

PACKAGE LEAFLET: Information for the patient

KAFEINE NATRIUM BENZOAT

Solution for injection – (96 mg + 104 mg) / 1 ml (20%)

(Caffeine anhydrous, Sodium benzoate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Kafeine natrium benzoat is and what it is used for?
2. Before you take Kafeine natrium benzoat
3. How to take Kafeine natrium benzoat?
4. Possible side effects
5. How to store Kafeine natrium benzoat
6. Further information

1. WHAT KAFEINE NATRIUM BENZOAT IS AND WHAT IT IS USED FOR

Caffeine is a substance that stimulates the CNS. It inhibits the enzyme phosphodiesterase and has an antagonistic effect at central adenosine receptors. In the CNS it acts primarily in the higher centres and gives a condition of wakefulness, increasing the rate and depth of respiration sometimes. Its stimulating action in vasomotor centers of medulla and the positive inotropic effect in the myocardium are compensated by the peripheral vasodilator effect in the arterioles, so it has little effect on blood pressure.

The diuretic action of caffeine is weaker than that of theophylline.

Caffeine can increase the absorption of ergotamine and sometimes is combined with the latter for

the treatment of migraine. To increase the solubility of caffeine, it is combined with sodium benzoate and so is obtained caffeine sodium benzoate, which is used in the form of solution for injection.

Caffeine is well distributed in the body. It crosses the central nervous system and passes in saliva; in small concentrations it passes into breast milk.

This medicine is to be given only under the direct supervision of a doctor.

Kafeine natrium benzoat is indicated:

- as breathing and blood circulation analeptic, mainly in diseases with high temperature and infectious diseases, as well as during poisoning.

Your doctor may have given Kafeine natrium benzoat for a different purpose. Ask your doctor if you want to know why you have been given Kafeine natrium benzoat.

2. BEFORE YOU TAKE KAFEINE NATRIUM BENZOAT

Do not take Kafeine natrium benzoat if you have:

- hypersensitivity to caffeine or other xanthine alkaloids;
- hypersensitivity to any of the other ingredients of the solution for injection;
- severe arterial hypertension;
- glaucoma.

The use of this drug must be avoided in neonates, because sodium benzoate may cause kernicterus.

If you think you have any of the conditions mentioned above, consult your doctor first and follow the advice given.

Take special care with Kafeine natrium benzoat

Caffeine should be used with caution in patients with: hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease (eg, congestive heart failure), liver function disorders, chronic alcoholism, chronic liver disease, severe hypoxia.

Taking other medicines

Concomitant treatment with other medicines can affect or be affected by Kafeine natrium benzoat. Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Remember to inform your doctor for the treatment with Kafeine natrium benzoat if you get any other drug during treatment.

Amiodarone can interact with caffeine inhibiting its hepatic metabolism, whereas isoniazide may inhibit oxidative enzymes in the liver and thus damage the excretion of caffeine.

Seek the advice of a doctor or pharmacist if simultaneously with Kafeine natrium benzoat you also receive the above mentioned drugs.

Taking Kafeine natrium benzoat with food and drinks

No data available.

Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant or are planning to become pregnant or if you are feeding your baby with breast milk.

Caffeine crosses the placenta and is excreted in breast milk.

It is advisable not to be taken by pregnant women because it affects the growth of the fetus as well as by mothers who breastfeed babies because it can cause irritability or insomnia in infants.

Driving and using machines

No data available.

3. HOW TO TAKE KAFEINE NATRIUM BENZOAT

Always take Kafeine natrium benzoat exactly as your doctor has told you. If you are not sure, contact with your doctor or pharmacist.

If you feel that the effects of Kafeine natrium benzoat are too strong or too weak, talk to your doctor or pharmacist.

Caffeine sodium benzoate can be used in single doses as follows:

average doses are 100 - 200 mg injected with special attention in the vein.

If necessary, the injections can be repeated.

The maximal daily dose should not overcome 1 g.

Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Kafeine natrium benzoat

If you take more Kafeine natrium benzoat than the amount that should be taken, or if the children have taken this drug by mistake, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions to be taken.

If you forget to take Kafeine natrium benzoat

If you forget a dose, take your next dose when it is time to take it usually.

Do not take a double dose to make up the missed dose.

If you have further questions about the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time not.

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

Possible side effects are: nausea, vomiting, abdominal pain, diarrhea, insomnia, headache, dizziness, anxiety and palpitations.

If you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KAFEINE NATRIUM BENZOAT

Keep out of the reach and sight of children!

Do not use Kafeine natrium benzoat after the expiry date stated on the package.

Do not store above 25°C!

6. FURTHER INFORMATION

What Kafeine natrium benzoat - Solution for injection contains

The **active substances** are caffeine anhydrous and sodium benzoate.

Each 1 ml ampoule contains 96 mg of caffeine anhydrous and 104 mg of sodium benzoate.

The **other ingredients** are: sodium-EDTA, sodium hydroxide, hydrochloric acid may be added for pH adjustment, water for injection.

Content of the pack

Box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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