Package leaflet: Information for the user
Ayendi 1600 microgram/actuation Nasal Spray
Ayendi 720 microgram/actuation Nasal Spray
Diamorphine hydrochloride
(referred to as Ayendi Nasal Spray throughout this leaflet)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

1. What Ayendi Nasal Spray is and why it is used

Ayendi Nasal Spray is a treatment for severe pain. The medicine is used to treat acute severe nociceptive pain in children and adolescents 2 to 15 years of age in a hospital setting. Ayendi Nasal Spray is also used for the treatment of acute severe nociceptive pain in adults.

2. What you need to know before you are given Ayendi Nasal Spray

Before you are given Ayendi Nasal Spray, your doctor will have to consider if it is necessary for you to be given the medicine.

3. How Ayendi Nasal Spray is given

The recommended dose is:

- 1600 mcg/actuation for children 30kg to 50kg
- 800 mcg/actuation for children 12 to <30kg
- 240 mcg/actuation for children <12 years

4. How much Ayendi Nasal Spray you will be given

The total dose given to you depends on your age and weight.

- 1600mcg/actuation for children 30kg to 50kg
- 800mcg/actuation for children 12 to <30kg
- 240mcg/actuation for children <12 years

5. How you will be given Ayendi Nasal Spray

The spray should be directed into alternate nostrils and according to the weight of the child.

6. How you will be given Ayendi Nasal Spray

- Children weighing between 12kg and less than 30kg.
- Patients should be dosed according to weight.
- Adolescents 2 to 15 years of age in a hospital setting.

7. How much Ayendi Nasal Spray you will be given

- 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 or in a hospital setting.

8. How you will be given Ayendi Nasal Spray

- Ayendi 1600 microgram/actuation Nasal Spray

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- Ayendi 720 microgram/actuation Nasal Spray

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- Ayendi Nasal Spray
Clear Type 1 neutral glass bottle (8ml or 17ml) with a nasal spray pump. Pack includes 9 disposable white polypropylene nasal tips.

Nasal spray, powder for solution

Clear Type 1 neutral glass bottle (8ml or 17ml) with a dark grey aerosol canister containing a white powder. The canister is flip oversear with a white (720mcg) or green (1600mcg) flip cover. The replacement tips are provided in individual tamper evident polypropylene nasal tips. A clear Type 1 neutral glass bottle (8ml or 17ml) with a nasal spray pump is used for the 17ml product.

How Ayendi Nasal Spray looks like and contents of the pack

Nasal spray powder for solution

Clear Type 1 nasal glass bottle (8ml or 17ml) with a screw cramped cap containing a white powder. The powder is reconstituted as a white powder for solution using a diluent supplied. The diluent is stored in a 10ml plastic vial with a white flip cover.

Oral spray, solution

Clear Type 1 nasal glass bottle (8ml or 17ml) with a white flip cover. The bottle contains a sodium chloride and water for injection as a solution for intranasal use. The suspension is dispensed using a nasal pump and soft spray nozzle.

What to do in an emergency

In an emergency, you should call the emergency services immediately.

How Ayendi Nasal Spray is manufactured and packaged

Ayendi Nasal Spray is manufactured and packaged at the following address: CP Pharmaceuticals Limited, Ash Road North, Liverpool, L6 9LH, United Kingdom. The spray will be stored at 2°C to 8°C until it is dispensed. Instructions for use will be included with the product. The medicine should be used within 2 weeks of being reconstituted.

Dosage and special precautions

Nasal Spray, solution

Before using Ayendi nasal spray, read the information and instructions on the label, especially the section titled "Special precautions for use," and consult your doctor or pharmacist. If you have any questions, ask your doctor or nurse.

Allergies and sensitivity

Please be ready to give the following information:

- Date of birth
- Allergies and previous adverse reactions
- Any other medicines you are taking
- Any other health problems or conditions

How to store Ayendi Nasal Spray

Ayendi Nasal Spray should be stored below 25°C and protected from light in the original packaging.

How Ayendi Nasal Spray works

Ayendi nasal spray is an opiate analgesic which has a rapid onset of activity and a prolonged duration of action. It is used to relieve pain in adults and children aged three and over. The spray can also be used to treat pain from injury or surgery. The spray is administered into the nasal cavity and acts on the central nervous system to relieve pain.

If you are allergic to any ingredient of Ayendi Nasal Spray, do not use it. If you are unsure whether you may be allergic to any ingredient, ask your doctor or pharmacist before using this medicine. If you have any doubts, give Ayendi Nasal Spray to your doctor or pharmacist.

Common side effects

Nasal Spray, solution

The most common side effects of Ayendi nasal spray are:

- Dizziness
- Feeling tired or sleepy
- Feeling anxiety or being nervous
- Changes in the sense of taste
- Changes in the sense of smell
- Changes in mood
- Changes in behavior

If any of the side effects persist or become troublesome, or if you notice any other side effects, please consult your doctor.

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<th>Common (affects 1 to 10 patients in 100)</th>
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Uncommon side effects

Nasal Spray, solution

The uncommon side effects of Ayendi nasal spray are:

- Reduced sexual drive or impotence after long-term use
- Abdominal pain
- Constipation
- Diarrhea
- Dry mouth
- Facial flushing
- Headache
- Mood changes
- Mental clouding or confusion
- Nausea
- Vomiting blood
- Pain in the abdomen
- Runny nose
- Inflammation of the surface of the eyes
- Drowsiness
- Dizziness
- Feeling or being hot
- Feeling tired or sleepy
- Feeling anxious

If any of the uncommon side effects persist or become troublesome, or if you notice any other unusual side effects, please consult your doctor.

How much Ayendi Nasal Spray costs

The cost of Ayendi nasal spray can vary depending on the dosage and route of administration. The cost can also be affected by factors such as the prescribed duration of treatment and the patient's insurance plan. It is important to consult with your doctor or pharmacist to determine the most appropriate dosage and route of administration.

How to order Ayendi Nasal Spray

Ayendi nasal spray is available for prescription through your doctor or pharmacist. You can obtain Ayendi nasal spray by visiting your doctor or pharmacist, or by calling the CP Pharmaceuticals customer service line. If you are unable to find Ayendi nasal spray in your area, you can also contact your doctor or pharmacist for additional information.

How to prepare Ayendi Nasal Spray

Ayendi nasal spray is supplied as a white powder in a nasal pump pack. The powder is reconstituted as a white powder for solution using a diluent supplied. The diluent is stored in a 10ml plastic vial with a white flip cover. The medicine should be used within 2 weeks of being reconstituted.

How to administer Ayendi Nasal Spray

Ayendi nasal spray is administered into the nasal cavity. The spray is given by pressing the nasal pump for a few seconds until a visible drop of medication is seen to be excreted from the tip of the spray head. The spray is given as a single dose every 15-30 minutes. The spray should be given as soon as possible after the pain occurs.

How to store Ayendi Nasal Spray

Ayendi nasal spray should be stored below 25°C and protected from light in the original packaging.

How Ayendi Nasal Spray works

Ayendi nasal spray is a potent opiate analgesic which has a rapid onset of activity and a prolonged duration of action. It is used to relieve pain in adults and children aged three and over. The spray can also be used to treat pain from injury or surgery. The spray is administered into the nasal cavity and acts on the central nervous system to relieve pain.