AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Brand Name : AGOVIT-6 TABLETS **Generic Name :** PYRIDOXINE TABLETS BP 25 MG	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1. NAME OF DRUG PRODUCT

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. Name of drug product

PYRIDOXINE HYDROCHLORIDE BP 25 MG TABLETS

1.1 (Trade) name of product

AGOVIT-6 TABLETS

1.2 Strength

Each uncoated tablet contains:
Pyridoxine Hydrochloride BP 25 mg

1.3 Pharmaceutical Dosage Form

Uncoated tablets

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2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Each uncoated tablet contains:
Pyridoxine Hydrochloride BP 25 mg

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Qty. / Tab.
ACTIVE			
Pyridoxine Hydrochloride	BP	25.0 mg	27.00 mg
INACTIVE			
Lactose	BP	-	100.00 mg
Microcrystalline Cellulose	BP	-	10.000 mg
Maize starch	BP	-	55.466 mg
Methyl paraben sodium	BP	-	0.5000 mg
propyl paraben sodium	BP	-	0.1000 mg
Talcum	BP	-	5.0000 mg
Magnesium stearate	BP	-	2.0000 mg
Sodium Starch Glycolate	BP	-	4.0000 mg
Colloidal Silicon Dioxide	BP	-	1.0000 mg

BP = British Pharmacopoeia.
USP = United State Pharmacopoeia.

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3. PHARMACEUTICAL DOSAGE FORM

Uncoated tablets

White, circular, flat uncoated tablets having a break line on one side and other side is plain of each tablet.

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Pyridoxine Hydrochloride is used for isoniazid-induced peripheral neuritis, idiopathic sideroblastic anaemia and Vitamin B_6 deficiency states.

4.2 Posology and method of administration

For isoniazid-induced peripheral neuritis

Adults: Treatment – 50mg three times daily
Prophylaxis – Not suitable with this dosage form

Children: This presentation is not recommended

For idiopathic sideroblastic anaemia

Adults: 100 to 400mg daily in divided doses

Children: This presentation is not recommended

For deficiency states

Adults: 50 to 150mg daily in divided doses

Children: This presentation is not recommended

Elderly: Dosage requirements appear to be similar to those for young adults

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

Many drugs may alter the metabolism or bioavailability of pyridoxine, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for pyridoxine. Pyridoxine hydrochloride may reduce the effect of levodopa, a drug used in the treatment of Parkinsons Disease unless a dopa decarboxylase inhibitor is also given.

4.6 Pregnancy and lactation

Data on exposed pregnancies indicate no adverse effects of pyridoxine in therapeutic doses on pregnancy or the health of the foetus or newborn child, or during lactation.

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Long term administration of large doses of pyridoxine is associated with the development of severe peripheral neuritis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

a) Symptoms – None reported

b) Treatment – no treatment necessary.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmaco-Kinetic Properties

Absorption

The B vitamins are readily absorbed from the gastrointestinal tract, except in malabsorption syndromes. Pyridoxine is absorbed mainly in the jejunum. The Cmax of pyridoxine is achieved within 5.5 hours.

Volume of distribution

Pyridoxine main active metabolite, pyridoxal 5'-phosphate, is released into the circulation (accounting for at least 60% of circulating vitamin B6) and is highly protein bound, primarily to albumin.

Protein binding

Pyridoxine main active metabolite, pyridoxal 5'-phosphate, is released into the circulation (accounting for at least 60% of circulating vitamin B6) and is highly protein bound, primarily to albumin.

Metabolism

Pyridoxine is a prodrug primarily metabolized in the liver. The metabolic scheme for pyridoxine is complex, with formation of primary and secondary metabolites along with interconversion back to pyridoxine. Pyridoxine's major metabolite is 4-pyridoxic acid.

Route of elimination

The major metabolite of pyridoxine, 4-pyridoxic acid, is inactive and is excreted in urine

5.2 Pharmaco-dynamic properties

Vitamin B6 (pyridoxine) is a water-soluble vitamin used in the prophylaxis and treatment of vitamin B6 deficiency and peripheral neuropathy in those receiving isoniazid (isonicotinic acid hydrazide, INH). Vitamin B6 has been found to lower systolic and diastolic blood pressure in a small group of subjects with essential hypertension. Hypertension is another risk factor for atherosclerosis and coronary heart disease. Another study showed pyridoxine hydrochloride to inhibit ADP- or epinephrine-induced platelet aggregation and to lower total cholesterol levels and increase HDL-cholesterol levels, again in a small group of subjects. Vitamin B6, in the form of pyridoxal 5'-phosphate, was found to protect vascular endothelial cells in culture from injury by activated platelets. Endothelial injury and dysfunction are critical initiating events in the pathogenesis of atherosclerosis. Human studies have demonstrated that vitamin B6 deficiency affects cellular and humoral responses of the immune system. Vitamin B6 deficiency results in altered lymphocyte differentiation and maturation, reduced delayed-type hypersensitivity (DTH) responses, impaired antibody production, decreased lymphocyte proliferation and decreased interleukin (IL)-2 production, among other immunologic activities.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the Summary of Product Characteristics.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose	BP	100.00 mg
Microcrystalline Cellulose	BP	10.000 mg
Maize starch	BP	55.466 mg
Methyl paraben sodium	BP	0.5000 mg
propyl paraben sodium	BP	0.1000 mg
Talcum	BP	5.0000 mg
Magnesium stearate	BP	2.0000 mg
Sodium Starch Glycolate	BP	4.0000 mg
Colloidal Silicon Dioxide	BP	1.0000 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store under normal storage condition (15°C to 30°C)
Protect from light.

6.5 Nature and Contents of Container

Jar pack 1000 tablets.
Material of construction of primary packaging material is attached.

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Date : 17/08/2021
Director of the manufacturer
(Signature, Full name, Stamp)

Date : 17/08/2021
Director of applicant company
(Signature, Full name, Stamp)