Proposed Patient Information Leaflet for ATROPINE SULPHATE FRESENIUS

SCHEDULING STATUS

S4

ATROPINE SULPHATE 0,5 mg/1 ml FRESENIUS

ATROPINE SULPHATE 1,0 mg/1 ml FRESENIUS

Solution for injection.

Sugar free.

Read the entire leaflet carefully before you are given ATROPINE SULPHATE FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What ATROPINE SULPHATE FRESENIUS is and what it is used for

- ATROPINE SULPHATE FRESENIUS is used to oppose the effects of the parasympathetic nervous system, for example:

    - During operations: to counteract the vagal effects that occur during anaesthesia. It can also be given with neostigmine to counteract some of the unwanted effects caused by the neostigmine.
- ATROPINE SULPHATE FRESENIUS is a specific antidote for the heart collapse that can result from indiscreet administration of a choline ester or an inhibitor of cholinesterase. It is also used to oppose the effects of reflex vagal heart slowing.
- ATROPINE SULPHATE FRESENIUS can also be used in the initial treatment of an acute heart attack where there is a slowing of the heart rate.
- It can be used in the treatment of muscarinic toxicity, and in poisoning caused by pesticides that are organophosphate cholinesterase inhibitors.
- ATROPINE SULPHATE FRESENIUS is used specifically as an antidote for the so-called rapid type of mushroom poisoning.

2. What you need to know before you are given ATROPINE SULPHATE FRESENIUS

You should not be administered ATROPINE SULPHATE FRESENIUS:

- if you are hypersensitive (allergic) to atropine sulphate or any of the other ingredients of ATROPINE SULPHATE FRESENIUS (listed in section 6);
- if you have closed angle glaucoma (abnormally high pressure within the eye), or if you have a narrow angle between your iris and cornea. Taking this medicine may increase the pressure within your eye and precipitate an acute attack;
- if you have prostatic enlargement;
- if you have a loss of intestinal movement;
- if you have a narrowing of the muscular outlet of the stomach;
- if you have a severe asthma attack;
- if you have myasthenia gravis, unless it is being given to counteract the effects of the medicine you have been given for treatment of this condition;
- if you have a high temperature;

- if you are taking a monoamine-oxidase inhibitor, or if you have stopped taking such a medicine in the last 10 days.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you have ulcerative colitis (inflammation and ulceration of the colon and rectum);
- if you suffer from heartburn;
- if you have a condition that increases your heart rate e.g. increased amount of thyroid hormone in your blood, heart failure or insufficiency;
- if you are experiencing a condition with decreased blood flow through your heart's blood vessels;
- if you have heart failure;
- if you are undergoing heart surgery or a heart transplant;
- if you have high blood pressure;
- if you are an elderly or young patient or if you have Down's syndrome, as you may experience more of the adverse effects associated with the use of this medicine;
- if you have lung disease;
- if you have Parkinson's disease;
- if you have diarrhoea;
- if you have difficulty urinating.

Other medicines and ATROPINE SULPHATE FRESENIUS

The effect of ATROPINE SULPHATE FRESENIUS can be increased when it is taken with certain other medicines. It can also cause increased amounts of other medicines in your body.
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Antihistamines, used to treat allergies.
- Antipsychotics, used to treat certain mental conditions, e.g. butyrophenones, phenothiazines, chlorpromazine, clozapine, olanzapine.
- Antispasmodics, used to treat stomach cramps.
- Beta-blockers, used to treat high blood pressure, heart problems and other conditions.
- Domperidone, used for nausea and vomiting (feeling sick or being sick).
- Ketoconazole, used to treat fungal infections.
- Medicines used to treat heart problems, e.g. digoxin, disopyramide, mexiletine.
- Medicines for Parkinson's disease, e.g. amantadine.
- Metoclopramide, used for nausea and vomiting (feeling sick or being sick) and for other gastrointestinal conditions.
- Monoamine-oxidase inhibitors, used to treat depression; taken within the last 10 days (see "You should not be administered ATROPINE SULPHATE FRESENIUS").
- Neostigmine, used to treat myasthenia gravis, a disease causing muscle weakness.
- Sublingual nitrates; medicines placed under the tongue for chest pain (angina).
- Propofol, used for anaesthesia during operations.
- Quinidine, used for muscle cramps and to treat malaria.
- Tricyclic antidepressants, used to treat depression.

Pregnancy and breastfeeding

ATROPINE SULPHATE FRESENIUS crosses the placenta and may cause an increased heart rate in an unborn baby. ATROPINE SULPHATE FRESENIUS should be avoided during breastfeeding as it can pass into the breast milk and cause undesirable effects on infants. Breast milk may be reduced.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare provider for advice before receiving ATROPINE SULPHATE FRESENIUS.

