SUMMARY PRODUCT CHARACTERISTICS

PRODUCT NAME: MULTIDEX SYRUP (Multivitamin syrup)	
SUMMARY PRODUCT CHARACTERISTICS (SPC)	

1. Name of the medicinal product
MULTIDEX SYRUP (Multivitamin syrup)

2. Quantitative composition
Each 5ml contains:

Vitamin A (as palmitate)	2500I.U.
Vitamin B1	1.5mg
Vitamin B2	1.5mg
Vitamin B6	1.0mg
Vitamin C	25mg
Nicotinamide	10mg
Flavoured syrupy base	q.s.

(Overages of vitamins added to compensate for loss on storage)

3. Pharmaceutical form
Syrup

4. Clinical particulars
4.1 Therapeutic indications
Multivitamin syrup is indicated for the prevention of vitamin deficiencies and for the maintenance of normal growth and health during the early years of infancy and childhood; multivitamin supplement.

4.2 Posology and method of administration
Posology
Children upto 2yrs. old: ½ teaspoonful daily
Children over 2yrs. old: 1 teaspoonful daily
Adults: 1 to 2 teaspoonful daily.
Method of administration
For oral administration.

4.3 Contraindications
Multivitamin syrup is contraindicated in individuals with known hypersensitivity to the product or any of its component including peanut oil.
Multivitamin syrup contain Arachis oil (peanut oil) and should not be taken by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Multivitamin syrup.

4.4 Special warnings and precautions for use
When Prescribing Multivalent syrup, as with all multi-vitamin preparation, allowance should be made for vitamins obtained from other source.
While children are taking Multivitamin syrup no other vitamin supplement containing vitamin A and D should be taken unless under medical supervision.
This Multivitamin syrup should not given to babies who are receiving more than 500mls of formula milk per day to avoid exceeding safe upper limit of Vitamin A.
Excessive dosage of vitamin A and D may lead to hypervitaminoses. Due allowance shloud always be made for intake of these vitamins fom other sources.
Patients with rare heredity problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicibe.

4.5 Interaction with other medicinal products and other forms of interaction: None

4.6 Fertility,pregnancy and lactation: Not indicated

4.7 Effects on ability to drive and use machines: Not known

4.8 Undesirable effects

Vitamin A palmitate: Adverse effects are extremely rare at daily doses of less than 9mg (16363.6 IU) .

Ascorbic acid (C), Nicotinamide, Pyridoxine(B6), Riboflavin(B2)&Thiamine(B1): These water soluble vitamins are generally non toxic compounds with wide margin of safety , the excess amount being rapidly excreted in the urine. Advese effects are not anticipated at the quantities present in Multivitamin syrup.

4.9 Overdose

a) Symptoms and sign: Multivitamin syrup contains levels of vitamin which present little risk in overdose.

Vitamin A: acute administration of high doses of vitamin A can cause headache, nausea,vomiting and irritability.

Vitamin B1: when taken orally, thiamine is non toxic . If large doses are ingested they are not stored by the but excreted unchanged by the kidneys.

Vitamin B2: Riboflavin has been found to practically be non toxic.

Vitamin B6: Acute doses less than 500mg per day appear to be safe. Excessive doses may lower serum folate concentration. Sensory neuropathy has been described with chronic dosing of 200mg daily

Nicotinamide: A single large overdose of nicotinamide is unlikely to have serious ill effects, though transient abnormalities of liver function might occur.

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

Treatment: Treatment should be supportive and symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

Vitamin B1: It is essential for proper carbohydrate metabolism and plays an essential role in the which plays in decarboxylation of alpha keto acid.

Vitamin B1: Riboflavin is essential role for utilisation of energy from food . It is component of co-enzymes which plays an essential role in oxidative/reductive metabolic reaction. Riboflavin is also necessary for the functioning of pyridoxine and nicotinic acid.

Vitamin B6: Vitamin B6 is constituent of co-emzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play important role in protein metabolism.

Nicotinamide: It is essential component to co-enzymes responsible for proper tissue respiration .

Vitamin C : Ascorbic acid is water soluble vitamin and powerful antidoxidant.

5.2 Pharmacokinetic properties.

Absorption: Vitamin A,B1,B2,B6 ,C,D and Nicotinamide are well absorbed from the gasro-intestinal tract.
Distribution: The vitamin present in Multivitamin syrup are widely distributed to all tissues in the body.
Metabolism and elimination
Vitamin A: It is hydrolysed in the intestinl lumen to retinol which is then absorbed. Retinol circulates in the blood bound to retinol binding protein which protects it from glomerular filtration.
Vitamin B1: Thiamine has plasma half life of 24 hours and is not stored to any in great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamin or as the metabolite, pyrimidine.
Vitamin B2: Following absorption Riboflavin is converte into co-enzyme: flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). Riboflavin is not stored in body tissues to any great extent and amounts in excess of the body's requirements are excreted in the urine largely unchanged.
Vitamin B6: The half life of pyridoxine ranges from 15-20 days. Once absorbed vitamin B6 converted to its active co-enzyme from pyridoxal 5- phosphate. Muscle is major storage site for pyridoxal 5-phosphate.
Nicotinamide: It is readily taken up into tissues and utilised for the synthesis of co-enzyme forms nicotinamide adenine dinucleotide (NAD) and adenine adenine dinucleotide phosphate (NADP).
Vitamin C: Ascorbic acid reaches a maximum plasma concentration 4 hours following oral administration after which there is rapid urinary excretion . Following oral administration 60% of dose is excreted in 24 hours either as ascorbic acid or its metabolite dihydroascorbic acid.

5.3 Preclinical safety data
Not available.

6. Pharmaceutical particulars

6.1 Incompatibilities
Not Applicable

6.2 Shelf life
2 years
6.3 Special precautions for storage
Store below 30°C. Protect from light and moisture.

6.4 Nature and contents of container
60ml and 100ml.

6.5 Special precautions for disposal and other handling:
Store in dry place below 30°C. Protect from light. Maintain this medication in well closed container.

7. Manufactured By:
Zain pharma limited
Plot No: 209/13741
Colchester Park'

Godown No.1,2,3
P.O. box:1000167-00101

9. Date of revision of the text

September 2020