

PATIENT INFORMATION LEAFLET

Complementary Medicine: **Health Supplement**
This unregistered medicine has not been evaluated by
SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

Elevit® Pregnancy Soft Gelatine Capsules
Sugar free

Read all of this leaflet carefully because it contains important information for you

Elevit® Pregnancy Soft Gelatine Capsules is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Elevit® Pregnancy Soft Gelatine Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Elevit® Pregnancy Soft Gelatine Capsules with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet?

1. What Elevit® Pregnancy Soft Gelatine Capsules is and what it is used for
2. What you need to know before you take Elevit® Pregnancy Soft Gelatine Capsules
3. How to take Elevit® Pregnancy Soft Gelatine Capsules
4. Possible side effects
5. How to store Elevit® Pregnancy Soft Gelatine Capsules
6. Contents of the pack and other information

1 What Elevit® Pregnancy Soft Gelatine Capsules is and what it is used for

Elevit® Pregnancy Soft Gelatine Capsules is a combination of folic acid, vitamins and minerals including Omega 3 DHA and Omega EPA supplement formulated to support good health for mom and baby, before, during and after pregnancy.

2 What you need to know before you take Elevit® Pregnancy Soft Gelatine Capsules**Do not take Elevit® Pregnancy Soft Gelatine Capsules:**

- If you are hypersensitive (allergic) to any of the other ingredients of Elevit® Pregnancy Soft Gelatine Capsules (listed in section 6).
- If you have too much iron in your blood (hemochromatosis) or kidney problems. This includes people on dialysis.
- If you have problems with how your body handles iron or copper, you should avoid this product.
- If you already have too much calcium in your blood (hypercalcaemia), a history of kidney stones (nephrolithiasis), or too much oxalate in their urine (hyperoxaluria) you should avoid this product.
- If you are allergic to docosahexaenoic acid (DHA), fish, fish oil or any other marine products.

- If you are allergic to soya or have peanut allergy.

Warnings and precautions

Don't exceed the recommended dose. Overdosing can lead to harmful effects. Special care should be taken with Elevit® Pregnancy Soft Gelatine Capsules:

- If you're already taking other vitamins, medications, or if you're under medical care, you should talk to a healthcare professional before using this product.
- Avoid using this product with other products containing Vitamin A, isotretinoin, etretinate, or beta-carotene, as it may lead to an excess of vitamin A (hypervitaminosis A).
- When taking this product, make sure to take it at least four hours apart from other medications unless otherwise specified.

Other medicines

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Active Ingredient	Drug	Description
Vitamin B ₆	Levodopa (prescription medicine used in the treatment of Parkinson’s disease)	Pyridoxine enhances the metabolism of levodopa, reducing its anti-parkinsonism effects. However, this interaction does not occur when carbidopa is in combination with levodopa (i.e. Sinemet®).
Folic Acid	Methotrexate (medicine used to treat rheumatoid arthritis and severe forms of a skin disease called psoriasis)	Folic acid supplementation may reduce the effectiveness of methotrexate in the treatment of acute lymphoblastic leukaemia, and theoretically, the efficacy in the treatment of other cancers.
Vitamin A	Retinoids* (a class of medicines derived from vitamin A)	Vitamin A supplementation must be avoided during treatment with vitamin A, retinoids, beta-carotene, and/or the synthetic isomers due to increased risk of vitamin A toxicity. Synthetic isomers include isotretinoin, etretinate, acitretin, and bexarotene.
Vitamin D3	Vitamin D analogues (vitamin supplements used for treating disorders caused by vitamin D deficiency)	Concomitant treatment with vitamin D analogues should be avoided due to increased risk of hypervitaminosis D and/or hypercalcemia. Vitamin D analogues include ergocalciferol and calcitriol. If deemed essential, serum and urine calcium levels should be monitored.
Vitamin A, Vitamin D, and Vitamin E	Orlistat (a certain type of weight-loss medication)	Gastro-intestinal absorption of vitamin A, vitamin D, and vitamin E is decreased with simultaneous administration. Separate intake of the product and these medications by four hours, unless otherwise specified, will minimize risk for any interaction.
Magnesium, Copper, Iron, Selenium, and Zinc	Tetracycline antibiotics	Polyvalent cations, such as copper, iron, selenium, and/or zinc, form complexes with certain substances resulting in decreased absorption of both substances. Separate intake of the product and these medications by 4 hours, unless otherwise specified, will minimize risk for this interaction.
	Quinolone antibiotics	
	Bisphosphonates	
	Levothyroxine	
	Methyldopa	
	Antiviral agents	
*Major		

Elevit® Pregnancy Soft Gelatine Capsules with food

Allowance should be made for intake of the vitamins and minerals from all other sources including fortified foods.

