Summary of Product Characteristics (SmPC)

1.0 Name of Medicinal Product

Vitamin C syrup

2.0 Qualitative and Quantitative composition

2.1 Qualitative declaration:

Each suspension bottle contains in 5ml:

Sodium Ascorbate…….100mg

3.0 Pharmaceutical form:

A golden yellow syrupy homogenous clear liquid.

4.0 Clinical particulars:

4.1 Clinical pharmacology

Vitamin C syrup, also known as ascorbic acid syrup, is a dietary supplement that provides a concentrated dose of vitamin C.

Mechanism of Action

Vitamin C is a water-soluble vitamin that plays a crucial role in various bodily functions, including:

1. Antioxidant activity: Vitamin C neutralizes free radicals, which can damage cells and contribute to chronic diseases.

2. Collagen synthesis: Vitamin C is essential for the production of collagen, a protein that gives structure to skin, bones, and connective tissue.

3. Iron absorption: Vitamin C enhances the absorption of iron from plant-based sources.

4. Immune function: Vitamin C supports immune function by promoting the production of white blood cells and activating natural killer cells.

4.2 Therapeutic indications

Chemiron's Vitamin C syrup is a power antioxidant which protects the body's cells from damage and helps to maintain proper immune function. It is also effective in:

- Fighting the common cold

- Preventing and treating scurvy
- Promoting wound and fracture healing
- Providing dietary supplementation of Vitamin C in children for grow and development

4.3 Posology and mode of administration

For oral administration only

Dosage

unless otherwise directed by a physician:

1 year -11 years:

2.5ml (half teaspoonful) twice daily

Adults and children over 12 years:

5ml (one teaspoonful) twice daily

4.4 Contra-indications:

Vitamin C syrup is generally considered safe for most individuals. However, there are certain conditions and situations where it may be contraindicated or should be used with caution:

Contraindications:

1. Severe kidney disease: High doses of vitamin C may worsen kidney function or increase the risk of kidney stones.

2. G6PD deficiency: Vitamin C may trigger hemolysis (red blood cell destruction) in individuals with G6PD deficiency.

3. Hemochromatosis: Vitamin C may increase iron absorption, which can worsen hemochromatosis (a condition characterized by excessive iron accumulation).

4. Kidney stones: High doses of vitamin C may increase the risk of kidney stone formation.

5. Hyperoxaluria: Vitamin C may increase oxalate levels, which can worsen hyperoxaluria (a condition characterized by excessive oxalate accumulation).

Common Side Effects:

Vitamin C syrup is generally considered safe and well-tolerated. However, like any supplement, it can cause some side effects, especially when taken in high doses or for extended periods. Here are some possible side effects of vitamin C syrup:

1. Gastrointestinal upset: Diarrhea, stomach cramps, nausea, and vomiting.

2. Abdominal pain: Mild to moderate abdominal pain or discomfort.

3. Bloating and gas: Increased bloating and gas due to the fermentation of vitamin C in the gut.

4. Headache: Mild to moderate headaches.

5. Fatigue: Feeling tired or sluggish.

Adverse Effects

Common adverse effects of vitamin C syrup include:

1. Gastrointestinal upset: Diarrhea, stomach cramps, and nausea may occur, especially at high doses.

2. Kidney stones: High doses of vitamin C may increase the risk of kidney stone formation.

4.6 Fertility, pregnancy and lactation

Fertility:

1. Sperm quality: Vitamin C may improve sperm quality, motility, and concentration, which can enhance male fertility.

2. Ovulation: Vitamin C may help regulate ovulation and improve egg quality, which can increase the chances of conception.

3. Hormone regulation: Vitamin C may help regulate hormone levels, including estrogen and progesterone, which are essential for fertility.

Pregnancy:

1. Fetal development: Vitamin C is essential for fetal development, particularly for the development of the brain, bones, and connective tissue.

2. Immune system: Vitamin C helps support the immune system during pregnancy, which can reduce the risk of infections and complications.

3. Morning sickness: Vitamin C may help alleviate morning sickness symptoms, such as nausea and vomiting.

4. Pregnancy complications: Vitamin C may help reduce the risk of pregnancy complications, such as preeclampsia and gestational diabetes.

Lactation:

1. Milk production: Vitamin C is essential for milk production and can help support lactation.

2. Infant development: Vitamin C in breast milk can help support infant development, particularly for the development of the immune system.

3. Maternal health: Vitamin C can help support maternal health during lactation, particularly for reducing the risk of infections and complications.

4.7 Effects on ability to drive and use machines

Vitamin C is generally considered safe and does not typically impair the ability to drive or use machines. However, it's essential to consider the following factors:

Factors to Consider:

1. Dose and formulation: High doses of vitamin C (>2,000 mg/day) may cause gastrointestinal side effects like diarrhea, stomach cramps, or nausea, which could potentially impair driving or machine operation.

2. Individual tolerance: Some individuals may be more sensitive to vitamin C's effects, which could impact their ability to drive or use machines.

3. Interactions with medications: Vitamin C may interact with certain medications, such as blood thinners, which could increase the risk of bleeding or other adverse effects.

