NOVAVIT FIZZ PATIENT INFORMATION LEAFLET

Category D 34.12 Complementary Medicine: Health Supplement – Multiple substance formulation

PROPRIETARY NAME (and dosage form)

NOVAVIT FIZZ (Effervescent tablets)

COMPOSITION

| Each effervescent tablet contains: | |
|---|------------|
| Vitamin A Acetate | 2 750 IU |
| Vitamin D3 | 500 IU |
| Vitamin E Acetate | 22,35 IU |
| Ascorbic Acid (Vitamin C) | 108 mg |
| Niacin (Vitamin B3) | 18 mg |
| Pyridoxine (Vitamin B6) | 5,18 mg |
| Riboflavin (Vitamin B2) | 4 mg |
| Thiamine Hydrochloride (Vitamin B1) | 4 mg |
| Beta-carotene | 0,6 mg |
| Calcium-D-Pantothenate (Vitamin B5) | 0,55 mg |
| Folic Acid | 0,5 mg |
| Biotin (Vitamin H) | 0,15 mg |
| Cyanocobalamin (Vitamin B12) | 0,0072 mg |
| Magnesium Oxide Heavy, providing Magnesium (elemental) | 100,708 mg |
| Dicalcium Phosphate , providing Calcium (elemental) | 100,19 mg |
| Dipotassium Phosphate , providing Potassium (elemental) | 40,41 mg |
| Zinc gluconate, providing Zinc (elemental) | 11,01 mg |
| Ferrous AAC, providing Ferrous (elemental) | 9 mg |
| Boron AAC, providing Boron (elemental) | 1 mg |
| Copper AAC, providing Copper (elemental) | 1 mg |
| Manganese AAC, providing Manganese (elemental) | 1 mg |
| Iodine AAC, providing Iodine (elemental) | 0,15 mg |
| Chromium Polynicotinate, providing Chromium (elemental) | 0,049 mg |
| Molybdenum AAC, providing Molybdenum (elemental) | 0,025 mg |
| Selenium AAC, providing Selenium (elemental) | 0,025 mg |
| L-Lysine | 25 mg |
| Citrus Bioflavonoids | 17,86 mg |

Other ingredients:

Effersoda, citric acid, sucralose, masking flavour, colour Carmoisine Red, PEG 6000, strawberry flavour.

SUGAR FREE.

Contains Sweetener (Sucralose 21.5 mg)

INDICATIONS AND USE

NOVAVIT FIZZ is a health supplement with a multiple substance formulation containing vitamins, minerals, citrus bioflavonoids and a source of an essential amino acid. It is a factor in the maintenance of good health.

Suitable for a vegan lifestyle and diabetics.

Vitamin A Acetate:

- Contributes to the maintenance of eyesight, skin, membranes and immune function.
- Contributes to the development and maintenance of night vision.
- Contributes to the development and maintenance of bones and teeth.

Thiamine Hydrochloride (Vitamin B1):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to normal growth.

Riboflavin (Vitamin B2):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to tissue formation.

Niacin (Vitamin B3):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to normal growth and development.

Calcium-D-Pantothenate (Vitamin B5):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to tissue formation.

Pyridoxine (Vitamin B6):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to tissue formation.

Cyanocobalamin (Vitamin B12):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to normal red blood cell formation.

Ascorbic Acid (Vitamin C):

- Helps to metabolise fats and proteins.
- Helps in the development and maintenance of bones, cartilage, teeth and gums.
- Helps in connective tissue formation.
- Helps in wound healing.
- An antioxidant for the maintenance of good health.

Vitamin D3 (Cholecalciferol):

- Helps in the development and maintenance of bones and teeth.
- Helps in the absorption and use of calcium and phosphorous.
- Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

Vitamin E Acetate:

• An antioxidant for the maintenance of good health.

Biotin (Vitamin H):

• Helps the body to metabolise carbohydrates, fats and proteins.

Folic Acid:

- Helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy (refer to INTERACTIONS).
- Helps the body to metabolise proteins.
- Helps to form red blood cells.

