SUMMARY OF PRODUCT CHARACTERIZATION (SMPC) FOR JESSY MULTIVITAMIN TABLET

1. Name of the medicinal product

Jessy Multivitamin Tablets

Multivitamins & Minerals Tablets

2. Qualitative and quantitative composition

Each tablet contains

Vitamin A..... 2500IU

Vitamin D3 ..... 250IU

Vitamin B1..... 600mcg

Vitamin C 13000mcg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet

4. Clinical particulars

4.1 Therapeutic indications

This product is a combination of vitamins used to prevent vitamin deficiency due to poor diet, certain illnesses, alcoholism, or during pregnancy and also to replenish vitamin post infection and post antibiotic therapy Vitamins are important building blocks of the body and help keep you in good health.

Each Tablet contains the following essential vitamins,; Vitamin A, Vitamin D3, Vitamin B1, and Vitamin C which plays a vital role in the efficient daily maintenance of many body processes:

4.2 Posology and method of administration

One Tablet to be taken daily or as directed by the physician

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special warnings and precautions for use

Whilst taking Jessy multivitamin Tablet both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

Do not take Jessy Multivitamin Tablet on an empty stomach.

Do not exceed the stated dose.

Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Not stated.

4.6 Pregnancy and lactation

Jessy Multivitamin Tablet may be administered during pregnancy and lactation at the recommendation of the physician.

4.7 Effects on ability to drive and use machines

None anticipated.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common: ≥ 1/10

Common: ≥ 1/100 to <1/10

Uncommon: ≥ 1/1,000 to <1/100

Rare: ≥ 1/10,000 to <1/1,000

Very rare: <1/10,000

Not known: cannot be estimated from the available data

Immune system disorders	Not known: Hypersensitivity reaction (such as rash)
Gastrointestinal disorders	Not known: Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

4.9 Overdose

No cases of overdosage due to Jessy Multivitamin Tablet therapy have been reported.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The following account summarises the pharmacological effects of the vitamins in Jessy Multivitamin Tablet and describes the conditions caused by deficiency of these.

Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes. Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

Vitamin D

Vitamin D is required for the absorption of calcium and phosphate from the gastro-intestinal tract and for their transport. Its involvement in the control of calcium metabolism and hence the normal calcification of bones is well documented. Deficiency of Vitamin D in children may result in the development of rickets.

Vitamin B_1 (Thiamine)

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

Vitamin C (Ascorbic Acid)

Vitamin C cannot be synthesised by man therefore a dietary source is necessary. It acts as a cofactor in numerous biological processes including the hydroxylation of proline to hydroxyproline. In deficiency, the formation of collagen is, therefore, impaired. Ascorbic acid is important in the hydroxylation of dopamine to noradrenaline and in hydroxylations occurring in steroid synthesis in the adrenals. It is a reducing agent in tyrosine metabolism and by acting as an electron donor in the conversion of folic acid to tetrahydrofolic acid is indirectly involved in the synthesis of purine and thymine. Vitamin C is also necessary for

the incorporation of iron into ferritin. Vitamin C increases the phagocytic function of leucocytes; it possesses anti-inflammatory activity and it promotes wound healing. Deficiency can produce scurvy. Features include swollen inflamed gums, petechial haemorrhages and subcutaneous bruising. The deficiency of collagen leads to development of thin watery ground substances in which blood vessels are insecurely fixed and readily ruptured. The supportive components of bone and cartilage are also deficient causing bones to fracture easily and teeth to become loose. Anaemia commonly occurs probably due to Vitamin C's role in iron metabolism.

5.2 Pharmacokinetic properties

The following account describes the absorption and fate of each of the active constituents of Jessy Multivitamin Tablet.

Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed. β -carotene (as in Jessy Multivitamin Tablet Tablet) is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

Vitamin D

The metabolism of ergocalciferol is similar to that of cholecalciferol. Cholecalciferol is absorbed from the gastro-intestinal tract into the circulation. In the liver, it is hydroxylated to 25-hydroxycholecalciferol, is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

Vitamin B_1 (Thiamine)

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

Vitamin C (Ascorbic Acid)

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose

Maize starch

Talc powder

PVP k30

Aerosil

6.2 Incompatibilities

No major incompatibilities are known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C. Protect from direct sunlight. Keep all medicines out of reach of children.

6.5 Nature and contents of container

HDPE white Jars and caps

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

Jessy Pharmaceutical company Limited

13B Acme Road Ogbaegbe Industrial,

Estate Ikeja Lagos Nigeria.

Manufactured by:

Daily Sun Pharmaceutical company Limited

Plot 3 & 4 Tomori industrial estate, off Idiroko road,

Ota Ogun State Nigeria.