



## Package leaflet: Information for the patient

### EPHEDRIN Biotika

#### Injection solution

Ephedrine hydrochloride 50 mg in 1 mL

**Read all of 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs are the same as yours.
- If you get any side effects tell to your doctor, pharmacist or nurse. This includes *any possible side effects* not listed in this leaflet. See section 4.

#### What is in this leaflet:

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

#### 1. What EPHEDRIN Biotika is and what it is used for

Ephedrine is a catecholamine with a combination of direct and indirect  $\alpha$ - and  $\beta$ - sympathomimetic effects. It significantly stimulates the cerebral cortex, subcortical areas, breathing and vasomotor center. Children are less susceptible to this central stimulant effect. It has a positive chronotropic and positive inotropic effect on the cardiac muscle, increases peripheral resistance and blood pressure. Elderly patients may be more sensitive to the cardiovascular effects. It dilates the bronchi, reduces intestinal tone and motility (intestinal tension and intestinal mobility), contracts sphincter, relaxes detrusor (muscle that expels urine from the bladder) and bladder wall, relaxes the muscles of the uterus. It causes mydriasis, but does not affect the eye's reaction to light. It thus has effects similar to adrenaline, but they are weaker, get slower and last longer. Tachyphylaxis and tolerance to the effects of ephedrine may occur with repetitive dosing. EPHEDRIN Biotika is used on allergic conditions (bronchial asthma, allergic rhinitis or pollinosis, angioedema, drug eruption) in combination with antihistamines.

Circulatory: vasomotor collapse, sinus bradycardia (decrease of heart rate below normal values), prone to orthostatic syncope (short-term collapse of the body, faintness in sudden and abrupt change of body position from lying to sitting or standing).

Centrally: enuresis nocturna, narcolepsy.

#### 2. What you need to know before you use EPHEDRIN Biotika

##### Do not use EPHEDRIN Biotika

- if you are allergic to Ephedrine hydrochloride or any of the other ingredients this medicine (listed in section 6),
- if you are allergic to other sympathomimetics,
- if you have arterial hypertension (increased blood pressure),
- in heart failure,
- for ischemic heart disease, especially for myocardial infarction,
- for traumatic shock,
- if you have sinus tachycardia (increased heart rate),
- if you have hyperthyroidism (increased thyroid activity),
- if you are breastfeeding.

#### Warning and precautions

Talk to your doctor, pharmacist or nurse before using EPHEDRIN Biotika.

**Drug addiction (dependence on ephedrine) may develop; in long-term use, mainly of higher doses toxic psychosis may develop.**

#### Other medicines and EPHEDRIN Biotika

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Concomitant administration of other supplementary preparation, e.g. preparations with potassium and magnesium may occur an additional effect.

Concomitant treatment with MAO inhibitors (group of antidepressants) may occur acute hypertensive crisis (sudden increase in blood pressure) and subarachnoid bleeding (intracranial hemorrhage). Therefore, it is not recommended to be given within 2 weeks after stopping treatment with MAO inhibitors.

After ephedrine administration may change of body's reactivity to adrenaline and noradrenaline. Caution is also needed with others cardiac stimulants and cardiotonic drugs (heart muscle stimulants).

Combination with halothane is unsuitable for the risk of ventricular fibrillation (heart rhythm disturbances).

Concurrent administration of higher doses of theophylline and aminophylline increases ephedrine toxicity.

Reserpine and oral contraceptives may reduce ephedrine effect.

It prolongs the half-life of dexamethasone in asthmatic patients.

During treatment with antihypertensives, patients are more susceptible to the vasoconstrictor effect (causing vascular withdrawal) of ephedrine

The solution of ephedrine is incompatible (may not be mixed) with hydrocortisone and some barbiturates.

#### Pregnancy and breast-feeding and fertility

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

##### Pregnancy

Teratogenic potential was proven in laboratory animals (possible impact of foetus damage). The damage was manifested by specific developmental abnormalities of cardiovascular system. In humans the teratogenic potential has not been proven so far. There is no information concerning ephedrine mutagenicity in the available literature sources and databases (ability to cause of genetic mutation).

