

For healthcare professionals only

ELBAVIT SYRUP

With Iron

Multivitamin

BOOST

THEIR HEALTH



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21/09/2024

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ELBAVIT SYRUP

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BOOST THEIR HEALTH

Elbavit provides children 14 Vitamin & mineral:^{1,2}

Iron

Calcium

B12

B7
(Biotin)

B6

B5

B1

E

C

B3

A

Pot.
Iodide

B2

D3

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References

1-Egyptian Drug Authority Elbavit with iron Approved leaflet date: 09/11/2022

2-Egyptian Drug Authority Elbavit Multivitamin Approved leaflet date: 04/10/2021

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BOOST THEIR HEALTH

Elbavit with iron¹

Assist in iron deficiency anemia.¹



Stimulate the formation of blood cells.¹



boosts the immune system.¹



General tonic.¹



Dose¹

• Children: 5 ml (one teaspoonful)

kcal

Essential for metabolic activities for all ages.¹

Overcomes daily stress & tension.¹



B7

Source of Biotin.¹

B12

Source of vitamin B12.¹

References:

1-Egyptian Drug Authority Elbavit with iron Approved leaflet date: 09/11/2022.



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Elbavit multi-Vitamin¹

source of vitamin c.¹



Source of vit. D3.¹

D3

Dose¹

For children from **1** to under **7 years** of age **8 ml** daily,

For children from **7 years** and adults **10 ml** daily.



source of Calcium.¹

B7

Source of biotin.¹



Pineapple
Taste



MULTI VITAMINS

references:

1-Egyptian Drug Authority Elbavit Multivitamin Approved leaflet: 4-10-2021.

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Elbavit with iron prescribing information

Active ingredients: Vitamins and minerals

Pharmaceutical form: Syrup

Composition:

Each 5ml contains:

Calcium Pantothenate Eq. to 0.841 mg of elemental calcium and eq. to 9.2 mg pantothenic acid	10.0000 mg
Calcium gluconate Eq. to 2.232 of elemental calcium	25.0000 mg
Calcium Phospholactate (13% Ca) Eq. to 3.25 mg elemental Calcium	25.0000 mg
Dexapanthenol	2.0000 mg
Potassium iodide Equivalent to 150 ug of Iodine	0.1962 mg
Vitamin A Palmitate 1,000,000 IU /gm Eq. to 1800 IU	1.80 mg
Vitamin D ₃ 1,000,000 IU /gm in oil Eq. to 400 IU	0.4000 mg
Thiamine HCl Eq. to 1.783 mg of thiamin (Vit. B1)	2.0000 mg
Riboflavin sodium phosphate Eq. to 1.7 mg Riboflavin (Vit. B2)	2.1605 mg
Pyridoxin HCl Eq. to 1.6459 mg of Pyridoxine (Vit. B6)	2.0000 mg
Biotin 100%	0.2000 mg
Vitamin B12 (Cyanocobalamine) crystalline	0.0060 mg
Ascorbic acid, vit c	60.0000 mg
Vitamin E acetate oily (dl alpha tocopheryl acetate) Equivalent to 30 IU	30.0000 mg
Nicotinamide	20.0000 mg
Ferrous sulfate heptahydrate Equivalent to 9 mg of elemental iron	44.80 mg

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Inactive:

Sorbirtol 70% solution, Glycerin 99.5% ,Xanthan gum fine powder, Tween 20, Sodium benzoate, Ethyl Maltol, Pineapple flavor (Butyrate ethyl, Allyl Hexanoate, Isoamyl butyrate ,Benzyl alcohol, Gamma heptalactone, Hexyl acetate, Monopropylene glycol, Purified water) , Citric acid monohydrate, Sucrose.

Physical characters: yellow viscous with sweet taste and fruity odour.

Pharmacological action:

- Elbavit with iron provides a group of vitamins and minerals which are essential for metabolic activities for all ages and stimulates the formation of blood cells, particularly during the age of growth. It also promotes the formation of teeth and bone and boosts the immune system.
- Elbavit with iron contains Ferrous Sulfate required to assist iron deficiency anemia and prevent vitamin deficiency in pregnancy.

Indications:

1. Vitamins and mineral deficiency for all ages due to malnutrition or base of antibiotics.
2. General tonic.
3. To enhance immunity against infections.
4. To promote growth and formation of strong bone and healthy teeth.
5. To overcome daily stress and tension.
6. Ferrous Sulfate as iron source for iron deficiency anemia and to prevent vitamin deficiency in pregnancy.