Boron AAC (Boron):

• A factor in the maintenance of good health.

Dicalcium Phosphate (Calcium):

- Contributes to the development and maintenance of bones and teeth.
- Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.

Chromium polynicotinate (Chromium):

- Provides support for healthy glucose metabolism.
- Helps the body to metabolise carbohydrates and fats.

Copper AAC (Copper):

- Helps to produce and repair connective tissue.
- Helps to form red blood cells.

Iodine AAC (Iodine):

Contributes to the normal production of the thyroid hormones and normal thyroid function.

Ferrous AAC (Ferrous):

• Helps to form red blood cells and helps in their proper function.

Magnesium Oxide Heavy (Magnesium):

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to the development and maintenance of bones and teeth.
- Contributes to tissue formation.
- Contributes to the maintenance of normal muscle function.

Manganese AAC (Manganese):

- Helps the body to metabolise carbohydrates, fats and protein.
- Contributes to the development and maintenance of normal bones.

Molybdenum AAC (Molybdenum):

Helps the body to metabolise proteins.

Dipotassium Phosphate (Potassium):

• A factor in the maintenance of good health.

Selenium AAC (Selenium):

• An antioxidant for the maintenance of good health.

Zinc Gluconate (Zinc):

- Helps in connective tissue formation.
- Helps to maintain healthy skin.
- Helps the body to metabolise carbohydrates, fats and proteins.
- Helps to maintain immune function.

Citrus Bioflavonoids:

Provides antioxidants.

The use of NOVAVIT FIZZ effervescent tablets should not replace a well-balanced diet.

CONTRAINDICATIONS

Known hypersensitivity or allergy to any of the ingredients, including the ingredients listed (under Other ingredients).

NOT TO BE TAKEN BY CHILDREN UNDER THE AGE OF 18 YEARS.

PRECAUTIONS

If you are suffering from a medical condition consult with your healthcare provider prior to taking NOVAVIT FIZZ effervescent tablets.

WARNINGS

Mild cases of gastro-intestinal disturbances can occur. This can be controlled by taking the effervescent tablets with or shortly after a meal.

INTERACTIONS

Vitamin and mineral supplements can interact with certain medications or affect how medications work in your body. If you are currently taking other medications consult with your healthcare provider before taking NOVAVIT FIZZ effervescent tablets.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult with your healthcare provider for advice before taking NOVAVIT FIZZ effervescent tablets.

INSTRUCTIONS ON HOW TO TAKE THE MEDICINE

Adults over 18 years of age:

Dissolve one effervescent tablet daily in a half to a full glass of water, preferably after breakfast. Do not exceed the recommended dose unless instructed to do so by a healthcare provider.

Do not share your medicines with anyone else.

In the event of overdosage, stop drinking the effervescent tablets and consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

SIDE EFFECTS

Affecting the stomach:

Stomach (abdominal) discomfort, constipation, diarrhoea and feeling sick (nausea) (also refer to WARNINGS and PRECAUTIONS).

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

STORAGE AND DISPOSAL INFORMATION

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C in a cool, dry place.

Protect from light and moisture.

Store in the original container and keep lid of container firmly closed when not in use.

Do not store in the bathroom.

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

Return all unused medicine to your pharmacist.

Do not dispose unused medicine in drains or sewerage systems (e.g., toilets).

PRESENTATION

Novavit Fizz 10's: Effervescent tablets in pre-printed laminated tubes with a white cap packed into a pre-printed carton box with a package leaflet.

Novavit Fizz 30's: Effervescent tablets in pre-printed laminated tubes with a white cap packed into a pre-printed carton box with a package leaflet.

IDENTIFICATION

Effervescent Tablet: Pinkish, speckled, round effervescent tablet.

When dissolved in water: Pink solution.

REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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 $\label{lem:professional Information for NOVAVIT FIZZ efferves cent tablets available on the Novagen Pharma website: $$ $$ \underline{\text{http://www.novagenpharma.co.za/products/wellness/novavit fizz}$$$