ATROPINE INJECTION BP MINIJET

PL 03265/0078

UKPAR

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ATROPINE INJECTION BP MINIJET

PL 03265/0078

LAY SUMMARY

On 24th November 2009, the MHRA granted International Medication Systems (UK) Limited a Marketing Authorisation (licence) for the medicinal product Atropine Injection BP Minijet (PL 03265/0078). This is a prescription only medicine (POM) used for Pre-medication before an anaesthetic, to treat a slow heart beat or a heart which has stopped altogether, to treat poisoning and to control the side effects of neostigmine (a medicine which increases nerve impulses to the muscles.

Atropine is an antimuscarinic. It temporarily blocks some nerve endings. This stops glands secreting, makes some muscles (such as in the gut) relax and speeds up the heart.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Atropine Injection BP Minijet outweigh the risks, hence a Marketing Authorisation has been granted.
ATROPINE INJECTION BP MINIJET

PL 03265/0078

SCIENTIFIC DISCUSSION

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**INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Atropine Injection BP Minijet (PL 03265/0078) to International Medication Systems (UK) Limited on 24th November 2009. The product is Prescription only medicine (POM).

This standard abridged application for Atropine Injection BP Minijet is submitted under Article 10.3 (Hybrid application).

This medicine is used for following indications.

- Acute myocardial infarction with AV conduction block due to excess vagal tone (Wenkebach Type I, second-degree AV block) and sinus bradycardia, with associated hypotension and increased ventricular irritability.

- Atropine can also be used in cardiopulmonary resuscitation for the treatment of sinus bradycardia accompanied by hypotension, hypoperfusion or ectopic arrhythmias.

- Parenteral atropine is indicated as an antisialogogue in anaesthetic premedication to prevent or reduce secretions of the respiratory tract.

- During anaesthesia, atropine may be used to prevent reflex bradycardia and restore cardiac rate and arterial pressure resulting from increased vagal activity associated with laryngoscopy, tracheal intubation and intra-abdominal manipulation. It may also be administered to block muscarinic effects when neostigmine is used to counteract muscle relaxants such as tubocurarine.

Parenteral atropine is an antidote for cardiovascular collapse following overdose of anticholinesterases; in the treatment of poisoning from organophosphorous insecticides or from chemical warfare 'nerve' gases and in the treatment of mushroom poisoning.

Atropine is an antimuscarinic agent which competitively antagonizes acetylcholine at postganglionic nerve endings, thus affecting receptors of the exocrine glands, smooth muscle, cardiac muscle and the central nervous system.
PHARMACEUTICAL ASSESSMENT

rINNM / BAN: Atropine Sulphate

Chemical Name: Bis[(1R,3r,5S)-8-methyl-8-azabicyclo[3.2.1]oct-3yl (2RS)-3-hydroxy-2-phenylpropanoate] sulphate.

Molecular Formula: \( C_{34} H_{48} N_2 O_{10} \cdot S, H_2 O \)

Chemical Structure:

Molecular Weight: 695

CAS No.: 5908-99-6

Appearance: A white, crystalline powder or colourless crystals.

Properties: It is very soluble in water, freely soluble in alcohol and practically insoluble in ether.

Atropine sulphate is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines (EDQM) certificate of suitability.
DRUG PRODUCT
Other ingredients
Other ingredients consist of pharmaceutical excipients, namely sodium citrate, sodium chloride, water for Injection and citric acid anhydrous.

All excipients are controlled to their respective European Pharmacopoeia specifications.

Satisfactory certificates of analysis have been provided for all excipients.

None of the excipients used contain materials of animal or human origin.

Pharmaceutical development
The objective of the product development programme was to produce solution for injection that could be considered a generic medicinal product of Atropine injection BP Minijet PL 03265/0013R.

The pharmaceutical development data submitted are satisfactory.

Manufacture
A description and flow-chart of the manufacturing method has been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out on batches of product. The results appear satisfactory.

Finished product specification
The finished product specification is satisfactory. Test methods have been described and have been adequately validated as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container Closure System
The solution is contained in a USP type I glass vial with an elastomeric closure which meets all the relevant USP specifications. The product is available as 10ml.

