

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® Breastfeeding Soft Gelatine Capsules**
Sugar free**Read all of this leaflet carefully because it contains important information for you**

Elevit® Breastfeeding Soft Gelatine Capsules is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Elevit® Breastfeeding 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® Breastfeeding 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® Breastfeeding Soft Gelatine Capsules is and what it is used for
2. What you need to know before you take Elevit® Breastfeeding Soft Gelatine Capsules
3. How to take Elevit® Breastfeeding Soft Gelatine Capsules
4. Possible side effects
5. How to store Elevit® Breastfeeding Soft Gelatine Capsules
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1 What Elevit® Breastfeeding Soft Gelatine Capsules is and what it is used for

Elevit® Breastfeeding Soft Gelatine Capsules is a combination of vitamins, minerals and Omega 3 supplement formulated to support the increased nutritional needs during breastfeeding for baby's ongoing healthy development.

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

- If you are hypersensitive (allergic) to any of the other ingredients of Elevit® Breastfeeding 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 your kidneys don't work as well as they should (renal insufficiency), this product isn't suitable for you.
- If you're already taking vitamin A, retinoids, beta-carotene, or similar substances like isotretinoin and etretinate, you shouldn't use 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® Breastfeeding 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.
- If you suffer from kidney stones or urinary stones you should be cautious when using vitamin supplements, such as calcium, ascorbic acid, and vitamin D may affect stone formation.
- 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 B₆	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 and vitamin D	Cholestyramine (cholesterol lowering medication)	Gastro-intestinal absorption of vitamin A and vitamin D 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.
Calcium, selenium, iron, and zinc.	Tetracycline antibiotics	Polyvalent cations, such as calcium, selenium, iron, 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,
	Quinolone antibiotics	
	Levothyroxine	
	Methyldopa	

Active Ingredient	Drug	Description
		will minimize risk for this interaction.
*Major		

Elevit® Breastfeeding 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® Breastfeeding Soft Gelatine Capsules is intended for use during pregnancy and lactation.

Driving and using machines

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

3 How to take Elevit® Breastfeeding Soft Gelatine Capsules

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

Always take Elevit® Breastfeeding 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 pregnant and breastfeeding woman is one capsule a day taken by mouth with water.

If you take more Elevit® Breastfeeding 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.

If you take too much of this product, you might suddenly get a headache, feel confused, or have stomach problems like constipation, diarrhoea, feeling sick, or throwing up. If you notice any of these things, stop using the product right away and get in touch with a doctor or nurse.

Taking too much of this product over a short or long period of time can lead to an overload of vitamins A and D in your body. It can also cause harmful effects due to excess of other ingredients in the product, such as vitamin C, zinc, selenium, and iron.

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® Breastfeeding Soft Gelatine Capsules

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

If you stop taking Elevit® Breastfeeding Soft Gelatine Capsules

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

4 Possible side effects

Elevit® Breastfeeding Soft Gelatine Capsules can have side effects.

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

If any of the following happens, stop taking Elevit® Breastfeeding 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® Breastfeeding 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

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,
- Slight yellow discoloration of urine (chromaturia)
- 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](https://www.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® Breastfeeding Soft Gelatine Capsules.

5 How to store Elevit® Breastfeeding Soft Gelatine Capsules

Store all medicines out of reach of children.

Store at or below 25 °C.

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

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

6 Contents of the pack and other information

What Elevit® Breastfeeding Soft Gelatine Capsules contains:

- The active substances are Vitamin A (βeta-carotene) 2400 IU; vitamin D (cholecalciferol) 200 IU; vitamin E (DL-α-Tocopheryl acetate) 7,5 IU; vitamin C (ascorbic acid) 60 mg; vitamin B1 (thiamine mononitrate) 1,4 mg; vitamin B2 (riboflavin) 1,6 mg; Vitamin B3 (Niacin) 17 mg; vitamin B5 (calcium pantothenate) 7 mg; vitamin B6 (pyridoxine hydrochloride) 2 mg; biotin 35 µg; folic acid (pteroylmonoglutamic acid) 200 µg; vitamin B12 (cyanocobalamin) 2 µg; calcium (calcium phosphate) 120 mg; iron (ferrous fumarate) 9 mg; zinc (zinc oxide) 5 mg; selenium (sodium selenite) 35 µg; iodine (potassium iodate) 150 µg; DHA (Docosahexaenoic acid) 200 mg and Lutein 250 µg.
- The other ingredients are soy lecithin, beeswax yellow, gelatine, glycerol, iron oxide black (E 172), and Iron oxide red (E 172).

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

Elevit® Breastfeeding 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.

Elevit® Breastfeeding Soft Gelatine Capsules may be available in packs of 30, 60, 90 or 100 capsules. Not all pack sizes may be available.

Holder of Certificate of Registration

Bayer (Pty) Ltd.
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South Africa
Co Reg. no.: 1968/011192/07
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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:
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