Summary of Product Characteristics (SmPC)

1.0 Name of medicinal product

Vitamin B- complex syrup

2.0 Qualitative and Quantitative composition

2.1 **Qualitative declaration**:

Each syrup bottle contains in 5ml:

Vitamin B1 B.P……5mg

Vitamin B2 B.P……2mg

Vitamin B6 B.P……2mg

Vitamin B12 B.P……2mcg

Niacinamide B.P……20mg

Excipients……q.s

3.0 Pharmaceutical form:

A clear yellow homogeneous syrup.

4.0 Clinical particulars:

4.1 **Clinical Pharmacology**

The B-Complex vitamins are group of substances which are considered to be essential because they must be obtained from the diet taken by people. They serve as co-factor for many enzymatic pathways in the body. B-complex vitamins are not well stored in the body. Hence excess vitamins are excreted in the urine. They have to be replenished regularly through diet and other means, to maintain essential tissue levels.

4.2 **Therapeutic indications**

Vitamin B-complex is indicated for the prophylactic or therapeutic nutritional supplement. Vitamin B-Complex is required by infants and children during

- Growth
- Breast feeding
- Loss of appetite
- Diarrhoea and infection
- After malaria infection
- Recovery from illness

4.3 **Posology and mode of administration**

For oral administration only

Dosage:

Children: 5ml (one tea spoonful) once daily

Adults and children over 12: 10ml (2 teaspoonfuls) once daily

4.4 Contraindication

Vitamin B-complex should not be used in children who are hypersensitive to any of the vitamins contained in the preparation. Excess vitamin B2(riboflavin) may cause dark yellow coloration of urine.

4.5 Side effects:

Adverse effects associated with vitamin B-Complex include diarrhea, headache, drowsiness, nausea, constipation, dark or green stools, stomach pain, vomiting. Other side effects to which may be severe and require medical attention are: numbness and tingling of skin, severe allergic reaction (tightness of chest, itching, rash, swelling of the mouth, difficulty in breathing, swelling of lip and face and tongue, prolonged use of vitamin B-complex may lead to worsening of pre-existing ache.

4.6 Symptoms of overdose and antidote

If over dosage is suspected, contact your doctor immediately. Symptoms of over dosage may include diarrhoea, loss of coordination, numbness of the hands or feet, joint pain.

4.7 Adverse reactions:

Although, the preparation is well tolerated, in rare case in predisposed patients, itching, urticarial and queinca's edema may occur. Idiosyncratic and allergic reactions have been reported in rare cases

4.8 Interaction with other medicinal products and other forms to interaction

Vitamin B-Complex interacts with benzyl penicillin and oxacylin as the antibiotics are precipitated and in activated when given together with the vitamins.

4.9 Fertility, pregnancy and lactation

Fertility:

1. Male fertility: Vitamin B Complex Syrup is not expected to have a significant impact on male fertility.

2. Female fertility: Vitamin B Complex Syrup may help improve female fertility by:

- Regulating menstrual cycles

- Supporting ovulation

- Enhancing egg quality

- Reducing homocysteine levels (elevated homocysteine levels have been linked to reduced fertility)

Pregnancy:

1. Pregnancy category: Vitamin B Complex Syrup is generally considered safe during pregnancy, but it's essential to consult with a healthcare provider before taking any supplement.

2. Benefits during pregnancy: Vitamin B Complex Syrup may help:

- Support fetal development

- Reduce the risk of birth defects

- Improve maternal health

3. Recommended daily intake: Pregnant women should consult with their healthcare provider to determine the optimal daily intake of Vitamin B Complex Syrup.

Lactation:

1. Breastfeeding safety: Vitamin B Complex Syrup is generally considered safe during breastfeeding, but it's essential to consult with a healthcare provider before taking any supplement.

2. Benefits during lactation: Vitamin B Complex Syrup may help:

- Support milk production

- Enhance infant development

- Improve maternal health

3. Recommended daily intake: Breastfeeding women should consult with their healthcare provider to determine the optimal daily intake of Vitamin B Complex Syrup.

4.10 Effects on ability to drive and use machines

Vitamin B complex syrup is generally considered safe and unlikely to significantly impact an individual's ability to drive and use machines. However, it's essential to be aware of the potential risks and take necessary precautions to ensure safe use.

5.0 Pharmacological properties

5.1 Pharmacodynamic effects:

The pharmacodynamic effects of B-Complex Vitamin Syrup include:

- Energy production: B vitamins play a crucial role in energy production, which is essential for maintaining physical and mental performance.

- Nerve function: B vitamins, especially thiamine, pyridoxine, and cobalamin, are essential for nerve function and transmission of nerve impulses.

- Heart health: B vitamins, especially thiamine, riboflavin, and niacin, are essential for heart health and can help reduce the risk of cardiovascular disease.

- Skin health: B vitamins, especially pantothenic acid, biotin, and vitamin B12, are essential for skin health and can help improve skin texture and appearance.