Specifications and Certificates of Analysis for all packaging have been provided. These are satisfactory. The primary packaging has been shown to comply with guidelines concerning materials in contact with parenteral products.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 2 years has been set with storage conditions “Do not store above 25°C” and “Keep the vial in the outer carton”.

ADMINISTRATIVE
Expert Report
A pharmaceutical expert report has been written by a suitably qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.
Summary of Product Characteristics (SPC)
This is consistent with the SPC for the reference product and is satisfactory.

Labelling
This is satisfactory.

Patient Information Leaflet (PIL)
This is consistent with the PIL for the reference product and is satisfactory.

MAA Form
This is satisfactory.

Conclusion
It is recommended that a Marketing Authorisation is granted for this application.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for applications of this type.
CLINICAL ASSESSMENT

1. INTRODUCTION
This is a standard abridged application for Marketing Authorisation submitted under Article 10.3 hybrid application for Atropine Injection BP Minijet (PL 03265/0078).

This application cross-refers to Atropine Injection BP Minijet 0.1mg/ml held by the applicant and was granted on 20th March 1991. The applicant is claiming that the reference product is an identical presentation to the application for Atropine Injection BP Minijet 3 mg/10 ml, differing only in strength. Therefore the application has been made as a line extension.

2. BACKGROUND
Atropine is an antimuscarinic agent which competitively antagonizes acetylcholine at postganglionic nerve endings, thus affecting receptors of the exocrine glands, smooth muscle, cardiac muscle and the central nervous system.

Peripheral effects include tachycardia, decreased production of saliva, sweat, bronchial, nasal, lachrymal and gastric secretions, decreased intestinal motility and inhibition of micturition.

Atropine increases sinus rate and sinoatrial and AV conduction. Usually heart rate is increased but there may be an initial bradycardia.

Atropine inhibits secretions throughout the respiratory tract and relaxes bronchial smooth muscle producing bronchodilatation.

3. INDICATIONS
The proposed indications are the same as those of Atropine Injection BP Minijet 0.1 mg/ml

4. DOSE AND DOSAGE SCHEDULE
The proposed posology is identical to that authorised for Atropine Injection BP Minijet 0.1 mg/ml

5. TOXICOLOGY
No new data is presented and none is required for this application.

6. CLINICAL PHARMACOLOGY
No new data is presented and none is required for this application.

7. EFFICACY
No new data is presented and none is required for this application.

8. SAFETY
No new data is presented and none is required for this application.
9. **EXPERT REPORT**
The Clinical Expert Report has been written by an appropriately qualified person and is a suitable summary of the clinical aspects of the dossier.

10. **SUMMARY OF PRODUCT CHARACTERISTICS**
This is consistent with the SPC for the reference product and satisfactory.

11. **PATIENT INFORMATION LEAFLET**
The Patient Information Leaflet is satisfactory.

12. **LABELLING**
The labelling is satisfactory.

13. **MAA**
The Marketing Authorisation Application form is satisfactory.

14. **DISCUSSION**
This national, standard, abridged application by International Medication Systems (UK) Limited cross-refers to Atropine Injection BP Minijet 0.1mg/ml. The pharmaceutical form is a solution for injection, thus no bioequivalence / bioavailability studies are required. Brief Quality, Nonclinical and Clinical Overviews are provided but there are no Nonclinical or Clinical Summaries as there are no study reports included with the application.

15. **CONCLUSION**
The grant of a marketing authorisation is recommended.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Atropine Injection BP Minijet (PL 03265/0078) are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

EFFICACY
No new data were submitted and none are required for application of this type.

The SPC, PIL and labelling are satisfactory and consistent with that for the reference product.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with Atropine is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is considered to be positive.
**ATROPINE INJECTION BP MINIJET**

**PL 03265/0078**

**STEPS TAKEN FOR ASSESSMENT**

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<td>1</td>
<td>The MHRA received the marketing authorisation applications on 8&lt;sup&gt;th&lt;/sup&gt; December 2006</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the applications valid on 2&lt;sup&gt;nd&lt;/sup&gt; February 2007</td>
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<td>Following assessment of the application the MHRA requested further information relating to the quality dossiers on 12&lt;sup&gt;th&lt;/sup&gt; July 2007 and 8&lt;sup&gt;th&lt;/sup&gt; January 2009</td>
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<td>The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 15&lt;sup&gt;th&lt;/sup&gt; November 2007 and 1&lt;sup&gt;st&lt;/sup&gt; July 2009</td>
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<td>The application was determined on 24&lt;sup&gt;th&lt;/sup&gt; November 2009</td>
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ATROPINE INJECTION BP MINIJET

PL 03265/0078

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Atropine Injection BP Minijet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Atropine Sulphate 0.3 mg/ml

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Sterile aqueous solution for parenteral administration to humans.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Acute myocardial infarction with AV conduction block due to excess vagal tone (Wenkebach Type I, second-degree AV block) and sinus bradycardia, with associated hypotension and increased ventricular irritability.