Warning:

This product contains sucrose which must not be used for patients with sugar intolerance.

May cause softening of the stool due to sorbitol

Ferrous sulfate may cause constipation, diarrhea or stomach upset.

Avoid if patient allergic to any of its contents.

Dosage:



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Children: 5 ml (one teaspoonful) once daily.

Adult: 10 ml (two teaspoonful) once daily.

Reporting of suspected adverse reactions:

It is important to report suspected adverse drug reactions after authorization. This allows continuous monitoring of the benefit / risk ratio of the medicine. Healthcare professionals are invited to report suspected adverse reactions through the Egyptian Pharmaceutical Vigilance Center. pv.followupcedacgypl.gOv.cg

Package and storage:

Store in dark place at temperature not exceeding 30 °C.

Carton box contain amber (type III) glass bottle containing 60 ml syrup with (LDPE) plastic ring & PP plastic cap+ insert leaflet.

License Holder and Manufacturer:

Apex pharma for pharmaceutical industries.

1. Always read the full prescribing information.

2. Other less common side effects are listed in full prescribing information.

Healthcare professionals should report any suspected adverse reactions to the Egyptian Pharmaco-vigilance Center (EPVC) & Pharmaco-vigilance department of Apex pharma on Pharmacovigilance@apexpharmaeg.com".

"يتعين على مقدمي الرعاية الصحية إبلاغ مركز اليقظة الصيدلانية المضي وكذلك قسم اليقظة بالشركة حال حدوث أي آثار عكسية من الدواء"

Egyptian Drug Authority Elbavit with iron Approved leaflet date: 09/11/2022

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Full product information is available on request at
APEX Pharma
Plot No. 226, the second sector, City Center
5th Settlement, New Cairo, Egypt

MULTI VITAMINS

CA

B12



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Elbavit Multivitamin Prescribing Information:

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in the package insert or exactly as your doctor or pharmacist has told you

- Keep this leaflet. You might want to read it again
- Ask your pharmacist if you need more information or advice.
- If your symptoms worsen or there is no improvement, you must consult a doctor
- If you get any side effects, talk to your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4

In this leaflet

- 1 What Elbavit is and what is it used for?
2. What should you know before taking Elbavit?
3. How to take Elbavit?
4. what side effects are possible
5. How to store Elbavit?
6. Contents of the pack and other information

1. What Elbavit is and what is it used for

-Elbavit is a multivitamin preparation. It used to prevent combined vitamin deficiencies

Note:

Elbavit is not suitable for the prevention of vitamin deficiencies that are associated with impaired absorption from the intestine. For the targeted prevention of a deficiency of a certain vitamin, higher-dose mono preparations are recommended



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2. What should you know before taking Elbavit?

Elbavit must not be taken

- If you are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6),
- If there is an increased calcium content in the blood (hypercalcaemia) and increased calcium excretion in the urine (hypercalciuria)

Warnings and Precautions

- Talk to your doctor or pharmacist before taking Elbavit, in particular if you have kidney stones and Boeck's disease (sarcoid).

Other medicines and Elbavit

- Tell your doctor or pharmacist if you are taking / using, have recently taken / used, or may take / use any other medicines.
- If other preparations containing vitamin A or vitamin D are taken at the same time, there is a possibility of vitamin A or vitamin D overdosing.
- There is a risk of hypercalcaemia (increase in blood calcium levels) when taking thiazide diuretics (medicines to promote water excretion) at the same time.
- If there is an increased calcium concentration in the blood and at the same time taking digitalis preparations (medicines to promote heart function), cardiac arrhythmias may occur.
- Vitamin B6 in daily doses of 5 mg or more can reduce the effect of L -Dopa (medicine used to treat Parkinson's disease).

Pregnancy and breast feeding

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding, if you suspect you may be pregnant or planning to become pregnant.

So far, no risks are known if the specified dosage range. Overdoses of vitamin A should be avoided during pregnancy because of the risk of malformations in children. The dose of vitamin A shouldn't exceed 2500 IU/day for pregnant women

Long-term overdoses of vitamin D during pregnancy must also be prevented, as the resulting increase in blood calcium levels can lead-to physical deformities and mental disabilities in the child. The vitamins contained in bad pass into breast milk.



