EPHEDRINE HYDROCHLORIDE MYX™ INJECTION

Ephedrine Hydrochloride MYX, solution for injection, 25 mg/1 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ephedrine Hydrochloride MYX. It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ephedrine Hydrochloride MYX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What Ephedrine Hydrochloride MYX Injection is used for

Ephedrine Hydrochloride MYX is used to treat the low blood pressure which may occur during spinal anaesthesia.

It works by contracting the blood vessels in your limbs, so that more blood is available for your heart.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

Ephedrine Hydrochloride MYX is available only with a doctor's prescription.

Ephedrine Hydrochloride MYX is not approved for use in children.

Before you are given Ephedrine Hydrochloride MYX Injection

When you must not given it

You should not be given Ephedrine Hydrochloride MYX if

- you have an allergy to ephedrine or any of the ingredients listed at the end of this leaflet
 - Symptoms of an allergic reaction to ephedrine may include:
 - shortness of breath, wheezing or difficulty in breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- you have, or have had any of the following medical conditions:
 - heart problems
 - pheochromocytoma (a rare tumour of the adrenal gland near the kidney)
 - closed angle glaucoma (a condition in which there is a build up of pressure in the eye)
 - mood/thought disorders and were given monoamine oxidase (MAO) inhibitors in last two weeks or about to commence on this group of medicines
- using an antibiotic medicine called linezolid
- undergoing general anaesthesia

- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed

if you are given this medicine after the expiry date has passed, it may not work as well or it may make you feel sick.

Before you are given it

Tell your doctor any of the following before you are given Ephedrine Hydrochloride MYX:

- if you have or have ever had any other health problems or medical conditions, including:
- high or low blood pressure
- prostrate problems or difficulty in passing urine
- · mental health disorders
- · thyroid problems
- diabetes
- 2. if you are pregnant or intend to become pregnant

Your doctor will discuss the risks and benefits of using Ephedrine Hydrochloride MYX.

- 3. **if you are breast-feeding or plan to breast-feed**Ephedrine Hydrochloride MYX
 is not recommended for use if
 - is not recommended for use if you are breastfeeding.
- 4. if you are an athlete or competing in sports

Ephedrine Hydrochloride MYX contains an active substance that may cause a positive reaction in anti-doping tests.

If you have not told your doctor about any of the above, tell them before you are given Ephedrine Hydrochloride MYX.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Ephedrine Hydrochloride MYX. These include:

- Medicines used to treat heart failure (e.g. digoxin)
- Alpha blockers (e.g. prazosin and methyldopa) or beta blockers (e.g. propranolol) used to treat high blood pressure
- Medicines used to treat mental health disorders such as amitriptyline, moclobemide, phenelzine, venlafaxine and dothiepin
- Medicines used in the treatment of migraine such as ergotamine and any derivatives
- Theophylline (a medicine used to treat asthma)
- Acetazolamide, dichlorphenamide, sodium bicarbonate, sodium citrate (medicines that make urine less acidic)
- Linezolid (an antibiotic)
- Medicines used to treat epilepsy such as phenytoin
- Medicines used to treat ADHD such as methylphenidate
- Medicines found commonly in over the counter cold and flu preparations such as pseudoephedrine and phenylephrine.

These medicines may be affected by Ephedrine Hydrochloride MYX, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given Ephedrine Hydrochloride MYX.

If you are not sure whether you should be given Ephedrine

Hydrochloride MYX, talk to your doctor.

How Ephedrine Hydrochloride MYX Injection is given

How much is given

Ephedrine Hydrochloride MYX is diluted with saline 0.9% and administered as an slow injection into a vein

Ephedrine Hydrochloride MYX must only be given by a doctor or nurse.

Your doctor will decide what dose of Ephedrine Hydrochloride MYX you will receive This depends on your medical condition and other factors, such as your weight. Sometimes only a single dose of is required.

If you take too much (overdose)

As Ephedrine Hydrochloride MYX is given to you under the supervision of an doctor, it is unlikely that you will receive an overdose. However, if you experience severe side effects tell your doctor immediately.

Immediately telephone your doctor or the Poisons Information Centre (call 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ephedrine Hydrochloride MYX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose include the side effects listed in the "Side Effects" section (see below), but are usually of a more severe nature.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are having Ephedrine Hydrochloride MYX.

Ephedrine Hydrochloride MYX may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side-effects.

Ask your doctor to answer any questions you may have.

While being given it

Tell your doctor or nurse immediately if you notice any of the following:

- headache
- dry nose, mouth or throat
- · fever or sweating
- nausea, vomiting or stomach pain
- mood or mental changes, such as nervousness, anxiety or irritability
- difficult or painful urination
- · chest pain
- breathing difficulties

Hydrochloride MYX.

• irregular, fast or slow heartbeat Some people may get other side effects while being given Ephedrine

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After having Ephedrine Hydrochloride MYX Injection

Storage

Ephedrine Hydrochloride MYX will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C, and it is protected from light.

Product description

What it looks like

Ephedrine Hydrochloride MYX is a clear and colourless solution.

Ephedrine Hydrochloride MYX is available in the followings strength and pack size: 25 mg/1 mL strength, 5 glass yellow ampoules per pack.

Ingredients

The active ingredient in Ephedrine Hydrochloride MYX is ephedrine hydrochloride.

Each ampoule contains 25 mg/mL of ephedrine hydrochloride.

Ephedrine Hydrochloride MYX also contains water for injections.

Ephedrine Hydrochloride MYX does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

Mayne Pharma International Pty Ltd ABN 88 007 870 984 1538 Main North Road Salisbury South SA 5106

Australian Registration Number 25 mg/1 mL: AUST R 243672

This leaflet was prepared in July 2016.

MYX is a trade mark of Mayne Pharma International Pty Ltd.