Atropine can also be used in cardiopulmonary resuscitation for the treatment of sinus bradycardia accompanied by hypotension, hypoperfusion or ectopic arrhythmias.

Parenteral atropine is indicated as an antisialogogue in anaesthetic premedication to prevent or reduce secretions of the respiratory tract.

During anaesthesia, atropine may be used to prevent reflex bradycardia and restore cardiac rate and arterial pressure resulting from increased vagal activity associated with laryngoscopy, tracheal intubation and intra-abdominal manipulation. It may also be administered to block muscarinic effects when neostigmine is used to counteract muscle relaxants such as tubocurarine.

Parenteral atropine is an antidote for cardiovascular collapse following overdose of anticholinesterases; in the treatment of poisoning from organophosphorous insecticides or from chemical warfare 'nerve' gases and in the treatment of mushroom poisoning.

4.2 Posology and method of administration
Adults, children over 12 and the elderly:

- Bradyarrhythmias: intramuscular or intravenous, 300 to 600 mcg (0.3 to 0.6 mg) every four to six hours to a total dose of 2 mg.

In cardiac resuscitation, intravenous 500 mcg (0.5 mg) repeated at 5 minute intervals until the desired heart rate is achieved. In asystole, 3 mg may be given intravenously as a once only single dose. If atropine cannot be administered intravenously during resuscitation, 2-3 times the intravenous dose may be administered via an endotracheal tube.

- Premedication before anaesthesia: intramuscular or subcutaneous, 300 to 600 mcg (0.3 to 0.6 mg) 30-60 minutes before surgery or the same dose intravenously immediately before surgery.

To control muscarinic side effects of neostigmine: intravenous, 600 to 1200 mcg (0.6 - 1.2 mg).
Anticholinesterase poisoning: intramuscular or intravenous, 1 to 2 mg repeated every 5 to 60 minutes until signs and symptoms disappear, up to a maximum of 100 mg in the first 24 hours.

**Children up to the age of 12 years:**

The usual intramuscular, intravenous or subcutaneous dose in children is 10 mcg/kg (0.01 mg/kg), but generally not exceeding 400 mcg (0.4 mg). If necessary, these doses may be repeated every 4-6 hours.

**Cardiac:** for advanced cardiac life support: intravenous, 20 mcg/kg (0.02 mg/kg) with a minimum dose of 10 mcg (0.01 mg) repeated at 5 minute intervals, to a maximum dose of 100 mcg (0.1 mg).

**Premedication before anaesthesia:** intramuscular or subcutaneous; 30-60 minutes before surgery.

- Up to 3 kg - 100 mcg (0.1mg)
- 7 - 9 kg - 200 mcg (0.2mg)
- 12 - 16 kg - 300 mcg (0.3mg)
- Over 20 kg - as for adults.

To control the muscarinic side effects of neostigmine: intravenous; neonates, infants and children - 20 mcg/kg (0.02 mg/kg). Maximum dosage 600 mcg.

Anticholinesterase poisoning: intramuscular or intravenous, 50 mcg/kg (0.05 mg/kg) every 10-30 minutes until muscarinic signs and symptoms disappear.

### 4.3 Contraindications

Contra-indications are not applicable to the use of atropine in life-threatening emergencies (eg. asystole).

Atropine is contraindicated in patients with known hypersensitivity to the drug, obstruction of the bladder neck eg due to prostatic hypertrophy, reflux oesophagitis, closed angle glaucoma, myasthenia gravis (unless used to treat the adverse effects of an anticholinesterase agent), paralytic ileus, severe ulcerative colitis and obstructive disease of the gastrointestinal tract.

