

Botans 62.5 Tablet

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(Bosentan 62.5 mg Tablet)

Composition:

Each film-coated tablet contains:

- **Bosentan I.P.** – 62.5 mg

Description:

Botans 62.5 Tablet contains **Bosentan**, an **endothelin receptor antagonist (ERA)** used primarily for the treatment of **pulmonary arterial hypertension (PAH)**. It works by **blocking endothelin-1 receptors**, leading to **vasodilation** and reduced **pulmonary blood pressure**, improving exercise capacity and delaying disease progression.

Pharmacological Action:

- **Bosentan (62.5 mg) - Endothelin Receptor Antagonist:**
 - Reduces **pulmonary arterial pressure**
 - Improves **blood flow** in the lungs
 - Enhances **exercise capacity**
 - Slows **PAH progression**

Indications:

Botans 62.5 Tablet is used for:

- **Pulmonary Arterial Hypertension (PAH) - WHO Group 1**
- **Improvement of exercise ability in PAH patients**
- **Delaying PAH progression in patients with mild-to-moderate symptoms**

Dosage & Administration:

- **Initial Dose:** 62.5 mg **twice daily** for 4 weeks
- **Maintenance Dose:** May be increased to **125 mg twice daily** based on response
- Should be taken **with or without food**
- **Swallow whole** with water; do not crush or chew

Contraindications:

- **Pregnancy - Highly teratogenic (Category X)**
- **Severe liver impairment** (monitor LFTs regularly)

- **Use with cyclosporine A or glyburide**
- **Hypersensitivity to Bosentan or any tablet components**

Warnings & Precautions:

- **Liver toxicity:** Regular **liver function tests (LFTs)** required
- **Hemoglobin decrease:** Monitor **hemoglobin levels**
- **Highly teratogenic:** Strict **pregnancy prevention** required
- **Fluid retention:** May cause **edema**; monitor patients with **heart failure**
- **Drug Interactions:** May reduce the effectiveness of **hormonal contraceptives**

Side Effects:

- **Common:** Headache, flushing, nasal congestion, dizziness
- **Serious:** Liver dysfunction, anemia, swelling of limbs, respiratory infections

Drug Interactions:

- **Cyclosporine A & Glyburide:** Contraindicated
- **Warfarin & Digoxin:** Monitor INR & cardiac function
- **Hormonal contraceptives:** May reduce efficacy (use alternative methods)

Storage Conditions:

- Store below **30°C** in a **dry place**
- Keep out of reach of **children**

Conclusion:

Botans 62.5 Tablet is a **clinically proven therapy** for **pulmonary arterial hypertension (PAH)**, improving **exercise tolerance** and **delaying disease progression**. Due to **potential liver toxicity and teratogenic effects**, **regular monitoring** and **strict contraceptive measures** are necessary.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

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