SUMMARY OF PRODUCT CHARACTERISTIC

1. NAME OF THE MEDICINAL PRODUCT

VITACORE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Ferric Ammonium Citrate USP….200 mg

Cyanocobalamin (Vit. B12) BP… 50 mcg

Pyridoxine Hydrochloride (Vitamin B6) BP….0.5 mg

Folic acid BP .....1.5 mg

Zinc Sulphate BP .....2.33 mg

In a flavored Syrup BaseApproved color used.

Excipient of safety concern

Sucrose…2000 mcg as Sweetener

Liquid Glucose….1500 mcg as Sweetener

Sorbitol……500 mcg as Sweetener

Sodium Methyl Paraben…10 mcg as Preservative

Sodium Propyl Paraben….1 mcg as Preservative

Sodium benzoate….10 mcg as Preservative

Disodium EDTA….0.0025 mcg as Preservative

3. PHARMACEUTICAL FORM

Oral Liquid.

Brown Colour Syrupy Liquid

4. CLINICAL PARTICULARS

4.1.Therapeutic indications

It is used as a treatment for vitamin and mineral deficiency and as an appetite stimulant during and after illness.

4.2.Posology and method of administration

Method of administration: Oral

Dosage:

Children 6 months to 3 years: 5 ml (1 teaspoonful) twice daily

Children 3 years to 12 years: 5 ml (1 teaspoonful) three times dailyAdults: 10 ml (2 teaspoonsful) three times daily

Elderly Patients: 10 ml (2 teaspoonsful) three times daily.

Iron is best absorbed on an empty stomach (usually if taken 1 hour before or 2 hours after meals).

4.3.Contraindications

Use in patients hypersensitive to any of the constituents.

Avoid taking antacids, dairy products, tea, or coffee within 2 hours before or after this medication because they will decrease its effectiveness.

4.4.Special warnings and precautions for use

1. Vitacore contains ferric ammonium citrate which may stain teeth
2. The stated dose should not be exceeded
3. No other medicine containing iron or vitamins B6 should be taken without prior medical consultation
4. This product contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine.
5. This product also contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not takethis medicine.
6. This product contains Zinc Sulphate, Hypersensitivity to Zinc should be monitored.

This product contains Sodium benzoate which increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue). Also, it contains Sodium methyl paraben and Sodium propyl paraben which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

4.5.Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

The absorption of tetracyclines, fluoroquinolones, bisphosphonates, levothyroxine (thyroxine), trientine and antiviral agents may be affected by the minerals in the product. When taking these medications concomitantly, doses should be separated by two hours to avoid any potential interaction.
Concurrent administration with antacids (aluminium, calcium or magnesium containing products) is not recommended as antacid therapy has been reported to decrease iron absorption. If concurrent use cannot be avoided, doses should be separated by two hours to avoid any potential interaction.
Potential interactions with the following medicinal products have been cited:

Levodopa, penicillamine, digitalis. When taking these medications concomitantly, doses should be separated by two hours to avoid any potential interaction.

Thiazide diuretics may decrease calcium excretion and increase magnesium and zinc excretion by the kidneys. If used concomitantly, serum calcium levels should be monitored and attention

should be drawn to if administration of Vitacore is sufficient to prevent deficiencies of magnesium and zinc.

4.6.Fertility, pregnancy and lactation

Safety in human pregnancy has not been established. It is not advisable to administer Vitacore in pregnancy or to women breast-feeding infants without medical supervision.
If iron containing products are considered essential during the first 13 weeks of pregnancy they should only be taken under medical supervision.

4.7.Effects on ability to drive and use machines

Not applicable

4.8.Undesirable effects

Side effects to this product are rare, but may include temporary staining of the teeth, rash and mild gastrointestinal disturbance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 reactions to **TMDA**

4.9.Overdose

No data available. Gross abuse of the product would be necessary to approach toxic levels in whichcase conservative measures should be adopted.

5. PHARMACOLOGICAL PROPERTIES

5.1.Pharmacodynamic properties

Pharmacotherapeutic group: Multivitamins, combinations; Multivitamins and other minerals incl. combinations, ATC code: B03AE04
This preparation is a multivitamin/multimineral formula containing vitamins in combination with minerals and trace elements to ensure an adequate micronutrient supply.

5.2.Pharmacokinetic properties

The active ingredients of this preparation, vitamins, minerals and trace elements, are essential micronutrients, which are widely distributed in the human body. 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.

Paediatric population

No pharmacokinetic studies have been conducted in children. The information provided above is relevant to use in adolescents.

5.3.Preclinical safety data

No Information Available

6. PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Sucrose, Liquid Glucose, Sorbitol, Sodium Methyl Paraben Sodium Propyl Paraben , Sodium Benzoate, Disodium EDTA, Ascorbic acid, Sodium Citrate, Vanilline, Flavour Orange, Flavour Tangerine, Colour Erythrosine Supra

Composition of Erythrosine Supra: [Erythrosine Supra(87-92%),Volatile Matter & Sodium chloride (6-11%),Sodium Sulphate(<2)]

6.2.Incompatibilities

None

6.3.Shelf life

24 months from the date of manufacturing.

6.4.Special precautions for storage

“Do not store above 30º C. Protect from light. Do not freeze the medicine”“Use within 3 months after opening the bottle.”
“Keep this medicine out of the sight and reach of children.”
“Prescription Only medicine”

6.5.Nature and contents of container

Amber coloured glass bottle having Brown colored syrupy liquid fitted with yellow colour aluminiumPP cap with measuring cup having printed label & packed in single printed carton with insert.

6.6.Special precautions for disposal and other handling

No Special Requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

TAN 22 HM 0482

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

05th December, 2022

10. DATE OF REVISION OF THE TEXT