### 4.4 Special warnings and precautions for use

Antimuscarinic agents should be used with caution in the elderly and children since these patients may be more susceptible to adverse effects. Atropine should also be used with caution in patients with hyperthyroidism, hepatic or renal disease or hypertension. Use with caution in febrile patients or when ambient temperature is high since antimuscarinics may cause an increase in temperature. Antimuscarinics block vagal inhibition of the SA nodal pacemaker and should thus be used with caution in patients with tachyarrhythmias, congestive heart failure or coronary heart disease. Parenterally administered atropine should be used cautiously in patients with chronic pulmonary disease since a reduction in bronchial secretions may lead to formation of bronchial plugs. Antimuscarinics should be used with extreme caution in patients with autonomic neuropathy.

Antimuscarinics decrease gastric motility, relax the lower oesophageal sphincter and may delay gastric emptying; they should therefore be used with caution in patients with gastric ulcer, oesophageal reflux or hiatus hernia associated with reflux oesophagitis, diarrhoea or GI infection.

This medicinal product contains less than 1mmol sodium (23mg) per dose, i.e. essentially ‘sodium-free’.
4.5 Interaction with other medicinal products and other forms of interaction

The effects of atropine may be enhanced by the concomitant administration of other drugs with anticholinergic activity eg. tricyclic antidepressants, antispasmodics, anti-parkinsonian drugs, some antihistamines, phenothiazines, disopyramide and quinidine. By delaying gastric emptying, atropine may alter the absorption of other drugs.

4.6 Pregnancy and lactation

Atropine crosses the placenta. Studies in humans have not been done and only limited information is available from animal studies. Intravenous administration of atropine during pregnancy or at term may cause tachycardia in the foetus. Atropine should only be administered to pregnant women if the benefits outweigh the risks to the foetus. Trace amounts of atropine appear in the breast milk and may cause antimuscarinic effects in the infant; lactation may be inhibited.

4.7 Effects on ability to drive and use machines

Not applicable; this preparation is intended for use only in emergencies.

4.8 Undesirable effects

Adverse effects are dose-related and usually reversible when therapy is discontinued. In relatively small doses, atropine reduces salivary, bronchial and sweat secretions; dry mouth and anhidrosis may develop, these effects being intensified as the dosage is increased. Reduced bronchial secretion may cause dehydration of residual secretion and consequent formation of thick bronchial plugs that are difficult to eject from the respiratory tract.

Larger doses dilate the pupil and inhibit accommodation of the eye, and block vagal impulses with consequent increase in heart rate with possible atrial arrhythmias, A-V dissociation and multiple ventricular ectopics; parasympathetic control of the urinary bladder and gastrointestinal tract is inhibited, causing urinary retention and constipation. Further increase in dosage inhibits gastric secretion. Anaphylaxis, urticaria and rash occasionally progressing to exfoliation may develop in some patients. Other effects include hallucinations, increased ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, dizziness, flushing, insomnia, nausea, vomiting and bloated feeling. Mental confusion and/or excitement may occur especially in the elderly.

4.9 Overdose

Symptoms: marked dryness of the mouth accompanied by a burning sensation, difficulty in swallowing, pronounced photophobia, flushing and dryness of the skin, raised body temperature, rash, nausea, vomiting, tachycardia and hypertension. Restlessness, tremor, confusion, excitement, hallucinations and delirium may result from CNS stimulation; this is followed by increasing drowsiness, stupor and general central depression terminating in death from circulatory and respiratory failure.

Treatment: In severe cases, physostigmine, 1 to 4 mg, should be administered intravenously, intramuscularly or subcutaneously, the dose may be repeated if necessary since it is rapidly eliminated from the body. Diazepam may be administered for sedation of the delirious patient but the risk of central depression occurring late in the course of atropine poisoning contraindicates large doses of sedative. An adequate airway should be maintained and respiratory failure may be treated with oxygen and carbon dioxide inhalation. Fever is reduced by the application of cold packs or sponging with tepid water. Adequate fluid intake is important. Urethral catheterisation may be necessary. If photophobia is present or likely, the patient should be nursed in a darkened room.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
ATC code A03BA 01, belladonna alkaloids, tertiary amines

Atropine is an antimuscarinic agent which competitively antagonizes acetylcholine at postganglionic nerve endings, thus affecting receptors of the exocrine glands, smooth muscle, cardiac muscle and the central nervous system.