4. Underlying medical conditions: Certain medical conditions, such as kidney disease or diabetes, may require caution when taking vitamin C supplements.

Effects on Driving and Machine Operation:

1. No significant impairment: Vitamin C is unlikely to significantly impair driving or machine operation in most individuals.

2. Potential for mild impairment: High doses or individual sensitivity may cause mild impairment, such as dizziness or nausea, which could affect driving or machine operation.

5.0 Pharmacological properties

5.1 Pharmacodynamics properties

The therapeutic effects of vitamin C syrup include:

1. Treating scurvy: Vitamin C is essential for preventing and treating scurvy, a disease caused by vitamin C deficiency.

2. Boosting immune function: Vitamin C supports immune function, which can help reduce the severity and duration of illnesses like the common cold.

3. Antioxidant effects: Vitamin C's antioxidant properties can help protect cells from damage caused by free radicals.

5.2 Pharmacokinetics properties

After oral administration, vitamin C is:

1. Rapidly absorbed: Vitamin C is absorbed quickly from the gastrointestinal tract, with peak plasma concentrations reached within 2-3 hours.

2. Distributed widely: Vitamin C is distributed throughout the body, with high concentrations found in the liver, kidneys, and adrenal glands.

3. Excreted in urine: Vitamin C is excreted in the urine, with a small amount excreted in the feces.

5.3 Preclinical safety data

Pre-clinical safety data for vitamin C syrup is limited. According to various sources, including the NAFDAC Greenbook Admin, there is no specific pre-clinical safety data available for several vitamin C syrup products.[1]

6.0 Pharmaceutical particulars

6.1 List of excipients

XANTHAN GUM
SODIUM CITRATE
SUGAR
SORBITOL 70%
CITRIC ACID
GLYCERIN
BENZOIC ACID
POTASSIUM SORBATE
COLOR FD&C YELLOW
ORANGE FLAVOR
WATER

6.2 Incompatibilities

Vitamin C 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 C syrup may be incompatible with oxidizing agents, such as hydrogen peroxide, bleach, or iodine.

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

3. Alkaline substances: Vitamin C syrup may be incompatible with alkaline substances like sodium hydroxide, calcium hydroxide, or magnesium hydroxide.

Physical Incompatibilities:

1. Light: Vitamin C syrup may be sensitive to light, which can cause degradation or discoloration.

2. Heat: High temperatures can 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 C syrup may interact with other medications, such as blood thinners, and affect their efficacy or safety.

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

6.3 Shelf life

3 years

6.4 Special precautions for safety

General Precautions:

1. Allergic reactions: Monitor for signs of allergic reactions, such as hives, itching, or difficulty breathing.

2. Gastrointestinal upset: Vitamin C syrup may cause stomach upset, nausea, or diarrhea, especially when taken in high doses.

3. Interactions with medications: Consult with a healthcare professional before taking vitamin C syrup, especially if you're taking medications like blood thinners, diabetes medications, or certain antibiotics.

Specific Precautions:

1. Kidney stones: High doses of vitamin C may increase the risk of kidney stone formation. Individuals with a history of kidney stones should consult with a healthcare professional.

2. G6PD deficiency: Vitamin C may cause hemolysis in individuals with G6PD deficiency. Consult with a healthcare professional before taking vitamin C syrup.

3. Pregnancy and lactation: While vitamin C is generally considered safe during pregnancy and lactation, high doses may cause adverse effects. Consult with a healthcare professional before taking vitamin C syrup.

4. Pediatric use: Vitamin C syrup is generally considered safe for pediatric use, but consult with a healthcare professional before administering to children.

Handling and Storage Precautions:

1. Protect from light: Store vitamin C syrup in a light-resistant container to prevent degradation.

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

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

Overdose Precautions:

1. Seek medical attention: In case of overdose, seek medical attention immediately.

2. Symptoms of overdose: Watch for symptoms of overdose, such as diarrhea, stomach cramps, and nausea.

6.5 Nature and contents of container

100ml Bottle with a dull yellow Ropp cap with “CHEMIRON” logo printed on the top surface.

6.6 Special precautions for disposal and other handling

Disposal

1. Medicine take-back programs: Check with your local authorities or pharmacies to see if they have a medicine take-back program.

2. Dispose of in trash: If a take-back program is not available, dispose of the suspension in the trash by:

- Removing any personal information from the packaging.
- Mixing the suspension with an undesirable substance.
- Placing the mixture in a sealed container or plastic bag.

3. Do not flush: Do not flush the suspension down the toilet or pour it down the drain.

Handling:

1. Keep out of reach of children: Store the suspension in a secure location, out of reach of children and pets.

2. Avoid contamination: Avoid contaminating the suspension by touching the dropper or bottle cap with your hands or other surfaces.

3. Clean and dry equipment: Clean and dry any equipment used to administer the suspension.

4. Labelling and packaging: Ensure that the suspension is properly labelled and packaged to avoid mix-ups or confusion.

Marketing authorisation holder:

Chemiron care limited

Manufacturer Name:

Chemiron care limited

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