Summary of Product Characteristics (SPC)

1. NAME OF THE MEDICINAL PRODUCT

PYRIDOX(Sulfadoxine & Pyrimethamine Tablets USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Quantity per tablet in mg
Sulfadoxine USP	500.0
Pyrimethamine USP	25.0
Maize Starch BP	54.58
Gelatin BP	3.0
Methyl hydroxybenzoate BP	0.4
Propyl hydroxybenzoate BP	0.065
Purified Talc BP	2.0
Magnesium Stearate BP	4.0
Microcrystalline cellulose BP	3.0
Sodium Starch Glycollate BP	10.0
Colloidal Anhydrous Silica BP	2.0

Note: BP = British Pharmacopoeia Edition
USP = United States Pharmacopoeia Edition

3. PHARMACEUTICAL FORM

Tablets (Oral)

White, circular, Flat face bevelled edge uncoated tablets plain on both side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PYRIDOX is indicated for the treatment of chloroquine-resistant malaria.

4.2 Dosage and Direction for Use

For the treatment: Adults: Take 2-3 tablets orally as a single dose.

Children (age > 2 months to 18 years):

The dose-dependent on the bodyweight is as follows:

Weight in kg	Number of tablets to be taken as a single dose
> 45	3
31-45	2

21-30	1 ½ (one and half)
11-20	1
5-10	½ (half)

For the prevention: Adults: One tablet once weekly; 2 tablets once every 2 weeks.

Take the first dose of PYRIDOX Tablets 1 or 2 days before going to areas where chloroquine-resistant Plasmodium falciparum malaria is common. PYRIDOX Tablets should be continued during the stay at the respective area and for 4 to 6 weeks after return.

Children (age > 2 months to 18 years): The dose-dependent on the bodyweight is as follows:

Weight in Kg	Number of tablets taken once weekly
> 45	1 ½
31-45	1
21-30	¾
11-20	½
5-10	¼

Take 3 tablets as early as possible after the completion of the 3-months of pregnancy.

It should be taken in the presence of the health care provider.

It should not be given during the first 3-months of pregnancy and to women taking cotrimoxazole.

PYRIDOX Tablets can be given either on an empty stomach or with food.

4.3 Contraindications

Do not use PYRIDOX Tablets in the following conditions:

• An allergy to any of the constituents of PYRIDOX Tablets,

• Impaired function of kidney and liver,

• Diseases affecting blood cells and platelets,

• Decreased haemoglobin level in blood due to deficiency of folic acid,

• Children < 2 months,

• In pregnancy at term and breast-feeding women.

4.4 Special warnings and precautions for use

Potentially life-threatening conditions like Stevens-

Johnson syndrome (disorder of the skin and mucous membranes) and toxic epidermal necrolysis (skin disorder) may occur.

PYRIDOX Tablets should be discontinued in the following conditions:

• Appearance of first skin rash,

• Occurrence of bacterial or fungal infections and

• Decreased blood cell count.

PYRIDOX Tablets should be used with care in patients with any of the following

condition:

• Impaired kidney or liver function

• Decrease haemoglobin level due to folic acid deficiency

• Severe allergy and bronchial asthma

• Glucose-6-phosphate dehydrogenase enzyme deficient individuals.

4.5 Interaction with other medicinal products and other forms of interaction

Please tell the health care provider if taking or have recently taken any of the following medicines: chloroquine, sulfonamides, trimethoprim, or trimethoprim-sulfamethoxazole combinations.

4.6 Fertility, Pregnancy and lactation

Ask the health care provider before taking any PYRIDOX Tablets in pregnant and lactating women.

Sulfadoxine should be avoided during the last month of pregnancy.

Folic acid supplementation may be required if PYRIDOX Tablets is given in pregnancy.

4.7 Effects on ability to drive and use machines

No impairment in mental alertness is observed

4.8 Undesirable effects

• It decreases the blood count of red blood cells, white blood cells and platelets. It increases the bleeding tendencies, break down of RBCs and abnormal haemoglobin.

• Various allergic skin reactions like rashes, hives, and itching, allergic reactions on sunlight exposure, swelling of the lips and larynx (voice box), difficulty in breathing, redness of the eye, swelling around eye, swelling of the heart and hair loss.

• Nausea, vomiting, diarrhoea, loss of appetite, indigestion, stomach pain, ulcers of tongue and mouth and increased level of liver enzymes.

• Headache, pain and swelling of nerves, mental depression, fits, impaired coordination of movement, ringing in the ear, impaired balance, fatigue, muscle weakness and nervousness.

• An appearance of blood and protein in the urine, increased level of creatinine and urea in blood and decreased frequency of passing urine.

4.9 Symptoms of Overdosage & Treatment

Acute intoxication may be manifested by headache, nausea, anorexia (loss of appetite), vomiting and central nervous system stimulation (including convulsions). Contact the health care provider immediately and say exactly how many tablets are taken. The health care provider will advise what to do. It is important to contact the health care provider even if you feel well.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Components in PYRIDOX Tablets act on the malarial parasites present in the red blood cells (RBCs). They inhibit enzymes involved in the synthesis of folinic acid (an active form of folic acid) in the malarial parasites and removes the parasite from the blood.

5.2 Pharmacokinetic properties

The peak concentration of sulfadoxine in the plasma (the fluid part of blood) is reached within 4 hours. The peak concentration of pyrimethamine in the plasma is reached within 2.1 - 7.7 hours. Both sulfadoxine and pyrimethamine can enter into the placenta (organ present in the female during pregnancy) and breast milk.

Approximately 90% of both the medicines bind to the protein present in plasma and accordingly lead to a longer duration of action. Both the medicines are expelled out in the urine.

5.3 Preclinical safety data

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP, Gelatin BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Purified Talc BP, Magnesium Stearate BP, Microcrystalline Cellulose BP, Sodium Starch Glycollate BP, Colloidal anhydrous silica BP.

6.2 Incompatibilities

None reported.

6.3 Shelf life

36 months (3 Years)

6.4 Special precautions for storage

Do not store above 30°C. Protect from the sunlight. Keep out of the reach of children.

6.5 Nature and contents of container

Aluminium & PVC blister of 3 tablets. Such single blister packed in an inner carton along with pack insert. 50 such inner cartons are packed in outer carton.

6.6 Special precautions for disposal and other handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF TEXT

Every two years.