SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Supradyn

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition in terms of the active ingredient(s) (INN):

Supradyn is a complete multivitamin and mineral preparation.

Quantitative composition in terms of the active ingredient(s) per dosage form:

Quantities for an effervescent tablet of approximately 4700 mg:

Name of ingredients	**Declaration**	**Stability overage**	**Actual content**
Active ingredients:			
Vitamins			
Vitamin A - in form of Vitamin A palmitate	3333 IU 33.33	 50%	5000IU 50.0 mg
Thiamine (B1) - in form of thiamine phosphoric acid ester chloride dihydrate	20.0	 10%	22 mg 27.2 mg
Riboflavin (B2) - in form of riboflavin sodium phosphate dihydrate	5.0	10%	(5.50 mg) 7.50 mg
Nicotinamide (B3)	50.0 mg	5%	52.5 mg
Pantothenic acid (B5) - in form of calcium pantothenate	 11.6 mg	 40%	 16.24 mg
Pyridoxine (B6) - in form of pyridoxine hydrochloride	 10.0 mg	 50%	 15.0 mg
Biotin(B8)	0.250 mg	10%	0.300mg
Folic acid (B9)	1.0 mg	25%	1.25 mg
Cyanocobalamin (B12) - in form of powder 0.1% water soluble:	0.0050mg 5.0 mg	30%	(0.0065mg) 6.5 mg
Ascorbic acid (C)	150.0 mg	10%	165.0 mg
Cholecalciferol (D3) - in form of cholecalciferol 100 CWS	 10.0 mg	 10%	 11.0mg
100 CWS			
D-α-Tocopherol (E) Equivalent to α-Tocopherol acetate	 10.0 mg	 10%	 (11.0mg)

Minerals and trace elements			
Magnesium 5.0 - in form of magnesium glycerophosphate	5.0 mg	- -	 48.0
Phosphorus - in form of calcium glycerophosphate - in form of magnesium glycerophosphate - in form of thiamine monophosphoric acid ester chloride	47.0mg	-	
Iron -in form of ferrous carbonated, saccharated	1.25mg	-	12.5
Manganese - in form of manganese sulfate(monohydrate)	0.5mg		1.538
Copper -In form of cupric sulphate(anhydrous)	0.1mg		 0.251 mg
Zinc - in form of zinc sulphate monohydrate(dihydrate)	0.5 mg		1.372 mg 25.63 mg
Molybdenum -In form of sodium molybdate(dihydrate)	0.1mg	-	 0.247

3. PHARMACEUTICAL FORM

Effervescent Tablets

4. CLINICAL PARTICULARS

4.1 Indication(s)

Multivitamin/multimineral for the prevention and treatment of general vitamin, mineral and trace element deficiencies of different origins due to increased requirements or reduced intakes.

4.2 Dosage and method of administration

4.2.1 Method of administration

Effervescent tablets: dissolved in a glass of water (200ml) and administered orally

4.2.2 Dosage regimen

One tablet daily for adults and adolescents from 12 years of age.

4.3 Contraindications

- Known hypersensitivity to any ingredient in the drug product
- Iron and/or copper metabolism disorders
- Existing hypervitaminosis A
- Existing hypervitaminosis D
- Hypercalcaemia
- Severe hypercalciuria
- 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;
- Patients receiving other single vitamins or multivitamin preparations, any other medication or those under medical care must consult a health care professional before taking this medicinal product. In particular, patients receiving vitamin K antagonists and/or any other anticoagulation treatment must consult a health care professional prior to use;
- This product must be taken with particular caution together with any other products containing Vitamin A, the synthetic isomers isotretinoin and etretinate, or beta-carotene, since large doses of vitamin A and/or the latter mentioned compounds may cause hypervitaminosis A;
- This product must be taken with particular caution together with other products containing vitamin D and/or calcium which may cause hypervitaminosis D and hypercalcaemia. In such cases the serum and urinary levels of calcium must be regularly monitored.

- 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.