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Elbavit contains sucrose (saccharose)

Please only Elbavit after consulting your doctor if you know that you suffer from an intolerance to certain sugars

Advice for diabetics

10 ml Elbavit contain 1.5 g sucrose (sugar). If you are on a diabetic diet, this should be taken into account.

Other notes

An occasional yellow coloration of the urine after ingestion is harmless and due to the vitamin B2 content.

3. How to take Elbavit?

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has discussed.
- Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- For children from 1 to under 7 years of age 8 ml daily,
- For children from 7 years and adults 10 ml daily.

Duration of application

- The duration of the application depends on the complaints. Elbavit should only be taken as long as the need cannot be covered by a suitable diet.
- Please ask your doctor about this.

If you take Elbavit more than you should

- If the dose recommendations are exceeded, there is a possibility of vitamin A and D overdosing, especially if other preparations containing vitamin A and D are administered at the same time.
- In the event of an overdose of Elbavit, please contact your doctor. A chronic overdose of vitamin A can occur in adults with impaired liver or kidney



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function, especially in patients undergoing blood washing (hemodialysis) and in patients with a severe form of lipid metabolism disorder (hypertriglyceridaemia type V), even at doses between 4500 - 18,000 IU (corresponding to 12.5 - 50 ml Elbavit) early symptoms of chronic poisoning include: dry skin, itching (pruritus), flaking, hair growth disorders, cracks in the skin (fissures), tiredness, tendency to bleed (hemorrhage) and bone Pain

-An overdose of vitamin D can lead to an often long, lasting and potentially threatening increase in the calcium concentration in the blood (hypercalcaemia). The symptoms are not very characteristic

If you forget to take Elbavit

Continue to use as described in the dose instructions do not take a double dose to make up for a forgotten dose.

If you stop taking Elbavit

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, this medicine can have side effects, although not everybody gets them.

Very rare side effects (may affect less than 1 in 10,000 people): allergic reactions to individual components (see also section 3)

- If you take Elbavit more than you should

Countermeasures

In the event of an allergic reaction, please discontinue the preparation . .

Reporting of side effects

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse



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reactions via:

- MAP E-mail address: Pharmacovigilance@multiapex.com
- EPVC (Egyptian Pharmacovigilance Center) website: www.epvc.gov.eg
- E-MAIL: pv.followup@edaegypt.gov.eg

5. How to store Elbavit?

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the container.
- The expiry date refers to the last day of the month.

Storage conditions and shelf life:

Store at temperature not exceeding 30°C and shelf life is 2 years

6. Contents of the pack and other information

What Elbavit contains?

Each 5 ml contains:

The active ingredients are:

Vitamin A palmitate 1.8mg (eq to-1800IU)

Vitamin E acetate 27.3 mg (eg to 30 IU)

Vitamin D3 0.4 µg (eg to 400-IU)

Thiamine hydrochloride (vit B1) 2.0 mg

Riboflavin 5-phosonate sodium 2.33 mg (eq to 1.7 mg base)

Pyridoxine hydrochloride (vit B6) 2.0 mg

Cyanocobalamine (vitamin B12) 6.0 µg.

Ascorbic acid (Vitamin C) 60 mg

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Nicotinamide (vitamin B3) 20 mg

Biotin 200 µg

Dexapanthenol 2 mg

Potassium Iodide 0.1962 mg(eq.to 150 µg iodine)

Calcium gluconate 25 mg

Calcium pantothenate 10 mg

Calcium Phospholactate 25 mg

-The other ingredients are:

Glycerol, Sorbitol 70%, Polysorbate 80, Xanthan Gum, Sodium benzoate, Citric acid monohydrate, sucrose, veltol plus flavor, pineapple flavor.

What Elbavit looks like and contents of the pack

Yellow viscous syrup with sweet and fruity pineapple odor

Elbavit is available in:

Amber glass bottle (type III) containing 60 ml syrup, HOPE cap & LOPE ring and expanded polyethylene liner in carton box and inner leaflet
Manufacturer and license holder

1. Always read the full prescribing information.
2. Other less common side effects are listed in full prescribing information.

Healthcare professionals should report any suspected adverse reactions to the Egyptian Pharmaco-vigilance Center (EPVC) & Pharmaco-vigilance department of Apex pharma on Pharmacovigilance@apexpharmaeg.com".

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