reaction and actions taken • Referral arrangements As a controlled drug, local regulations and procedures should be followed in order to maintain an accurate record/audit of use of Ayendi Nasal Spray (e.g. Controlled Drug Register).
3. PATIENT INFORMATION	
Information to be given to the patient	Patients should be advised about the risks and benefits of Ayendi Nasal Spray compared with alternative analgesia options. In particular the side effect profile of intranasal diamorphine should be explained. The patient/parent/guardian/carer should be advised to seek medical advice in the event of a severe adverse reaction.
Follow-up advice to be given to patient or carer	As Ayendi Nasal Spray is for acute (single dose) use, no follow-up advice is required.
4. TRAINING AND COMPETENCY REQUIREMENTS OF REGISTERED HEALTH PROFESSIONALS WORKING UNDER THIS PGD	
Qualifications and professional registration	This PGD should only be used by suitably qualified, named health professionals, such as nurses currently registered with the Nursing and Midwifery Council (NMC) or other trained and appropriately qualified professionals (e.g. pharmacists).
Initial training	All registered health professionals working under this PGD should receive training on how to use Ayendi Nasal Spray, including details of how to reconstitute, prime and administer the product. Training can be facilitated by experienced and qualified members of the Emergency Department or Pharmacy or can be arranged with the product manufacturers (Wockhardt UK).
Competency assessment	• The clinical manager/lead has evidence that the health professional: o Has undertaken training to carry out the clinical assessment of whether treatment according to the PGD is required o Has completed training on the legal aspects of the supply and administration of medicines under a PGD o Has demonstrated competency to work to a PGD o Has access to relevant sources of information (e.g. BNF for Children, Summary of Product Characteristics, appropriate clinical guidelines) • The registered health professional is professionally accountable for the supply or administration of Ayendi Nasal Spray under this PGD as defined in their own profession's Code of Professional Conduct.
Ongoing training & competency	All registered health professionals working under this PGD should be aware of any changes to the recommendations for Ayendi Nasal Spray. It is the responsibility of the individual to keep up-to-date with continued professional development.

5. DEVELOPMENT OF THIS PGD

NAME	JOB TITLE & ORGANISATION	SIGNATURE	DATE
Lead author	Please complete, where appropriate.		
Lead doctor	Please complete, where appropriate..		
Lead pharmacist	Please complete, where appropriate.		
Representative of other professional group using this PGD	Please complete, where appropriate.		
Other members of the PGD Working group	Please complete, where appropriate.		

6. AUTHORISATION OF THIS PGD

NAME	JOB TITLE & ORGANISATION	SIGNATURE	DATE
Senior doctor (e.g. Medical Director)	Please complete, where appropriate.		
Senior pharmacist (e.g. Chief Pharmacist)	Please complete, where appropriate.		
Senior representative of professional group using this PGD (e.g. Director of nursing)	Please complete, where appropriate.		
Person signing on behalf of authorizing body	Please complete, where appropriate.		

7. HISTORY OF THIS PGD

VERSION NUMBER	DETAILS OF CHANGES MADE	DATE

APPENDIX A – KEY REFERENCES/SUPPORTING INFORMATION

- Ayendi Nasal Spray 720 microgram/actuation *Summary of Product Characteristics*
- Ayendi Nasal Spray 1600 microgram/actuation *Summary of Product Characteristics*
- *College of Emergency Medicine* 'Best Practice Guidelines on Management of Pain in Children'
- British National Formulary (BNF) *BNF for Children*

APPENDIX B – HEALTH PROFESSIONALS AGGREEMENT TO PRACTISE UNDER THIS PGD

BY SIGNING THIS PATIENT GROUP DIRECTION (PGD) YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT. PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY. IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE.

NAME OF HEALTH PROFESSIONAL			
SIGNATURE		DATE	
NAME OF SENIOR REPRESENTATIVE AUTHORISING HEALTH PROFESSIONAL			
SIGNATURE		DATE	

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 1600microgram/ actuation bottles contain 160mg (8ml bottle) or 320mg (17ml bottle). For 720 microgram/actuation bottles contain 72mg (8ml bottle) or 144mg (17ml 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 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 anesthetics. 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 nasal spray - £107.90 per 8ml bottle, £112.50 per 17ml bottle
1600microgram/actuation nasal spray - £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 reactions 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).

IND07/16 March 2016