PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: HEALTH SUMPLEMENT
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

ELEVIT® BREASTFEEDING Soft Gelatine Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Elevit Breastfeeding contains multivitamins in combination with minerals, trace elements, lutein and omega 3 fatty acids.

Each soft gelatine capsule contains the following active ingredients:

Active Ingredient	Quantity
Vitamins	
Vitamin A (beta-carotene)	721,0 µg
Vitamin B1 (thiamine mononitrate)	1,4 mg
Vitamin B2 (riboflavin)	1,6 mg
Vitamin B3 (nicotinamide)	17 mg
Vitamin B5 (calcium-D-pantothenate)	7,0 mg
Vitamin B6 (pyridoxine hydrochloride)	2,0 mg
Biotin (D-biotin)	35,0 µg
Folic acid (pteroylmonoglutamic acid)	200,0 µg
Vitamin B12 (cyanocobalamin)	2,0 µg
Vitamin C (L-ascorbic acid)	60,0 mg
Vitamin D (cholecalciferol)	5,0 µg
Vitamin E (DL-α-tocopheryl acetate)	5,0 mg
Mineral and Trace Elements	
Calcium (calcium phosphate)	120,0 mg
Iodine (potassium iodate)	150,0 µg
Iron (ferrous fumarate)	9,0 mg
Selenium (sodium selenite)	35,0 µg
Zinc (zinc oxide)	5, mg
Other	
DHA (docosahexaenoic acid);	200,0 mg
Lutein	250,0 µg

Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Soft Gelatine Capsule.
Opaque brown oblong soft gelatine capsule containing reddish-brownish oily suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Elevit Breastfeeding is a combination of vitamins, minerals, lutein and omega 3 fatty acids supplement formulated to support the increased nutritional needs during the period of breastfeeding.

4.2 Posology and method of administration

Posology

For oral use.

One soft gelatine capsule daily to be taken as a whole with a glass of water preferably with a meal.

Special populations

Patients with hepatic impairment
Elevit Breastfeeding should be administered with caution under medical supervision in patients with hepatic impairment.

Patients with renal impairment
Elevit Breastfeeding is contraindicated in patients with severe impaired renal function (see section 4.3).

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Iron and/or copper metabolism disorders
- Existing hypervitaminosis D
- Hypercalcaemia
- Severe hypercalciuria
- Severe impaired renal function

4.4 Special warnings and precautions for use

The recommended dosage must not be exceeded. Very high doses of some ingredients, in particular vitamin A, vitamin D, iron and copper, can be harmful to health (see section 4 .9).

Patients receiving other single vitamins or multivitamin preparations, any other medication or those under medical care should consult a health care professional before taking this product (see section 4.5).

Elevit Breastfeeding must be taken with particular caution together with any other products, including supplements and /or fortified foods /drinks containing Vitamin A, the synthetic isomers isotretinoin and etretinate, or beta-carotene, since large doses of the latter mentioned compounds are considered harmful to the foetus and may cause hypervitaminosis A.

Elevit Breastfeeding must be taken with particular caution together with other products, including supplements and /or fortified foods /drinks containing Vitamin D, since large daily doses may cause hypervitaminosis D (see section 4.9).

As calcium, ascorbic acid and Vitamin D may have an effect on stone formation, patients with nephrolithiasis or urolithiasis should use caution when using vitamin supplements.

4.5 Interaction with other medicines and other forms of interaction

When used as recommended no specific interactions are expected. However, potential interactions for single ingredients are reported in the literature, thus patients receiving any other medication or those under medical care should consult a physician or healthcare professional before taking Elevit Breastfeeding.

Drug interactions

The absorption of iron may be decreased by concurrent administration with antacids, gastric acid suppressive medications, fluoroquinolone, bisphosphonates, levodopa, levothyroxine, penicillamine, tetracycline antibiotics or trientine. If simultaneous use of one of these medications is necessary, administration should be separated by 2 to 3 hours.

Products containing calcium, magnesium, iron, copper or zinc may interact with orally administered antacids, antibiotics (tetracyclines, fluoroquinolones), levodopa, bisphosphonates, penicillamine, thyroxine, trientine, digitalis, antiviral agents and thiazide diuretics. If simultaneous use is necessary, administration of the two products should be separated by 2 hours.

Food interactions

Since oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption, it is not recommended to take this product within two hours of eating foods containing high oxalic acid or phytic acid concentrations.

4.6 Fertility, pregnancy and lactation

Elevit Breastfeeding is indicated for use while breastfeeding; however, the recommended dosage must not be exceeded (see section 4.9). As for every medicine, please consult your health care professional.

Pregnancy

Vitamin A doses of more than 10 000 IU per day may be teratogenic if administered during the first trimester of pregnancy. Thus, Elevit Breastfeeding must be taken with particular caution together with other medicines containing vitamin A, the synthetic isomers isotretinoin and etretinate, or beta-carotene, since large doses of the latter mentioned compounds are considered harmful to the foetus.

Chronic overdose of vitamin D might be harmful to the foetus.

For pregnant women, the Institute of Medicine (USA) has set the Tolerable Upper Intake Levels (UL) of vitamin D of 100 µg (4 000 IU) per day, which is considered as safe.

Breastfeeding

Permanent overdose of vitamin D might be harmful to the neonate.

The vitamins and minerals in Elevit Breastfeeding are excreted into breast milk. This must be taken into consideration if the infant is receiving any respective supplements.

For lactating women the Institute of Medicine (USA) has set the Tolerable Upper Intake Levels (UL) of vitamin D of 100 µg (4 000 IU) per day, which is considered as safe.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The following adverse reactions have been identified during post-approval use of several similar Elevit preparations. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.

