Bharat Parenterals Limited
Registered Office & Works:
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CIN NO: U24231GJ1992PLC018237

BIOMECOLOXIN - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name:

Meclozine and Pyridoxine Tablet

Trade Name: BIOMECOLOXIN

1.2 Strength:

Each film coated tablet contains:

Meclozine Hydrochloride BP	25 mg
Pyridoxine Hydrochloride BP	50 mg

1.3 Pharmaceutical form:

Solid Oral Dosage form – Tablets

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Label Claim (mg)	Qty./Tablet (mg)	Function
Dry Mixing				
1.	Meclozine Hydrochloride BP*	25.00	25.00	Active
2.	Pyridoxine Hydrochloride BP *	50.00	50.00	Active
3.	Maize Starch BP	----	50.000	Diluent
4.	Microcrystalline Cellulose BP**	----	200.000	Diluent
Blending & Lubrication				
5.	Croscarmellose Sodium BP	----	5.000	Disintegrant
6.	Magnesium Stearate BP	----	2.000	Lubricant
Total Weight of Uncoated Tablet			**332.000**	
7.	Isopropyl alcohol BP		52.290	Coating solvent
8.	Dichloromethane BP		97.110	Coating solvent
9.	COL.EL-MB-1004 White (Elegance Coat) IH		10.000	Film coating agent
Total Weight of film coated Tablets			**342.000**	

3. Pharmaceutical form:

Dosage Form: Solid Oral Dosage form - Tablets

Visual & Physical characteristics of the product

A white coloured circular, biconvex, film coated tablet having an embossed conical flask B on one side of the tablet.

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4. Clinical particulars:

4.1. Therapeutic indications:

BIOMECOLOXIN is indicated for the management of nausea, vomiting and dizzinessassociated with motion sickness and of pregnancy, anaesthesia and radiation therapy.

4.2. Posology and method of administration:

The dosage is to be determined by the physician.

In the treatment of nausea caused by pregnancy, anaesthesia or radiation therapy, the recommended dose for adults is 25 to 50 mg daily, possibly increased, depending upon' clinical response, to 100 mg daily in divided doses.

For the treatment of motion sickness in adults, the initial recommended dose of 25 to 50 mg should be taken one hour prior to embarkation for protection against motion sickness.

Thereafter, the dose may be repeated every 24 hours for the duration of the journey.

BIOMECOLOXIN should be administered in children under 12 years of age only with the prescription and the follow-up of a physician. The recommended doses are then usually 1 mg of Meclozine/kg/day, in divided doses

4.3. Contraindications:

BIOMECOLOXIN is contraindicated in individuals who have shown a previous hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use:

Since drowsiness may on occasions occur with use of this drug, patients should be warned of this possibility and cautioned against or operating dangerous machinery. Patients should avoid alcoholic beverages while taking the drug.

Due to its potential anti-cholinergic action, this -used with caution in patients with asthma, glaucoma or enlargement of the prostate gland. Like any other drug, BIOMECOLOXIN should be used pregnancy only on the prescription of a physician and if clearly necessary.

4.5 Interaction with other medicinal products and other forms of interaction:

Meclozine: Additive effects with CNS depressants, neuroleptics, anticholinergics, alcohol.

4.6 Pregnancy and lactation:

Pregnancy

Category B: Either animal-reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the 1st trimester (and there is no evidence of a risk in later trimesters).

4.7. Effects on ability to drive and use machines:

None Applicable

4.8 Undesirable effects:

Drowsiness, dry mouth and or rare occasions, blurred vision have been reported. These symptoms are often transient and resolve generally spontaneously after a few days or reduction of the dosage.

4.9. Overdose:

An overdose with an antihistamine like meclozine might cause symptoms such as: Dilated pupils, Flushing, an irregular heart rhythm (arrhythmia), Hallucinations, Seizures, A rapid heart rate, High blood pressure, High or low bod Drowsiness, Excitation, Dry mouth, Nausea and vomiting, Constipation, Coma, Loss of life. Treatment may involve supportive care, which consists of treating the symptoms that occur as a result of the overdose.

Supportive treatment overdose of meclozine may include:

Fluids through an intravenous line (IV)

Medicines to increase blood pressure, control an irregular heart rhythm, or control seizures.

Close monitoring of the heart and lungs

A breathing tube to help with breathing

Other treatments based on complications that occur.

Symptom of an overdose of vitamin B6 (pyridoxine) is numbness or unusual tingling sensations in the hands and feet. Treatment for an overdose, if necessary, will likely involve supportive care.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Meclizine, a piperazine-derivative H1-receptor antagonist, is used as an antivertigo/antiemetic agent. Meclozine management of nausea, vomiting and dizziness associated with motion sickness and vertigo in diseases affecting the vestibular apparatus.

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Pyridoxine (Vitamin B6), used in combination with Meclozine, reduces nausea and vomiting due to pregnancy.

5.2 Pharmacokinetic properties:

Onset: Meclozine 1 hr

Duration: Meclozine: 8 - 24 hr

Absorption:

Meclozine: Well absorbed.

Pyridoxine: Readily absorbed from GI tract except in malabsorption syndrome or following gastric resection.

Metabolism:

Meclozine: Hepatic.

Pyridoxine: Convened to pyridoxal phosphate and pyridoxamine phosphate in the liver; riboflavin needed for further conversion of pyridoxine pyridoxal phosphate which are the principal forms of the vitamin in the blood. Pyridoxal is further oxidised to4-pyridoxicacid in Liver.

Excretion:

Meclozine: Plasma half-life: 6 hr.

Pyridoxine: Excreted in urine (4-pyridoxic acid).

5.3 Preclinical safety data

No preclinical data

6. Pharmaceutical particulars:

6.1. List of Excipients:

The excipients used in the formulation of Meclozine and Pyridoxine Tablets. The list of excipients is as follows:

Maize Starch

Microcrystalline Cellulose

Croscarmellose Sodium

Magnesium Stearate

Isopropyl alcohol

Dichloromethane

BIOMECOLOXIN - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

COL.EL-MB-1004 White (Elegance Coat)

6.2 Incompatibilities:

Not applicable

6.3. Shelf life:

60 months

6.4. Special precautions for storage:

Store in a well closed container, below 30°C and in a dry place.

6.5. Nature and contents of container:

Pack size: MECOLOXIN tablets are supplied in jars of 250 tablets

6.6. Special precautions for disposal:

No special requirement.

7. Applicant

Name and Address of Applicant

M/s. Biomedicine Sckivs Pharm.Nig Ltd,

Premise Address: No. 16, Anionwu Street Odoakpu, P.O.BOX:7846, Onitsha Nigeria,

Tel: +234803507884, +2348024517997.

E-mail: sckivspharm@yahoo.com

Name and Address of manufacturer:

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