

Package leaflet: Information for the patient

PIL191.1

Methylthioninium Chloride 10 mg/ml Sterile Solution

Methylthioninium Chloride

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This leaflet is written to you as an adult. You may also be reading this on behalf of your child.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, tell your doctor, nurse or pharmacist. This includes any side effects not listed in this leaflet. See section 4.
- The full name of your medicine is Methylthioninium Chloride 10 mg/ml Sterile Solution. In this leaflet the shorter name Methylthioninium Chloride is used.

What is in this leaflet:

1. What Methylthioninium Chloride is and what it is used for
2. What you need to know before you have Methylthioninium Chloride
3. How Methylthioninium Chloride is used
4. Possible side effects
5. How to store Methylthioninium Chloride
6. Contents of the pack and other information

1. What Methylthioninium Chloride is and what it is used for

Methylthioninium Chloride 10 mg/ml Sterile Solution contains the active substance 'Methylthioninium Chloride'.

It may be given to adults or children of all ages.

What Methylthioninium Chloride is used for

This medicine is used to treat a blood problem called 'methaemoglobinaemia' that may be:

- due to a medicine or chemical
- passed down through families (inherited).

This blood problem may make your skin and lips turn blue (called 'cyanosis'), make you short of breath, feel weak, and have headache and sickness.

2. What you need to know before you have Methylthioninium Chloride

Do not have this medicine if:

- you are allergic to Methylthioninium Chloride or other substances called 'thiazine' dyes
- you are pregnant or breast-feeding
- you have severe kidney problems
- you have methaemoglobinaemia due to 'chlorate' poisoning – this is because this medicine can make the poisoning worse
- you have methaemoglobinaemia after being treated with sodium nitrite for cyanide poisoning - this is because this medicine can make the poisoning worse
- you have been told that you have either 'glucose-6-phosphate dehydrogenase deficiency (G6PD)' or 'NAPDH reductase deficiency' – this is because this medicine may cause an unusual breakdown of red blood cells in these cases (called 'haemolytic anaemia').

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before having it.

Warnings and precautions

Before you start this medicine, talk to your doctor, nurse or pharmacist if:

- you are diabetic – this is because the medicine may be diluted with a glucose solution. The amount of glucose may affect your blood glucose levels
- you have methaemoglobinaemia either due to the toxin 'aniline' or to the anti-bacterial agent 'dapson' – your dose of this medicine may need to be reduced
- you have moderate kidney problems – your dose of this medicine may need to be reduced.

If any of the above applies to you (or you are not sure), talk to your doctor, nurse or pharmacist before having this medicine.

While you are having this medicine, talk to your doctor, nurse or pharmacist if:

- you think that there is a problem with the injection, for example the medicine leaks out after an injection into a vein – this is because the medicine may cause an abscess on your skin
- you are planning to spend time in the sunshine whilst having this medicine – this is because your skin may be more likely to burn or develop a rash from the sun. You should use sunscreen and protective clothing as a precaution.

If any of the above applies to you (or you are not sure), talk to your doctor, nurse or pharmacist while having this medicine.

Tests and check-ups

Your doctor may run tests to make sure that this medicine is working properly and so that they can spot any side effects early. When taken for a long time, this medicine may cause anaemia. Your doctor may also run tests to check for this.

Tell any other doctor who is treating you that you are having this medicine as it can interfere with test results.

Other medicines and Methylthioninium Chloride

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, recreational drugs, supplements and herbal medicines.

This medicine may affect the blood levels of other medicines. Tell your doctor or pharmacist if you are taking any other medicines and they can check if these are affected by this medicine.

Tell your doctor, nurse or pharmacist if you are taking any of the following medicines. This is because you may need to stop or reduce the dose of these medicines if you are also having Methylthioninium Chloride:

- medicines for depression such as phenelzine, isocarboxazid, tranylcypromine, duloxetine, moclobemide, clomipramine, mirtazapine, venlafaxine, desvenlafaxine, amitriptyline, imipramine, tryptophan, amfebutamone, lithium, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or St John's wort (a herbal medicine)
- buspirone – for anxiety
- bupropion – a medicine to help you stop smoking.

If any of the above applies to you (or you are not sure), talk to your doctor, nurse or pharmacist before having this medicine.

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant or breast-feeding. Do not breast-feed for at least 8 days after having this medicine.

If you think you may be pregnant or are planning to have a baby or breast-feed, ask your doctor, nurse or pharmacist for advice before having this medicine.

Fertility

Laboratory tests show that sperm movement may be affected by this medicine. This may affect your chances of getting pregnant.

Driving and using machines

You may feel dizzy or confused, or have problems with your eyes after having this medicine. If this happens, do not drive or cycle, or use any tools or machines.

3. How Methylthioninium Chloride is used

Always follow any instructions from your doctor, nurse or pharmacist. Check with your doctor, nurse or pharmacist if you are not sure what they have told you.

How much to have

The dose and how much you should have depends on:

- how bad your symptoms are
- how much you weigh – your 'lean body weight'.

Your doctor will decide what is right for you.

For severe blood problems (methaemoglobinaemia)

In this case you will usually have this medicine as an injection into a vein.

The recommended dose for adults and children over 3 months old is:

- 1 to 2 mg (0.1 to 0.2 ml) for each kilogram you weigh – your doctor will work that out
- injected over at least 5 minutes.

