

1.3.1	Pikovit
SPC, Labeling and Package Leaflet	AM

1. NAME OF THE MEDICINAL PRODUCT

Pikovit® syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

5 ml of syrup (1 measuring spoon) contains:
900 I.U. of vitamin A as retinyl palmitate,
100 I.U. of cholecalciferol (vitamin D₃),
1 mg of riboflavin sodium phosphate (vitamin B₂),
0.6 mg of pyridoxine hydrochloride (vitamin B₆),
1 mg of thiamine hydrochloride (vitamin B₁),
1 µg of cyanocobalamin (vitamin B₁₂),
50 mg of ascorbic acid (vitamin C),
5 mg of nicotinamide and
2 mg of dexpanthenol (D-panthenol).

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

The syrup is a thick viscous liquid, light yellow to brownish-orange with a citrus odour and sour taste. Barely visible specks are allowed.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Pikovit syrup is intended as a preventive measure:

- in decreased appetite,
- to enhance body's resistance to infections and colds,
- in the convalescence period after illness,
- in insufficient growth (stunting),
- as a dietary vitamin supplement, especially in the winter and spring,
- in increased physical and mental strains in school children,
- as an adjunct to antibiotic therapy.

4.2 Posology and method of administration

Children 1 to 3 years of age: 1 measuring spoon (5 ml) of syrup twice daily.

Children 4 to 6 years of age: 1 measuring spoon (5 ml) of syrup 3 times daily.

Children 7 to 14 years of age: 1 measuring spoon (5 ml) of syrup 3 to 4 times daily.

Method of administration

The syrup is intended for oral use.

Shake the bottle well before administration.

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The syrup can be given to the child with the measuring spoon or mixed with tea, juice or mashed fruit puree. In case of poor appetite, the syrup should be taken daily for 1 month. The next course is possible after 1 to 3 months or as recommended by the doctor.

4.3 Contraindications

The drug is contraindicated in:

- hypersensitivity to any of the ingredients of the drug,
- hypervitaminosis A and/or D.

4.4 Special warnings and special precautions for use

Do not use Pikovit syrup in children under 1 year of age.

Prior to concomitant administration of other vitamin and vitamin-mineral preparations, a doctor or pharmacist should be consulted.

If a hypersensitivity reaction occurs, the medicine should be withdrawn.

Yellow discolouration of the urine may occur, due to riboflavin content. This effect is harmless.

Pikovit syrup is not recommended for diabetic patients because 5 ml of syrup (1 measuring spoon) contains 3 g of sugar.

Special information about some of the ingredients

Pikovit contains sucrose and glucose.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency should not take this medicine.

Pikovit contains red colour 4R (E124), that may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Vitamin C potentiates the therapeutic and adverse effects of sulfanilamide antibiotics (including crystalluria).

4.6 Pregnancy and lactation

Pregnant women and nursing mothers should take vitamins on doctor's advice. The vitamin doses in the syrup are adapted to children.

4.7 Effects on ability to drive and use machines

This medicine is not known to affect the ability to drive and use machines. It has no effect on the motor skills of children.

4.8 Undesirable effects

Hypersensitivity reactions may occur. If a hypersensitivity reaction occurs, treatment should be discontinued and a doctor or pharmacist consulted.

4.9 Overdose

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With the recommended dosing, no intoxication is anticipated. Prolonged administration of very large doses may lead to hypervitaminosis A and D although the risk of overdose with the syrup is minimal.

Do not exceed the recommended daily dose. In cases of accidental overdose, consult your doctor immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

According to ATC classification, Pikovit syrup is classified into the group of multivitamins, plain (A11BA).

Pikovit syrup contains a complex of vitamins, which are important in the metabolic processes in the body and necessary for normal growth and development, as well as to maintain and strengthen health.

Vitamin A regulates the growth and development of the child's body. It is also a component of antioxidative system, it is a component of cell membranes and is essential for the maintenance of the protective function of skin and mucous membranes. It is also involved in photochemical reactions in vision and stimulates cell-mediated immunity.

Vitamin D₃ is important for maintenance of calcium and phosphorus balance in the body; in cases of calcium deficiency, rickets can develop.

Vitamin B₁ is involved in carbohydrate metabolism and contributes to the normal functioning of the nervous system.

Vitamin B₂ contributes to the regeneration of tissues, including skin cells.

Vitamin B₆ is involved in the regulation of carbohydrate, protein and fat metabolism. It is also involved in the formation of haemoglobin, as well as thyroid hormones, it also helps to maintain the structure and function of bones, teeth and gums.

Vitamin B₁₂ is involved in blood formation, it promotes the normal function of the nervous system.

Vitamin C is the major antioxidant vitamin. It is involved in iron absorption from the gastrointestinal tract. It is involved in the formation of connective tissue, it normalizes vascular permeability and is involved in toxin removal. It increases the body's resistance to infections and mitigates the inflammatory reaction

Nicotinamide activates metabolic processes in tissues, it improves regeneration processes and is involved in synthesis of steroid hormones.

D-panthenol is involved in protein metabolism, synthesis of fatty acids and cholesterol, it is involved in energy-yielding metabolism. It also promotes the growth of bifidobacteria, which are an important component of the gut flora.

5.2 Pharmacokinetic properties

There are no data on Pikovit syrup.

5.3 Preclinical safety data

Acute and chronic toxicity studies with the syrup have not been performed. For doses of vitamins that are recommended by the RDA and US RDA and are also contained in the syrup, there are no reports of any harmful effects. Vitamins are substances required for normal functioning of the body and they are found in the daily diet.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Agar, tragacanth, sucrose, liquid glucose, orange oil flavour, orange concentrate, grapefruit concentrate, polysorbate 80, citric acid, red colour 4R (E124), sodium benzoate, purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Protect from light. Do not store above 25°C.
Keep out of the reach of children.

6.5 Nature and contents of container

Bottle (glass), plastic measuring spoon: 150 ml of syrup, in a folding box.

6.6 Instructions for use/handling

No special instructions required.

7. MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

8. MARKETING AUTHORISATION NUMBER

9. MARKETING AUTHORISATION DATE

10. DATE OF THE LATEST REVISION OF THE SPC