CHEMILIFE DROP SMPC

1- Name of the medicinal product

Chemi life drop

2- Qualitative and quantative composition

Chemilife drop contains Thiamine HCL (B1) 1 mg, Pyridoxine (B6) 0.5 mg, Nicotinamide 5mg, Riboflavin (B2) 0.4 mg, Vit.C 50 mg, Vit.A 3000 IUA, VitaminD3 400 IU. In each of 0.6 ml dose.

3- Pharmaceutical form

4- A yellow to orange oral drops solution which darkens upon storage.

4.1- Therapeutic indications

Chemilife drops is indicated for the prevention of vitamin deficiencies and maintenance of normal growth and health during early years of infancy and childhood .

4.2- Posology and method of administration Adults and children over 12 years

Not appropriate

Chidren 1-11 years

Oral one 0.6 ml dose taken daily

Maximum daily dose 0.6 ml.

Children under 1 year

Oral 0.3 ml dose taken daily.

Maximum daily dose

0.3 ml daily

4.3- Contraindications

Chemilife drop is contraindicated in the individuals with known hypersensitivity to the product or any of its component.

4.4- Special warnings and precautions

When prescribing Chemilife drops as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources.

While children taking Chemilife drops no other vitamin supplements containing vitamin A & D should be taken unless under medical supervision.

Excess dosages of Vitamin A & D may lead to hypervitaminosis. Due to allowance should always be made to intake of these vitamins from other sources.

4.5- Interactions with other medicinal products .

None

4.6- Pregnancy & lactation

Not indicated

4.7- Effects on drive and machine operations

Not known

4.8- Vitamin A- Adverse effects are extremely rare at daily doses less than 15 mg

Vitamin D2 – The only known adverse effect of vitamin D occurs when excessive doses are taken.

Ascorbic acid, Nicotinamide, Pyridoxine, Riboflavin and Thiamine

These water-soluble vitamins are generally non-toxic compounds with wide range of safety. The excess amount being rapidly excreted in the urine. Adverse effects are not anticipated at the quantities present in Chemilife drop.

4.9- Overdose

Chemilife drops contains levels of vitamins which present little risk in overdosage.

Vitamin A

Acute administration of high doses of vitamin A can cause headache , nausea and vomiting. In infants' acute toxicity can lead to transient hydrocephalus. All these effects disappear within 24 hours of taking retinol.

Vitamin D2

Excessive doses of vitamin D, 60,000 units per day can result in hypercalcemia and hypercalciuria.

Vitamin B1

When taken orally, thiamine in nontoxic , If large doses are indigested they are not stored by the body but excreted unchanged by the kidneys.

Vitamin B2

Riboflavin has been found non – toxic.

Vitamin B6

Acute doses less than 500 mg per day appear to be safe. Excessive doses may lower serum folate concentrations. Sensory neuropathy has been described with chronic dosing of 200 mg daily.

Nicotinamide

A single large overdose of nicotinamide is unlikely to have serious ill; effects.

Ascorbic Acid (Vitamin C)

Ascorbic acid is not stored to a great extent by the body any excess amounts are eliminated in the urine. Ascorbic acid is thought to become toxic at the chronic dose in excess of 6 g.

5- Pharmacological properties

5.1- Pharmacodynamic properties

Vitamin A

Vitamin A plays an important role in the function of the retina, the growth and function of epithelial tissue, bone growth, reproduction and embryonic development.

Vitamin D 2-

Vitamin D is a regulator of both carbohydrate and phosphate homeostasis

Thiamine HCL (Vitamin B1)

Vitamin B 1 is essential for proper carbohydrate metabolism and play essential role is decarboxylation of alpha keto acids.

Riboflavin (B2)

Riboflavin is essential for the utilization of energy from the food. It is a component of co-enzymes which plays an essential role in oxidative / reductive metabolic reactions.

Pyridoxine HCL (B6)

Vitamin B6 is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate , both play and important role in protein metabolism.

Nicotinamide

Nicotinamide is an essential component of co-enzymes responsible for proper tissue repair.

Ascorbic acid (Vitamin C)

Ascorbic acid is a water-soluble vitamin and powerful anti-oxidant.

It is a co factor in numerous biological processes such as metabolism of folic acid , amino acid oxidation and the absorption and transport of iron.

5.2- Pharmacokinetics properties

Absorption

Vitamin A, B1, B2, B6, C D AND Nicotinamide are well absorbed from the GI Tract.

Distribution

The vitamins present in Chemi life drops are widely distributed to all the tissue in the body.

Metabolism & Elimination

Vitamin A

Vitamin A is hydrolyzed in the essential lumen to retinol which is then absorbed. Retinol circulates in the blood bound to retinol binding protein which protects it from glomerular filtration. The complex circulates in the targeted tissues where the vitamin is released, permeates the cells and binds intracellularly to cellular retinol binding protein . On this absorbed retinol 20-50 % is either conjugated or oxidized to various products and excreted over a matter of days in the urine and feces, while the reminder is stored. This stored retinol is gradually metabolized by the liver and peripheral tissues.

Vitamin D 2

Vitamin D circulates in the blood associated with vitamin D binding protein. It is stored in fat deposits.

Thiamine HCL (B1)

Thiamine has a plasma half-life of 24 hours and is not stored to any great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamins or as the metabolize pyrimidine.

Riboflavin (B2)

Following absorption riboflavin is converted into the co-enzymes, flavin mononucleotide and flavin adenine dinucleotide.

Riboflavin is not stored in body tissues to any target extent and amount in excess of the body’s requirements are excreted in the urine largely unchanged .

Pyridoxine HCL (Vitamin B6)

The half-life of pyroxidne tanges from 15-20 days . Once absorbed vitamin B6 is converted to it's active co-enzyme form pyrixidal 5 phosphate. Muscles in the major storage site for pyroxidal 5- phosphate ,It is degraded in the liver to 4- pyridoxic acid which is eliminated by the kidneys .

Nicotinamide

Nicotinamide is readily taken up into the tissues and utilized for the synthesis of the co-enzyme forms nicotinamide adenine Di nuclide and nicotidine senone Di nuclide phosphate , Nicotidine is degraded in the liver and other organs to a number of products that are excreted.

Ascorbic acid (Vitamin C)

Ascorbic acid reaches a maximum plasma concentration 4 hours following oral administration after which there is rapid urinary excretion. Following the oral administration 60% of the dose is excreted in 24 hours either as ascorbic acid or its metabolite dehydroascorbic acid.

Pharmacokinetics & Renal impairment

There have been no specific studies of Chemilife drops in renal impairment.

5.3- Preclinical safety data

There is insuffient information to determine the mutagenic potential of the active ingredients, however very large doses of Vitamin C are claimed to be mutagenic.

6- Pharmaceutical particulars

6.1- List of excipients

Sugar

Sodium hydroxide

Sorbitol

Glycerine

Pine apple flavour

Orange flavour

Coliur sunset yellow.

6.2-Shelf life

18 months from date of manufacturing

Once opened use within 4 weeks.

6.3- Special precaution for storage

Do not store above 25-degree C.

6.4- Nature and contents of the container

Chemilife drops are presented in an amber type III 15 ml glass bottle with ROPP aluminum caps.

7- Marketing Authorization holder

Chemiron care ltd.
Plot C21/3, Anioma road
Agbara Industrail Estate , Ogun state , Nigeria.

8. Manufacture

JAWA INTERNATIONAL LTD., JAWA HOUSE,
PLOT 6 ABIMBOLA WAY , ISOLO INDUSTRIAL ESTATE,
ISOLO, LAGOS, NIGERIA .