

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® Pre-conception Film Coated Tablets**
Sugar free**Read all of this leaflet carefully because it contains important information for you**

Elevit® Pre-conception Film Coated Tablets is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Elevit® Pre-conception Film Coated Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Elevit® Pre-conception Film Coated Tablets 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® Pre-conception Film Coated Tablets is and what it is used for
2. What you need to know before you take Elevit® Pre-conception Film Coated Tablets
3. How to take Elevit® Pre-conception Film Coated Tablets
4. Possible side effects
5. How to store Elevit® Pre-conception Film Coated Tablets
6. Contents of the pack and other information

1 WHAT ELEVIT® PRE-CONCEPTION FILM COATED TABLETS IS AND WHAT IT IS USED FOR

Elevit® Pre-conception Film Coated Tablets is a combination of folic acid, vitamins and minerals supplement formulated to support good health for mom and baby, before pregnancy and during pregnancy.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE ELEVIT® PRE-CONCEPTION FILM COATED TABLETS**Do not take Elevit® Pre-conception Film Coated Tablets:**

- If you are hypersensitive (allergic) to any of the other ingredients of Elevit® Pre-conception Film Coated Tablets (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.

Warnings and precautions

Don't exceed the recommended dose. Overdosing can lead to harmful effects. Special care should be taken with Elevit® Pre-conception Film Coated Tablets:

- 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® Pre-conception Film Coated Tablets with food

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

Pregnancy and breastfeeding

Elevit® Pre-conception Film Coated Tablets is suitable for use before and during pregnancy and lactation at the recommended dose.

Driving and using machines

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

3 HOW TO TAKE ELEVIT® PRE-CONCEPTION FILM COATED TABLETS

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

Always take Elevit® Pre-conception Film Coated Tablets 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 (1) tablet per day for women planning to become pregnant until end of first trimester.

If you take more Elevit® Pre-conception Film Coated Tablets 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® Pre-conception Film Coated Tablets

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

If you stop taking Elevit® Pre-conception Film Coated Tablets

Elevit® Pre-conception Film Coated Tablets have no withdrawal symptoms or effects should you stop, or interrupt, or end treatment early.

4 POSSIBLE SIDE EFFECTS

Elevit® Pre-conception Film Coated Tablets can have side effects.

Not all side effects reported for Elevit® Pre-conception Film Coated Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Elevit® Pre-conception Film Coated Tablets, please consult your health care provider for advice.

If any of the following happens, stop taking Elevit® Pre-conception Film Coated Tablets 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® Pre-conception Film Coated Tablets. 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® Pre-conception Film Coated Tablets.

5 HOW TO STORE ELEVIT® PRE-CONCEPTION FILM COATED TABLETS

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® Pre-conception Film Coated Tablets contains:

- The active substances are: Vitamin A (retinyl palmitate) 2566 IU; vitamin D (cholecalciferol) 200 IU; vitamin E (dl-alpha-tocopheryl) 10 mg; vitamin B1 (thiamine mononitrate) 1,4 mg; vitamin B2 (riboflavin 5'-phosphate) 1,4 mg; niacin (nicotinamide) 18 mg; vitamin B5 (calcium pantothenate) 6 mg; vitamin B6 (pyridoxine hydrochloride) 1,9 mg; folic acid (calcium-L-methylfolate) 400 µg; vitamin B12 (cyanocobalamin) 2,6 µg; vitamin C (ascorbic acid) 85 mg; biotin (D-biotin) 30 µg; calcium (calcium carbonate, calcium D-pantothenate & calcium-L-methylfolate) 125 mg; Copper (cupric sulfate) 1 mg; iodine (potassium iodide) 150 µg; iron (ferrous fumarate) 14 mg; magnesium (magnesium oxide) 100 mg; manganese (manganese sulfate monohydrate) 2 mg; selenium (sodium selenite) 60 µg; and Zinc (zinc citrate) 11 mg.

- The other ingredient are: Microcrystalline cellulose, sodium croscarmellose, talc, magnesium stearate, silicon dioxide, aquapolish F white 014.149 MS, hydroxypropylmethylcellulose, hydroxypropylcellulose, polyethylene glycol (PEG) 4000, rice starch, and sucrose esters of fatty acids.

What Elevit® Pre-conception Film Coated Tablets looks like and contents of the pack

Elevit® Pre-conception Film Coated Tablets is presented as a pearl white to off-white with shades of light grey, oval and biconvex film-coated tablet.

The tablets 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

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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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