Pregnancy and breastfeeding

Elevit® Pregnancy Soft Gelatine Capsules is suitable for use before and during pregnancy and whilst breastfeeding.

Driving and using machines

The product has no or negligible influence on the ability to drive and use machines.

3 How to take Elevit® Pregnancy Soft Gelatine Capsules

Do not share medicines prescribed for you with any other person.

Always take Elevit® Pregnancy Soft Gelatine Capsules exactly as described in this leaflet or as your doctor, or pharmacist has told you. Check with your doctor or, pharmacist if you are not sure.

The usual dose for adults is one capsule a day taken by mouth with water.

If you take more Elevit® Pregnancy Soft Gelatine Capsules than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation.

The specific signs that you've taken too much can vary a lot. They depend on things such as how your body reacts and your given circumstances. So, it's important to pay attention to how you're feeling and get medical help if you think you've taken too much.

If you forget to take Elevit® Pregnancy Soft Gelatine Capsules

Do not take double dose to make up for forgotten individual doses.

If you stop taking Elevit® Pregnancy Soft Gelatine Capsules

Elevit® Pregnancy Soft Gelatine Capsules have no withdrawal symptoms or effects should you stop, or interrupt, or end treatment early.

4 Possible side effects

Elevit® Pregnancy Soft Gelatine Capsules can have side effects.

Not all side effects reported for Elevit® Pregnancy Soft Gelatine Capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Elevit® Pregnancy Soft Gelatine Capsules, please consult your health care provider for advice.

If any of the following happens, stop taking Elevit® Pregnancy Soft Gelatine Capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Elevit® Pregnancy Soft Gelatine Capsules. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Blood in the urine or pain with urination,
- Needing to go urgently or frequently, or
- bedwetting.

These are all serious side effects. You may have hypercalciuria and may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Nausea,
- Abdominal discomfort,
- Diarrhoea,
- and vomiting.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (<https://www.safetrack-public.bayer.com>). By reporting side effects, you can help provide more information on the safety of Elevit® Pregnancy Soft Gelatine Capsules.

5 How to store Elevit® Pregnancy Soft Gelatine Capsules

Store all medicines out of reach of children.

Store at or below 25 °C.

Store blisters in the carton and protect from direct sunlight.

Do not use after the expiry date stated on the label and carton.

Do not dispose of unused medicines in drains or sewerage (e.g. toilets).

6 Contents of the pack and other information

What Elevit® Pregnancy Soft Gelatine Capsules contains:

- The active substances are: Vitamin A (beta-carotene) 771 µg; vitamin D (cholecalciferol) 5 µg; vitamin E (dl-alpha-tocopheryl acetate) 15 IU; vitamin B1 (thiamine mononitrate) 1,4 mg; vitamin B2 (riboflavin) 1,4 mg; niacin (nicotinamide) 18 mg; vitamin B5 (calcium pantothenate) 6 mg; vitamin B6 (pyridoxine hydrochloride) 1,9 mg; folic acid (pteroylmonoglutamic acid & calcium l-methylfolate) 400 µg; vitamin B12 (cyanocobalamin) 2,6 µg; biotin (d-biotin) 30 µg; vitamin C (calcium ascorbate) 85 mg; DHA (docosahexaenoic acid omega 3) 200 mg; EPA (eicosapentaenoic acid omega 3) 80 mg; iodine (potassium iodate) 150 µg; iron (ferrous fumarate) 14 mg; magnesium (magnesium oxide) 57 mg; selenium (sodium selenite) 60 µg; copper (cupric sulfate) 1 mg; and zinc (zinc oxide) 10 mg.

- The other ingredient are silicon dioxide; beeswax yellow; gelatin; glycerol; purified water; iron oxide black and iron oxide red.

What Elevit® Pregnancy Soft Gelatine Capsules looks like and contents of the pack

Elevit® Pregnancy Soft Gelatine Capsules is soft, gelatine, oblong brown opaque capsules, containing reddish-brownish oily suspension.

The soft gelatine capsules are packed in press-thru blister packs sealed with aluminium lid foil. Blister strips are packed inside folding carton, possibly with a leaflet enclosed.

Holder of Certificate of Registration

Bayer (Pty) Ltd
Collaboration Hub, 1st Floor, Waterfall Circle
9 Country Estate Drive, Waterfall City
Midrand, 2090
South Africa
Co Reg. no.: 1968/011192/07
Tel: +27 11 921 5000

Registration number(s)

To be confirmed upon registration.

Access to the corresponding Professional Information

The corresponding professional information, as well as patient information leaflet in other language(s), may be obtained electronically on the following web address: <https://www.bayer.co.za>.

Manufacturer:
BERLIMED, S.A. CL Francisco Alonso n° 7, Polfgono Industrial Santa Rosa, Alcala de Henares, 28806 Madrid, Spain