For products containing lactose only:

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

For effervescent tablets:

- The effervescent tablets must not be taken by patients with phenylketonuria since the product contains a source of phenylalanine (aspartame);
- The effervescent tablets contain 301 mg sodium. Sodium content of older formulae may differ from the above. To be taken into consideration by patients on a controlled sodium diet;

4.5 Interaction with other medicinal products 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.

It has been reported that vitamin K containing drugs should be used with caution in patients receiving anticoagulants.

Thus, patients receiving any other medication or those under medical care should consult a physician or health care professional before taking this medicinal product.

4.5.1 Drug – Drug Interaction

- Products containing calcium, magnesium, iron, copper or zinc may interact with orally administered antacids, gastric acid suppressive medications, antibiotics (tetracyclines, fluoroquinolones), levodopa, levothyroxine, thyroxine, biphosphonates, penicillamine, trientine, digitalis, antiviral agents and thiazide diuretics. If simultaneous use is necessary, administration of the two products should be separated by 2 hours.
- Pyridoxine (vitamin B6), even at low doses, accelerates the peripheral metabolization of levodopa, as a result of which the dopaminergic action of levodopa in the treatment of Parkinson's disease is antagonized. This antagonism is counteracted by combination with a decarboxylase inhibitor.

4.5.2 Drug – Food Interaction

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

4.6 Fertility, pregnancy and lactation

This medicinal product can be used during pregnancy and lactation; however, the recommended dosage must not be exceeded. As for every medicinal product, please consult your health care professional.

4.6.1 Pregnancy

Chronic overdose with vitamin A is teratogenic if administered during the first trimester of pregnancy. For pregnant women, the Institute of Medicine (USA) has set the Tolerable Upper Intake Level (UL) of vitamin A to 3000 µg (10'000 IU) per day. This must be taken into consideration if receiving any other drugs containing vitamin A, the synthetic isomers isotrentinoin and etretinate, or beta-carotene.

Chronic overdose of vitamin D might be harmful to the fetus. For pregnant women, the Institute of Medicine (USA) has set the Tolerable Upper Intake Levels (UL) of vitamin D of 100µg (4000 IU) per day, which is considered as safe. This must be taken into consideration if receiving other supplements.

4.6.2 Lactation

The vitamins and minerals in this medicinal product are excreted into breast milk, but harmful effects on the child are not expected at therapeutic doses. However, this must be taken into consideration if the infant is receiving other supplements.

Chronic overdose of vitamin D might be harmful to the neonate. For lactating women the Institute of Medicine (USA) has set the Tolerable Upper Intake Levels (UL) of vitamin D of 100µg (4000IU) per day, which is considered as safe. This must be taken into consideration if the infant is receiving other supplements.

4.6.3 Fertility

There are no data on the effect of the medicinal product on fertility.

4.7 Effects on ability to drive or use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

The following adverse reactions have been identified during post-approval use of the medicinal product. 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, diarrhea, 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.

Nervous system disorders

Headache, dizziness, insomnia, nervousness may occur.

Metabolism and nutrition disorders

Hypercalciuria.

Renal and urinary disorders

Chromaturia (slight yellow discoloration of urine). This effect is harmless and is due to the vitamin B2 contained in the preparation.

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, diarrhea, nausea, and vomiting might be indicative for an acute overdose

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

Vitamin C overdose (over 15 g) may cause hemolytic anemia in certain individuals with a deficiency of glucose-6-phosphate dehydrogenase.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Sucrose, Mannitol, Tartaric acid, Sodium hydrogen carbonate,

Lemon flavour PHS-413330, Lemon flavour 860032 TD1090, Ethanol 96%

Water purified.

5.2 Incompatibilities

Not applicable

5.3 Shelf life

3 Years

5.4 Special precautions for storage

Do not store above 25ºC

5.5 Nature and contents of container

Supradyn effervescent tablets are packed in aluminium tubes, with a desiccant unit in the stopper.

6. MANUFACTURED BY

Delpharm Gaillard 33,
rue de l'Industrie
74240 Gaillard
FRANCE

7. MARKETING AUTHORIZATION NUMBER

05363/07329/REN/2020

8. DATE OF AUTHORIZATION

Sep 28, 2020

9. DATE OF REVISION OF THE TEXT

19 -9-2018
CCDS Version 5