After one hour, you may get another dose, up to a maximum of 7 mg for each kilogram you weigh, for the whole treatment, or up to 4 mg for each kilogram you weigh if your condition is due to dapsone or aniline.

Children under 3 months old have lower doses of 0.3 to 0.5 mg (0.03 to 0.05 ml) for every kilogram they weigh.

For less severe blood problems (methaemoglobinaemia)

Where your condition is less severe the medicine can usually be taken by mouth.

The recommended dose for adults is:

- 3 to 6 mg (0.3 to 0.6 ml) for each kilogram you weigh – your doctor will work that out.
- usually 300 mg (30 ml) each day in adults – given by mouth
- split into separate doses over a day.

You will also need to take 500 mg of ascorbic acid each day.

How you will have Methylthioninium Chloride

You may have this medicine in one of two ways:

- by mouth
- as an injection into a vein – called 'intravenous' or IV.

If you are preparing the medicine yourself, to take by mouth:

- you need to dilute it with water before taking it – this is to help stop upset stomach or pain or problems passing water
- for every 5 to 10 ml of this medicine the doctor tells you to take, mix this with 100 to 200 ml of a special water called 'water for injections' (even though you are not injecting it)

You will also need to take 500 mg of ascorbic acid each day while taking Methylthioninium Chloride for inherited methaemoglobinaemia.

If you have had more of this medicine than you should

If you have had too much of this medicine go straight back to the hospital.

You may experience the following:

- chest pain or tightness
- fast heartbeat
- feeling short of breath, breathing fast or unusually
- feeling dizzy or faint
- blurred vision
- your condition may get worse (e.g. blue lips from lack of oxygen, problems breathing)

If you have too much of this medicine you will get medical support and the medicine will be removed. If your condition is serious you may need a blood transfusion.

If you are worried or develop any other symptom or sign that concerns you, report to the hospital immediately.

If you forget to have this medicine

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any side effects not listed in this leaflet.

Blue colouring

This medicine makes your saliva, mucous membranes, teeth and skin turn blue and your urine and stools turn blue-green. This is normal, and expected to happen. However if you have trouble breathing when your mouth area turns blue, go to a hospital straight away.

Tell a doctor straight away if you get any of the following serious side effects – you may need urgent attention:

- chest pain
- low blood pressure (dizziness may be a sign of low blood pressure)
- fast or irregular heartbeat
- fast or troubled breathing
- painful and swollen veins, sometimes with a small blood clot (called 'thrombophlebitis') – this can happen when high doses are not diluted enough
- your condition gets worse – this can happen with very high doses. Infants and patients with glucose-6-phosphate dehydrogenase deficiency are especially likely to get this side effect
- infants may also get yellow skin or eyes
- rash, swelling of your lips, mouth, tongue or throat, with difficulty breathing – these may be signs of a serious allergic reaction (anaphylaxis)
- problems speaking
- sweating more than normal
- fever.

If you get any of the serious side effects listed above, tell a doctor straight away.

Tell a doctor straight away if any of the following side effects worry you:

- stomach pain, feeling or being sick
- diarrhoea
- headache
- feeling dizzy, agitated, confused or anxious
- shaking
- blurred vision
- high blood pressure
- allergic reaction (itchy skin, rash)
- pain or problems when passing water
- pain or ulcers in the areas where the medicine has been used during a medical procedure. (Note: any dye left on the skin after an operation can be carefully cleaned off with a mild bleach solution).

Tell a doctor straight away if you get any of the side effects above and they worry you.

Reporting side effects

If you get any side effects, tell your doctor, nurse or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Yellow Card Scheme (for reporting side effects)

Website: www.mhra.gov.uk/yellowcard

5. How to store Methylthioninium Chloride

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the vial label and the outer carton after 'EXP'. The expiry date refers to the last day of that month.
- Use within 24 hours of dilution.
- Do not store above room temperature (25°C).
- Do not refrigerate or freeze.
- Keep the vials in the original package, to protect them from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Doing this will help protect the environment.

6. Contents of the pack and other information

What this medicine contains

- The active substance is Methylthioninium Chloride.
Each 1 ml of solution contains 10 mg of Methylthioninium Chloride.
- The other ingredient is water for injections.

What this medicine looks like and contents of the pack

- It is a clear, blue coloured sterile solution.
- It comes in clear glass vials containing 5 ml of solution.
Each carton contains 5 vials.

Marketing Authorisation Holder

Phebra Limited, 24-25 New Bond Street, 1st Floor, London, England, W1S 2RR.

Manufacturer

Flexipharm Austrading Limited, Unit 12, Farnborough Business Centre, Eelmoor Road, Farnborough, GU14 7XA.

This leaflet was last revised in September 2019

The following information is intended for healthcare professionals only:

Preparation for intravenous administration

Use immediately on opening. Inject very slowly over a period of at least 5 minutes.

This medicine must not be injected into the spinal cord (intrathecal injection).

Methylthioninium Chloride may be diluted in 50 ml glucose 50 mg/ml (5%) solution for injection to avoid local pain, in particular in the paediatric population.

Not more than 350mg (35 ml of the solution) of Methylthioninium Chloride should be diluted in each 500 ml of liquid.

Methylthioninium Chloride must not be diluted with sodium chloride (NaCl) solution for injection because it has been demonstrated that chloride reduces the solubility of Methylthioninium Chloride.

Additional information on how Methylthioninium Chloride can be given is provided in section 3 of the Package Leaflet.

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