

Package leaflet: Information for the patient

Efedrin Unimedic 5 mg/ml solution for injection

ephedrine hydrochloride

Read all of this leaflet carefully before you receive 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Efedrin Unimedic is and what it is used for

Efedrin Unimedic is used to treat hypotension that can occur during different types of anesthesia. The product may only be used by or under the supervision of an anesthesiologist.

2. What you need to know before you receive Efedrin Unimedic

You should not receive Efedrin Unimedic:

- if you are allergic to ephedrine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before receiving Efedrin Unimedic if you:

- have high blood pressure
- have a heart disease
- have diabetes
- have an overactive thyroid gland
- know or suspect that you have glaucoma (increased pressure in the eye)
- have an enlarged prostate gland
- have a severely reduced kidney function

Other medicines and Efedrin Unimedic

Tell your doctor if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you take any of the following medicines:

- Medicines with a similar effect as ephedrine (eg phenylephrine)
- Certain medicines against nasal congestion (eg phenylpropanolamine, pseudoephedrine)
- A medicine against ADHD (methylfenidate)
- Certain medicines that reduce pain during surgery (volatile halogenic anaesthetics)
- Medicines against depression such as tricyclic antidepressants (eg clomipramine, amitriptylin, nortriptylin) or serotonergic noradrenergic medicines (eg venlafaxin, reboxetin, duloxetine) or a monoamine oxidase inhibitor (MAOI) (eg moclobemide)

Talk to your doctor if you are taking or during the past 14 days have been taking a medicine called monoaminooxidase inhibitor (MAOI) used to treat depression.

- Medicines used to lower blood pressure (eg clonidine, guanetidine and medicines called alpha and beta blockers)
- Certain medicines used to treat heart failure and/or irregular heart beats (cardiac glycosides eg digitalis, quinidine)
- An antibiotic used to treat serious infections (linezolid)
- Certain medicines used in Parkinsons disease (eg rasagilin, safinamide, levodopa, bromocriptin, selegilin, entacapone, tolcapone)
- A medicine against pulmonary diseases such as asthma (teophylline)
- Medicines decreasing inflammation and other consequences of allergic reactions (corticosteroids eg dexamethasone)
- A medicine used during labour (oxytocine)

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this medicine.

Efedrin Unimedic may cause increased heart beats in the foetus. It shall not be used during pregnancy unless the doctor decides it is necessary. It may be used during a Cæsarian section to prevent low blood pressure.

Breast-feeding

Talk to your doctor if you are breast-feeding. You should avoid breast-feeding for two days after receiving this medicine.

Driving and using machines

Not relevant.

Efedrin Unimedic contains sodium

This medicine contains 32 mg sodium (main component of cooking/table salt) in each 10 ml ampoule . This is equivalent to 1,6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Efedrin Unimedic is administered

This medicine will be administered by health care personnel with appropriate training and experience. Your doctor will decide on the dose appropriate for you.

If you have received more Efedrin Unimedic than you should

Receiving too much Efedrin Unimedic may lead to symptoms such as nausea, vomiting, high temperature, paranoid psychosis, irregular heartbeats, high blood pressure, decreased breathing frequency, seizures and coma. If these symptoms occur alert the health care personnel.

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

4. Possible side effects

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

Common (may affect up to 1 in 10 people)

- confusion, anxiety, depression
- nervousness, irritability, restlessness, weakness, sleeping problems (insomnia), headache, sweating
- high blood pressure, increased heartbeats (palpitation, tachycardia)
- breathing difficulties (dyspnoea)

- nausea, vomiting

Rare (may affect up to 1 in 1000 people)

- irregular heart beats (cardiac arrhythmias)
- inability to urinate (acute urinary retention)

Not known (frequency cannot be estimated from the available data)

- hypersensitivity
- psychotic states (such as delusions and hallucinations), fear
- tremor (Shaking eg of hands), excessive salivation
- episodes of narrow angle glaucoma (an eye disease with a damaged optic nerve)
- angina, slow heart beats (reflex bradycardia), cardiac arrest, low blood pressure
- bleeding in the brain (cerebral haemorrhage)
- water retention in the lungs (pulmonary oedema)
- loss of appetite
- low blood levels of potassium (hypokalemia), altered blood glucose levels

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Efedrin Unimedic

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 label and carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Efedrin Unimedic contains

- The active substance is ephedrine hydrochloride. 1 ml solution for injection contains 5 mg ephedrine hydrochloride. Each 10 ml ampoule contains 50 mg ephedrine hydrochloride.
- The other ingredients are sodium citrate, citric acid, sodium chloride, hydrochloric acid, sodium hydroxide, water for injections.

What Efedrin Unimedic looks like and contents of the pack

Efedrin Unimedic is a clear solution.

10 x 10 ml clear glass ampouls are packed in a carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Unimedic Pharma AB

Box 6216

102 34 Stockholm

Sweden

Tel: to be completed nationally

e-mail: To be completed nationally

Manufacturer

Unimedic AB
Storjordenvägen 2
864 31 Matfors

This leaflet was last revised in March 2018

<[To be completed nationally]>

Other sources of information

<Detailed information on this medicine is available on the website of {name of MS Agency (link)}>