



Multivitamin preparation with minerals and trace elements for women before, during and after pregnancy

Read this leaflet carefully because it contains important information. This medicine has either been prescribed for you by your doctor or you have obtained it in a pharmacy without prescription. To get the greatest possible benefit, use the medicine according to this package leaflet or as instructed by the doctor or pharmacist. Keep this leaflet. You may need to read it again.

Elevit Pronatal

What Elevit Pronatal is and what it is used for

Elevit Pronatal contains 12 vitamins, 3 minerals and 4 trace elements that are formulated to meet the needs of women who are pregnant or breastfeeding. These active substances cannot be produced by the body itself but have to be supplied through food. They are essential to maintain all life processes such as breathing, digestion, energy production, reproduction and growth, etc., while at the same time serving as building blocks for tissue and organs.

Women who are pregnant or breastfeeding have a higher metabolic rate, as they have to provide not only for their own body but also for that of their child. They therefore need 50 -100% more vitamins and minerals than women who are not pregnant. In the case of iron, which is essential for blood production, this need triples to an amount that can often no longer be achieved even with a balanced diet.

A good supply of the vitamin folic acid can reduce the risk of severe birth defects (such as spina bifida) in the fetus. The very first weeks of pregnancy are crucial to this. Elevit Pronatal should therefore already be taken before pregnancy, in order to ensure an adequate supply of vital substances at the start of pregnancy.

The active substances contained in Elevit Pronatal are dosed in such a way that they also ensure a supply to mother and child even when a balanced diet is not always guaranteed (due to work, lack of vegetables in winter, frequent vomiting, etc.). Elevit Pronatal thus prevents the occurrence of deficiency symptoms that can manifest in the mother as tiredness or feeling "out of sorts". It also prevents anaemia that is caused by an iron and folic acid deficiency, with the result that an appropriate treatment is in many cases no longer necessary.

Other factors that need to be considered

Generally avoid alcohol and nicotine. Eat a moderate but balanced diet by enriching your meals with fruit and fresh vegetables. Your doctor will no doubt be happy to advise you on putting together your meals.

When not to use Elevit Pronatal

If you already have excess levels of vitamin A and/or D (hypervitaminosis) or if you are being treated with other products containing vitamin A and/or D at the same time, if you have kidney failure or have a calcium or iron utilisation disorder, or if you are allergic to one of the ingredients of Elevit Pronatal.

Interactions

Interactions have been reported between Elevit Pronatal and the following substances:

Tetracyclines: Because of the possibility of mutual inhibition of absorption, products containing iron should not be used during treatment with tetracyclines.

If tetracyclines must be taken concurrently, an interval of around two hours should be observed.

Antiepileptics/anticonvulsants: High doses of folic acid in particular can reduce the antiepileptic efficacy of antiepileptics/anticonvulsants, e.g. carbamazepine, phenytoin, primidone and barbiturates.

When Elevit Pronatal should be used with caution

Elevit Pronatal should not be taken over extended periods in doses higher than those recommended.

Inform your doctor or pharmacist if you are suffering from any illnesses, have any allergies or are taking other medicines or using other medicines externally (including those you purchase yourself).

Elevit Pronatal and pregnancy and breastfeeding

Vitamins, minerals and trace elements may be taken without risk in quantities corresponding to daily requirements.

It has been found, however, that an increased daily intake of vitamin A during pregnancy can increase the risk of deformity in the unborn child.

One Elevit Pronatal tablet contains, among other things, vitamin A. The quantity it contains corresponds to daily requirements. If you are or might become pregnant, you may take Elevit Pronatal but you must be sure not to exceed the prescribed dose. It should be noted that the daily requirement for vitamin A (contained in e.g. liver, liver products, cheese and eggs) can be met or even exceeded with a balanced diet (liver, some products containing liver). Consumption of large amounts of liver in addition to the use of Elevit Pronatal should be avoided. In case of doubt, ask your doctor or pharmacist for advice.

How to use Elevit Pronatal

Unless otherwise indicated by your doctor, adult women should take one tablet at breakfast-time together with their

breakfast drink.

If you suffer from morning sickness, you can also take the tablet at lunch. It is also possible to take it during your evening meal, but this is less advisable.

With a view to a planned pregnancy, you should already take Elevit Pronatal at least one month before the intended start of the pregnancy. If you do not become pregnant for some time, the dosage can be halved after two to three months, namely to one half tablet daily or one tablet every other day.

Do not only take Elevit Pronatal while you are pregnant and breastfeeding, but continue taking it for a further two to three months. This is particularly important if you intend to take contraceptives ("the pill") to prevent another pregnancy. Elevit Pronatal is designed for use before, during and after pregnancy, so that special dosage instructions for children, adolescents and the elderly are unnecessary.

Always take the dosage stated in this package leaflet or prescribed by your doctor. If you think that the effect of the medicine is too weak or too strong, speak to your doctor or pharmacist.

Possible side effects of Elevit Pronatal

The following side effects may occur when taking Elevit Pronatal: constipation, nausea, gastrointestinal problems and headaches.

In sensitive women, Elevit Pronatal can cause hyperstimulation in very rare cases. If this applies to you, you should not take the product in the evening.

Stool discolouration due to iron excretion is common.

In rare cases, dark discolouration of urine has been observed.

In very rare cases, there have been allergic reactions (asthma, urticaria) as well as localised skin reactions (itching, rash).

If an allergic reaction occurs, you should stop taking Elevit Pronatal and contact your doctor.

Inform your doctor or pharmacist if you notice any side effects that are not described here.

Further information

The product may only be used up to the date marked "EXP" on the container. Do not store Elevit Pronatal above 25°C and keep in original package. Keep the medicine out of reach of children.

Your doctor and pharmacist have access to the detailed summary of product characteristics and will be happy to provide you with further information.

What Elevit Pronatal contains

1 tablet contains the following active substances:

12 vitamins: 1080 µg (3,600 IU) vitamin A (retinol palmitate), 1.6 mg vitamin B1 (thiamine hydrochloride), 1.8 mg vitamin B2 (riboflavin), 2.6 mg vitamin B6 (pyridoxine hydrochloride), 4 µg vitamin B12 (cyanocobalamin), 100 mg vitamin C (ascorbic acid), 12.5 µg (500 IU) vitamin D3 (cholecalciferol), 15 mg vitamin E (dl- α -tocopherol acetate), 0.2 mg biotin, 10 mg calcium pantothenate, 0.8 mg folic acid, 19 mg nicotinamide.

3 minerals: 125 mg calcium, 100 mg magnesium, 125 mg phosphorus.

4 trace elements: 60 mg iron, 1 mg copper, 1 mg manganese, 7.5 mg zinc

Excipients: Lactose monohydrate, mannitol, macrogol 400, glycerol distearate, gelatin, microcrystalline cellulose, ethylcellulose, sodium starch glycolate, magnesium stearate, povidone K90+K30, industrial methylated spirit 99%, purified water, hypromellose, ethylcellulose aqueous dispersion (solid parts), macrogol 6000, talc, titanium dioxide E171, Iron oxide yellow E172.

Where Elevit Pronatal can be obtained and pack sizes available

Available in pharmacies without prescription.

Packs containing 30 and 100 tablets (scored).

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This package leaflet was last reviewed in June 2010.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

**Council of Arab Health Ministers
Union of Arab Pharmacists**

Bayer