Peripheral effects include tachycardia, decreased production of saliva, sweat, bronchial, nasal, lachrymal and gastric secretions, decreased intestinal motility and inhibition of micturition.

Atropine increases sinus rate and sinoatrial and AV conduction. Usually heart rate is increased but there may be an initial bradycardia.

Atropine inhibits secretions throughout the respiratory tract and relaxes bronchial smooth muscle producing bronchodilatation.

5.2 Pharmacokinetic properties
Following intravenous administration, the peak increase in heart rate occurs within 2 to 4 minutes. Peak plasma concentrations of atropine after intramuscular administration are reached within 30 minutes, although peak effects on the heart, sweating and salivation may occur nearer one hour after intramuscular administration.

Plasma levels after intramuscular and intravenous injection are comparable at one hour. Atropine is distributed widely throughout the body and crosses the blood brain barrier. The elimination half life is about 2 to 5 hours. Up to 50% of the dose is protein bound. It disappears rapidly from the circulation.

Atropine is metabolised in the liver by oxidation and conjugation to give inactive metabolites.

About 50% of the dose is excreted within 4 hours and 90% in 24 hours in the urine, about 30 to 50% as unchanged drug.

5.3 Preclinical safety data
Not applicable since atropine has been used in clinical practice for many years and its effects in man are well known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium Citrate Dihydrate
Citric Acid Monohydrate
Sodium Chloride
Water for Injection

6.2 Incompatibilities
None known

6.3 Shelf life
24 months

6.4 Special precautions for storage
Do not store above 25°C. Keep the vial in the outer container.
6.5  **Nature and contents of container**
The solution is contained in a USP type I glass vial with an elastomeric closure which meets all the relevant USP specifications. The product is available as 10ml.

6.6  **Special precautions for disposal**
The container is specially designed for use with the IMS Minijet injector. Use once and discard residue.

Any unused product should be disposed of in accordance with local requirements.

7  **MARKETING AUTHORISATION HOLDER**
International Medication Systems (UK) Ltd
208 Bath Road
Slough
Berkshire
SL1 3WE

8  **MARKETING AUTHORISATION NUMBER(S)**
PL 03265/0078

9  **DATE OF FIRST AUTHOURISATION/RENEWAL OF THE AUTHORISATION**
24/11/2009

10  **DATE OF REVISION OF THE TEXT**
24/11/2009
PATIENT INFORMATION LEAFLET (PIL)
ATROPINE INJECTION BP MINIJET® 3mg/10ml
SOLUTION FOR INJECTION
Patient Information Leaflet

Read all of this leaflet carefully
Please note this medicine is mainly used in emergency situations and the doctor will have decided that you needed it.

It is unlikely, therefore, that you will have read this leaflet before the medicine was administered to you.
- Keep this leaflet. You may need to read it again
- If you have any further questions, ask the doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell the doctor or nurse.

In this leaflet:
1. What Atropine Injection BP Minijet is and what it is used for
2. Before or after you are given Atropine Injection BP Minijet
3. How to use Atropine Injection BP Minijet
4. Possible side effects
5. How to store Atropine Injection BP Minijet
6. Further information.

1. What Atropine Injection BP Minijet is and what it is used for
Your medicine is called Atropine Injection BP Minijet.

Atropine is an antimuscarinic. It temporarily blocks some nerve endings. This stops glands secreting, makes some muscles (such as in the gut) relax and speeds up the heart.

This medicine is used for:
- Pre-medication before an anaesthetic
- To treat a slow heart beat or a heart which has stopped altogether
- To treat poisoning
- To control the side effects of neostigmine (a medicine which increases nerve impulses to the muscles).

2. Before or after you are given Atropine Injection BP Minijet
Tell the doctor if the answer is yes to any of the following statements. Do you have/suffer from:
- Reflux oesophagitis (a condition that causes severe heart burn, increased belching and upper stomach pain)
- Closed angle glaucoma (an eye condition that causes sudden blurred vision with pain and redness)
- Myasthenia gravis (a condition that causes extreme tiredness and muscle weakness)
- Paralytic ileus (a condition of the gut that causes severe constipation and bloating caused by inactivity of your intestines)
- Severe ulcerative colitis, or have a blockage in your intestines
- Allergy to any of the ingredients
- Trouble passing water (e.g. due to an enlarged prostate gland).