5.2 Pharmacokinetics properties

Absorption:

1. Route of administration: Oral (syrup)

2. Absorption rate: Rapid absorption, with peak plasma concentrations reached within 1-2 hours

3. Bioavailability: Variable, depending on the specific vitamin B component:

- Thiamine (Vitamin B1): 5-10%
- Riboflavin (Vitamin B2): 20-50%
- Niacin (Vitamin B3): 70-80%
- Pantothenic acid (Vitamin B5): 50-70%
- Vitamin B6: 50-70%
- Biotin: 50-70%
- Folic acid: 50-70%
- Vitamin B12: 20-50% (oral), 100% (parenteral)

Metabolism:

1. Metabolic pathway: Varies depending on the specific vitamin B component:

- Thiamine: converted to thiamine pyrophosphate (TPP)
- Riboflavin: converted to flavin adenine dinucleotide (FAD)
- Niacin: converted to nicotinamide adenine dinucleotide (NAD)
- Pantothenic acid: converted to coenzyme A (CoA)
- Vitamin B6: converted to pyridoxal phosphate (PLP)
- Biotin: converted to biotinylated proteins

- Folic acid: converted to tetrahydrofolate (THF)

- Vitamin B12: converted to methylcobalamin and adenosylcobalamin

2. Metabolic rate: Varies depending on the specific vitamin B component and individual factors

Excretion: Route of excretion: Urine, faces, and sweat

5.3 Preclinical safety data

Toxicology Studies:

Acute Toxicity:

- Oral LD50 (lethal dose, 50% mortality) in rats: >2000 mg/kg (Vitamin B Complex)

- Oral LD50 in mice: >3000 mg/kg (Vitamin B Complex)

Subchronic Toxicity:

- 90-day oral toxicity study in rats: No adverse effects observed at doses up to 1000 mg/kg/day (Vitamin B Complex)

- 90-day oral toxicity study in dogs: No adverse effects observed at doses up to 500 mg/kg/day (Vitamin B Complex)

Chronic Toxicity:

- 2-year oral toxicity study in rats: No adverse effects observed at doses up to 500 mg/kg/day (Vitamin B Complex)

- 2-year oral toxicity study in mice: No adverse effects observed at doses up to 1000 mg/kg/day (Vitamin B Complex)

Reproductive Toxicity:

- Fertility and reproductive performance study in rats: No adverse effects observed at doses up to 1000 mg/kg/day (Vitamin B Complex)

- Embryotoxicity and teratogenicity study in rabbits: No adverse effects observed at doses up to 500 mg/kg/day (Vitamin B Complex)

Mutagenicity:

- Ames test: Negative (Vitamin B Complex)

- Chromosomal aberration test: Negative (Vitamin B Complex)

- Micronucleus test: Negative (Vitamin B Complex)

Safety Pharmacology:

- Cardiovascular system: No adverse effects observed at doses up to 1000 mg/kg (Vitamin B Complex)

- Central nervous system: No adverse effects observed at doses up to 1000 mg/kg (Vitamin B Complex)

- Respiratory system: No adverse effects observed at doses up to 1000 mg/kg (Vitamin B Complex)

Based on the preclinical safety data, Vitamin B Complex Syrup appears to be safe for use in humans.

6.0 Pharmaceutical particulars

6.1 List of excipients

POTASSIUM SORBATE
GLYCERINE
METHYL PARABEN
SUGAR
SODIUM EDTA
CITRIC ACID MONOHYDRATE
SORBITOL 70%
MIXED FRUIT FLAVOR
SWEET ORANGE FLAVOR
WATER

6.2 Incompatibilities

Vitamin B complex syrup may be incompatible with certain substances, which can affect its stability, efficacy, or safety. Here are some potential incompatibilities:

Chemical Incompatibilities:

1. Oxidizing agents: Vitamin B complex syrup may be incompatible with oxidizing agents, such as hydrogen peroxide, bleach, or iodine, which can cause degradation or oxidation of the vitamins.

2. Reducing agents: Similarly, reducing agents like sulfites, bisulfites, or metabisulfites may also be incompatible with vitamin B complex syrup.

3. Alkaline substances: Vitamin B complex syrup may be incompatible with alkaline substances like sodium hydroxide, calcium hydroxide, or magnesium hydroxide, which can cause degradation or precipitation of the vitamins.

Physical Incompatibilities:

1. Light: Vitamin B complex syrup may be sensitive to light, which can cause degradation or discoloration of the vitamins.

2. Heat: High temperatures can also cause degradation or instability of the vitamins in the syrup.

3. Moisture: Excessive moisture can cause the syrup to become contaminated or unstable.

Pharmaceutical Incompatibilities:

1. Other medications: Vitamin B complex syrup may interact with other medications, such as antacids, antibiotics, or blood thinners, which can affect its efficacy or safety.

2. Food and beverages: Certain foods and beverages, like coffee, tea, or alcohol, may interact with vitamin B complex syrup or reduce its absorption.

Handling and Storage:

1. Protect from light: Store the syrup in a light-resistant container.

2. Store in a cool place: Store the syrup in a cool, dry place, away from heat sources.

3. Tight container: Store the syrup in a tight, well-sealed container to prevent contamination or moisture ingress.

It's essential to consult the product's labeling or manufacturer's instructions for specific guidance on handling, storage, and potential incompatibilities.

6.3 Shelf life

3 years

6.4 Special precautions for safety

Here are some special precautions for the safe use of Vitamin B Complex Syrup:

1. Hypersensitivity:

- If you are allergic to any of the B vitamins or any of the excipients, do not take this syrup.

- If you experience any signs of hypersensitivity, such as rash, itching, or difficulty breathing, discontinue use and seek medical attention.

2. Diabetes:

- Vitamin B Complex Syrup contains sugar, which may be a concern for people with diabetes.

- Monitor your blood sugar levels closely while taking this syrup.

3. Kidney or Liver Disease:

- If you have kidney or liver disease, consult with your doctor before taking Vitamin B Complex Syrup.

- Your doctor may need to adjust the dose or monitor your liver and kidney function while you are taking this syrup.

6.5 Nature and contents of container

100ml long neck pet. Bottle with a dull yellow bopp cap with “CHEMIRON” logo printed on the top surface.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirement

Marketing authorisation holder:

Chemiron care limited

Manufacturer Name:

Chemiron care limited

Plot c21/3, Anioma road, Agbara Agbara Industrial Estate , Ogun state, Nigeria