Gastrointestinal Disorders
Gastrointestinal and abdominal pain, constipation, diarrhoea, nausea and vomiting may occur.

Immune system disorders
In isolated cases this product may cause allergic or anaphylactic reaction. Symptoms may include hives, facial swelling, wheezing, skin reddening, rash, blisters, and shock. If an allergic reaction occurs, treatment must be stopped and a health care professional consulted.

Metabolism and nutrition disorders
Hypercalciuria.

Nervous system disorders
Headache, dizziness, insomnia, nervousness may occur.

A slight yellow discoloration of urine may be noticed. This effect is harmless and is due to the vitamin B2 contained in the preparation.

The product contains iron, which may lead to a black colouring of the stool. This effect is harmless and does not have any clinical relevance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the 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).

4.9 Overdose

There is no evidence that this product can lead to an overdose when used as recommended.

Most, if not all reports concerning overdoses of vitamins and minerals are associated with concomitant intake of high dosed single and/or multivitamin preparations. Acute or long-term overdose can cause hypervitaminosis A and D and hypercalcaemia as well as iron and copper toxicity.

Uncharacteristic initial symptoms, such as abrupt onset of headache, confusion, and gastrointestinal disturbances such as constipation, diarrhoea, nausea, and vomiting might be indicative for an acute overdose.

If such symptoms occur, treatment must be stopped and a health care professional consulted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: category D 34.12 (Multiple substance formulation).
Pharmacotherapeutic group: Multivitamins and minerals / trace elements
ATC Code: A11AA03

Elevit Breastfeeding is a multivitamin/multimineral formula containing vitamins in combination with minerals, trace elements, lutein and omega 3 fatty acids especially designed to ensure an adequate micronutrient supply for both the breastfeeding mother and child.

Vitamins are essential nutrients. They are indispensable for the normal development and growth of the foetus and the infant, for the metabolism and formation of carbohydrates, energy, lipids, nucleic acids and proteins, as well as for the synthesis of amino acids, collagen and neurotransmitters.

Multivitamins/multimineral preparations are indicated to prevent and correct nutritional micronutrient deficiencies. Pregnancy and lactation represent periods with increased micronutrient requirements and, as a consequence, increased risks of micronutrient deficiencies for both the mother and the child. Especially during pregnancy, micronutrient deficiencies exhibit a more serious health risk, as they may also impair the normal development of the unborn child. Supplementation with folic acid or folic acid-containing multivitamins is recommended to decrease the risk of congenital malformations including neural tube defects. Neural tube defects develop in the first weeks after conception, a period during which pregnancy may not have been diagnosed yet, thus supplementation with folic acid is essential at the stage when pregnancy is being planned.

5.2 Pharmacokinetic properties

Human health and well-being is naturally dependent on the continuous uptake and management of vitamins and minerals and their absorption, distribution, metabolism and elimination are maintained by specific physiological mechanisms.
The active ingredients of this preparation, vitamins, minerals and trace elements, are essential micronutrients, which are widely distributed in the human body. The discrimination between the physiological nutrient concentration in the plasma and its changes after additional intake of corresponding pharmaceutical preparations is, on the one hand, difficult to assess and conveys, on the other hand, little or no information on the biological activity of the individual nutrient in the target tissue. The plasma and tissue levels of micronutrients are homeostatically regulated and affected by various factors such as diurnal fluctuations, nutritional status, growth, and pregnancy and lactation No pharmacokinetic data are available on the active ingredients of this preparation, but the pharmacokinetic properties of the individual components have been extensively documented.

Absorption
The absorption of Vitamin C is through the oropharynx, stomach and the entire length of the small intestine. The absorption of Vitamins A, B2, B3 and B6 are primarily through upper small intestine. The absorption of Vitamins B1, D, E, folate, biotin and the minerals/trace elements copper, iron, magnesium, potassium, selenium, zinc and manganese are through the entire length of the small intestine. The absorption of calcium pantothenate, calcium and iodine are through the entire length of the small intestine and the colon.

Distribution
Primarily all vitamins and minerals are required for cellular functions and are distributed throughout the body. Water soluble vitamins are stored only to a minor extent, while fat soluble can be stored in liver and adipose tissue.

Metabolism/Biotransformation

Folate and Vitamin A are metabolised by the intestinal cells. Liver is the primary organ for metabolism/biotransformation of Vitamins A, B6, B12, C, D, E and calcium pantothenate. Copper, iron and selenium are incorporated into plasma proteins in the liver. Vitamin D is further metabolised by the kidney.

Excretion/Elimination
Folate and Vitamin A enter enterohepatic circulation, and are eliminated by the faeces and kidneys. The major route of elimination for iron is through tissue and blood loss. All the other vitamins, minerals and trace elements are eliminated through kidneys. In addition, Vitamins D, E, B12, copper, potassium, selenium, zinc and manganese can be eliminated though faeces.

5.3 Preclinical safety data

There is no specific study with this product but the preclinical safety of the individual components has been extensively documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soy lecithin
Beeswax yellow
Gelatin
Glycerol
Iron oxide black
Iron oxide red

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C.

Nature and contents of container

Elevit Breastfeeding is packed in PVC/PCTFE/Alu blisters. Blister strips are packed inside folding box.
The product is available in packs of 30, 60, 90 or 100 capsules.
Not all pack sizes may be available.

Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

To be confirmed upon registration.

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

To be confirmed upon registration.

10 DATE OF REVISION OF TEXT

TBC

11 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

To be confirmed upon registration.

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