EPHEDRINE Biotika may be administered only when the benefit for mother outweighs the risk for foetus. In spite of the mentioned above, care is required during ephedrine administration to pregnant women as ephedrine crosses the placental barrier.

Parenteral administration of ephedrine during labour may cause foetal tachycardia. EPHEDRIN Biotika does not administer when the blood pressure in mother exceeds 130/80 mm Hg.

##### Breast-feeding

The amount of ephedrine in breast milk reaches concentration that may jeopardize breast-fed child. If mother condition requires ephedrine administration, the breastfeeding has to be interrupted.

#### Effects on ability to drive and use machines

Even EPHEDRIN Biotika has centrally stimulating effects, they may be manifested by nervous irritability, headache, therefore the patient ability to drive or to operate machinery is assessed by physician according to the current state of the patient.

#### 3. How to use EPHEDRIN Biotika

Always use the medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In vasomotor collapse 25-50 mg (0.5 to 1 mL) may be administered subcutaneously or intramuscularly.

In bronchospasm (coronary artery stenosis) the initial dose 12.5-25 mg is administered, followed by dose according to patient response.

When intravenous administration is required, the dose of 0.4 mL (20 mg) is diluted in isotonic saline solution up to 20 mL and is administered very slowly.

The maximum single dose in subcutaneous or in intramuscular administration is 50 mg, the maximum daily dose in subcutaneous or in intramuscular administration is 150 mg.

##### Use on children

Children up to 1 year of age: exceptionally 5 mg (0.1 mL) subcutaneously or 2.5 mg (0.05 mL) intravenously, 1 to 2-times daily.

For children 1 to 6 years of age 12.5 mg (0.25 mL) subcutaneously or 5 mg (0.1 mL) intravenously, administered 1 to 2-times daily

For children 6 to 15 years of age 25 mg (0.5 mL) subcutaneously or 10 mg (0.2 mL) intravenously, administered 1 to 2-times daily.

#### If you take more EPHEDRIN Biotika than you should

This medicine will be administered to you by a doctor or nurse and therefore it is unlikely that you will receive a bad dose.

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

*Symptoms of overdose:* nausea, pyrexia, hypertension, tachycardia, cardiac arrhythmia, precordial pain, palpitation, dyspnoea, cramp, restlessness, tremors, insomnia, confusion, irritation, hallucinations. Hypokalaemia (potassium deficiency in the body) and respiratory alkalosis (decrease in carbon dioxide concentration in arterial blood) may occur.

*Treatment of overdose:* is symptomatic, focused on management of the central effects by neuroleptics and anxiolytics. Adjustment of severe hypokalemia and respiratory alkalosis is necessary. It is possible to adjust tachyarrhythmia or hypertension by administration of alpha-blockers (fentolamine), beta-blockers (propranolol, esmolol), combined alpha- and beta-blockers (labetalol) or nitroprusside during cardiovascular function monitoring.

#### 4. Possible side effects

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

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people
Not known:	frequency cannot be estimated from the available data

##### Common (may affect up to 1 in 10 people):

ataxia (lack of voluntary coordination of muscle movements), headache, insomnia, disorder  
muscle weakness, tremors  
palpitations, dysrhythmia,  
hypertension,  
paranoid psychosis, delusions, hallucinations, micturition disorders  
nausea, vomiting,  
contact dermatitis.

##### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 EPHEDRIN Biotika

Do not store above 25 °C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible damage to the medicine.

Do not throw any medicines via wastewater or household waste. Any unused medicinal product should be returned to the pharmacy. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What EPHEDRIN Biotika contains

- The active substance is Ephedrine hydrochloride 50 mg in 1 mL.
- Other ingredients are water for injection, sodium hydroxide.

##### What EPHEDRIN Biotika looks like and contents of the pack

EPHEDRIN Biotika is a clear colorless solution, almost free of particles.

Pack size:

The pack contains 10 glass ampoules of 1 mL

##### Marketing authorization holder

BB Pharma a.s. Durychova 101/66,  
142 00 Praha 4 - Lhotka, Czech Republic

##### Manufacturer

HBM Pharma s.r.o., Sklabinská 30,  
036 80 Martin, Slovak Republic

**This information for the patient was the last updated in February 2017.**