Driving and using machines

ATROPINE SULPHATE FRESENIUS may cause blurred vision, drowsiness, confusion, hallucinations and other psychiatric effects (see "**Possible side effects**" and "**If you receive more ATROPINE SULPHATE FRESENIUS than you should**"). Do not drive, operate machinery or take part in any activities that could, if you are affected, put yourself or others at risk.
The condition for which you are receiving the injection may also impair your ability to drive or use machinery.

3. How you will be given ATROPINE SULPHATE FRESENIUS

You will not be expected to give yourself ATROPINE SULPHATE FRESENIUS. It will be given to you by a person who is qualified to do so.
Your doctor will decide what the dose is and for how long you will receive ATROPINE SULPHATE FRESENIUS. This will vary from patient to patient. It will depend on your condition and other factors, such as your physical condition, body mass, age as well as other medicines that you are taking at the time or after.
ATROPINE SULPHATE FRESENIUS is administered by injection:

- into a muscle;
- just below the skin;
- into a vein.

If you receive more ATROPINE SULPHATE FRESENIUS than you should

As ATROPINE SULPHATE FRESENIUS is administered under controlled conditions and the effects thereof are closely monitored, the likelihood of overdosage is extremely rare.
However, if you experience severe side effects after being given ATROPINE SULPHATE FRESENIUS, tell your doctor immediately.
Symptoms of ATROPINE SULPHATE FRESENIUS overdose can develop quickly and include:

- illusions, disorientation, hallucinations and extreme excitement;
- dry mouth accompanied by a burning sensation, difficulty in swallowing;
- blurred vision and your eyes may become very sensitive to light;

- your skin may feel hot, dry and appear flushed;
- a rash, especially over your face, neck and upper part of your body;
- your body temperature may be higher than usual, your pulse can become faster and weaker, and you may have palpitations;
- your blood pressure can increase;
- feeling sick or being sick (nausea or vomiting);
- you may feel a stronger urge to urinate but have difficulty urinating;
- restlessness, trembling, confusion and giddiness.

The above-mentioned effects of stimulation are followed by increasing drowsiness, unresponsiveness, unconsciousness, heart and lung failure and death.

If you missed a dose of ATROPINE SULPHATE FRESENIUS

Since a healthcare provider will administer ATROPINE SULPHATE FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

ATROPINE SULPHATE FRESENIUS can have side effects.

Not all side effects reported for ATROPINE SULPHATE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ATROPINE SULPHATE FRESENIUS please consult your doctor, pharmacist or other healthcare provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;

- your heart rate can be affected. It may increase, decrease or become irregular;
- heart block, especially after a heart transplantation, heart attack;
- you may experience difficulty in urinating.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you experience any of the following reactions after receiving ATROPINE SULPHATE FRESENIUS:

- reduced tone and movement of the intestines, and constipation;
- reflux may be worsened;
- nausea or vomiting (feeling sick or being sick);
- reduced amounts of fluid in the stomach;
- dry mouth with difficulty in swallowing, thirst;
- increased pressure inside the eyes, your pupils may dilate, and it may become difficult to focus the eyes, and your eyes can become sensitive to sunlight;
- the mucous in your respiratory tract can become thicker and form plugs;
- confusion, hallucinations, restlessness;
- dizziness;
- flushing and dryness or peeling of the skin, rash, itching;
- fever;
- in patients with Parkinson's disease sudden withdrawal of large doses can lead to vomiting (being sick), unusual lack of energy, sweating and increased amounts of saliva.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ATROPINE SULPHATE FRESENIUS.

5. How to store ATROPINE SULPHATE FRESENIUS

- Store all medicines out of reach of children.
- ATROPINE SULPHATE FRESENIUS will be stored in the pharmacy or in the hospital wards. The injection is kept at or below 30 °C, protected from light.

6. Contents of the pack and other information

What ATROPINE SULPHATE FRESENIUS contains

The active substance is atropine sulphate.

The other ingredients are water for injection and sulphuric acid (for pH-adjustment).

What ATROPINE SULPHATE FRESENIUS looks like and contents of the pack

ATROPINE SULPHATE FRESENIUS is a clear, colourless solution filled into clear glass ampoules.

Pack size: 10 x 1 ml ampoules.

Holder of Certificates of Registration and Manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

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Korsten 6020

Gqeberha

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ATROPINE SULPHATE 0,5 mg/1 ml FRESENIUS: L/5.4/342

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