Tell the doctor if the answer is yes to any of the following statements, as special care should then be taken. Do you have/are:
- Pregnant or breast-feeding
- High blood pressure
- Liver, kidney or lung disease
- Hyperthyroidism (where your body makes too much thyroid hormone)
- Nervous system problems
- Raised temperature
- Stomach ulcer
- Hiatus hernia (this occurs in the upper part of the stomach)
- Diarrhoea, gastroenteritis or any other infection of the gut.

Tell the doctor if you are taking any other medicines:
- Prescribed medicines, especially:
  o Tricyclic antidepressants
  o Drugs for Parkinson’s disease
  o Some antihistamines
  o Antispasmodics (e.g. for irritable bowel syndrome)
  o Phenothiazines (for mental illness)
  o Disopyramide or quinidine (for heart problems).
- Any medicines available without prescription.
3. How to use Atropine Injection BP Minijet

This medicine will be given to you as an injection by the doctor.

This injection will be given either:
- Into a vein
- Into a muscle
- Under the skin
- Via a breathing tube in your windpipe.

The doctor will decide what dose is right for you and this will depend on what it is being used to treat.

If you have any further questions on the use of this product, please ask the doctor.

4. Possible side effects

As with all medicines, Atropine Injection BP Minijet may cause some side effects.

Side effects are more likely with higher doses, but usually disappear once treatment stops.

Rarely an allergic reaction may develop. This may cause skin rashes, severe itching, peeling of the skin, swelling of the face (especially around the lips and eyes), tightening of the throat and difficulty breathing or swallowing, fever, dehydration, shock and fainting. These are all very serious side effects. Tell the doctor immediately if you experience any of these side effects.

Possible side effects include reduced saliva (spit), sweat and phlegm (this can make phlegm more difficult to cough up), enlarged pupils (this may make your vision blurred), a faster or irregular heartbeat, difficulty in passing urine, constipation, hallucinations, increased eye pressure, loss of taste, headache, nervousness, drowsiness, weakness, blushing, sleeplessness, and bloated feeling.

Occasional side effects that may occur include mental confusion and/or excitement (especially in the elderly), nausea, vomiting and dizziness.

If you have any side effects that become serious, or if you have any other side effects not mentioned in this leaflet, please tell the doctor.

5. How to store Atropine Injection BP Minijet

This medicine will be stored for you by the doctor under the following conditions:
- Keep out of the reach and sight of children
- Do not store above 25°C
- Keep the container in the outer carton.

Do not use this medicine after the date shown on the carton and vial label.

The hospital pharmacist will dispose of any medicine no longer required.

Do not dispose of this medicine via waste water or household waste. This will help to protect the environment.

6. Further information

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask the doctor or nurse who will have the information you need and will advise you.

What Atropine Injection BP Minijet contains

The active substance is atropine sulphate, 0.3mg/ml available in a 10ml vial.

To make it into an injection, it also contains:
- Sodium citrate dihydrate
- Citric acid monohydrate
- Sodium chloride
- Water for Injections.

What Atropine Injection BP Minijet looks like and contents of the pack

Solution for injection.

The container consists of a 10ml pre-filled glass vial with an injector device.

Marketing Authorisation Holder and Manufacturer

MA Holder: International Medication Systems (UK) Ltd., 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

Manufacturer: Ashton Pharmaceuticals Ltd, Ashton-under-Lyne, OL7 9RR, UK.

Date of preparation of the leaflet: November 2006
UKPAR Atropine Injection BP Minijet

LABELLING

ATROPINE
INJECTION BP MINIJET®

SOLUTION FOR INJECTION
FOR IV, IM OR SC USE. SINGLE DOSE.
DO NOT STORE ABOVE 25°C / KEEP CONTAINER IN OUTER CARTON.
Atropine sulphate, 300 micrograms / ml; sodium chloride,
citric acid monohydrate, sodium citrate dihydrate, water for injection,
sodium content not more than 5 mg/ml.
KEEP OUT OF REACH AND SIGHT OF CHILDREN

Approx. 30 µg
Available

PL Holder
INTERNATIONAL MEDICATION SYSTEMS (UK) LTD.
Sough, SL1 3WE, UK.

POM
PL 03265/0078