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WEI GE BAN LÜ®

XIU ZHENG TANG®

## Instructions for Phentolamine Mesylate Tablets

Please read the instructions carefully, and use under the guidance of a physician.

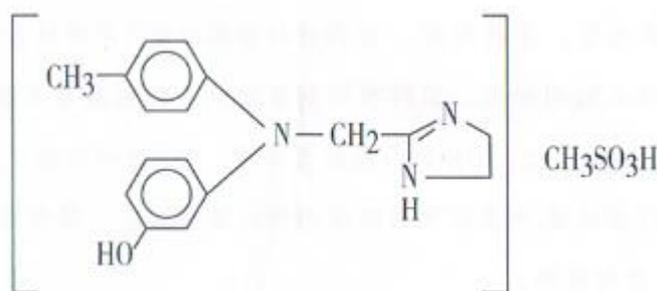
### 【Drug Name】

Generic [Chinese] name: 甲磺酸酚妥拉明片

English name: Phentolamine Mesylate Tablets

Chinese phonetic spelling: Jiahuangsuan Fentuolaming Pian

【Constituents】 The primary constituent of this product is Phentolamine Mesylate, having a chemical name of 3-[[[(4,5-Dihydro-1H-Imidazol-2-yl)methyl](4-tolyl)amino] phenol methanesulfonate. Chemical structural formula:



Molecular formula:  $C_{17}H_{19}N_3O \cdot CH_4O_3S$  Molecular weight: 377.46

【Characteristics】 This product is a white colored tablet-like product.

【Indications】 For use with male erectile dysfunction.

【Specifications】 50mg

【Dosage and Administration】 Take 1 tablet orally, 30 minutes prior to sexual activity. Use no more than once, daily. The maximum recommended daily dosage is 1.5 tablets.

【Adverse Reactions】 Common adverse reactions include nasal congestion, headache, dizziness, tachycardia, nausea, palpitations, and facial flushing. A small number of patients may experience mild changes in heart rate, systolic blood pressure, and diastolic blood pressure; and very few patients may experience orthostatic hypotension.

【Contraindications】 Individuals with hypotension (systolic blood pressure <90mmHg, diastolic blood pressure <60mmHg), severe arteriosclerosis, angina pectoris, myocardial infarction, coronary artery insufficiency, liver and kidney dysfunction, patients with gastric ulcers, those who are taking anti-hypertensive drugs, and those who are allergic to this product should abstain from using this product.

【Notes】 1. Patients with gastritis should use with caution. 2. Patients with diabetes, and patients with mental illnesses, should use with caution. 3. Do not operate a vehicle, a boat or dangerous machinery while taking this medication.

【Drug Use by Pregnant or Lactating Women】 This drug product is not intended for use by said group.

【Drug Use by Children】 This drug product is not intended for use by said group.

**【Drug Use by the Elderly】** Use of this product by the elderly is more likely to induce hypothermia.

**【Drug Interactions】** 1. Avoid mixing with iron. 2. When used with guanethidine, the incidence of orthostatic hypotension or bradycardia increases. 3. Sedative and hypnotic drugs such as phenobarbital and glutethimide, and anti-hypertensive drugs such as reserpine and verticil can enhance the anti-hypertensive effect of this product. 4. When combined with cardiac glycosides, toxicity can be increased. 5. When used with diazoxide, the effect of diazoxide in suppressing the release of insulin is inhibited. 6. When combined with sympathomimetic amine drugs, it offsets or weakens their peripheral vasoconstriction. 7. This product is prohibited from use in combination with nitroglycerin drugs.

**【Drug Overdose】** When severe hypotension occurs due to excessive dose, norepinephrine can be given via intravenous drop. However, epinephrine should not be used to avoid the further lowering of blood pressure.

**【Pharmacology and Toxicology】** This product is a short-acting  $\alpha$ -adrenergic receptor blocker, which has effects on both  $\alpha_1$  and  $\alpha_2$  receptors. It can cause dilation of blood vessels and reduce peripheral vascular resistance, which can cause the smooth muscle of the cavernous sinus of the penis to relax, allowing more blood to flow into the cavernous tissues, and simultaneously inhibit the blood flow out of the cavernous body, leading to erection. The drug maintains erectile function without being affected by sex hormones, mood and nerves, and can maintain and promote long-term erections. Recommended drug dosage has no effect on those who lack sexual stimulation.

**【Pharmacokinetics】** Taking 50mg of this product orally, it will reach its maximum effect after 30 minutes, and will last 3 to 6 hours. The half-life of an intravenous injection is approx. 19 minutes. Drugs are rapidly metabolized in the body, the majority of which are excreted in urine as inactive metabolites, of which the original form accounts for about 13%.

**【Storage】** Store sealed and away from light.

**【Packaging】** Double-sided composite aluminum packaging, 2 tablets/box.

**【Expiry Period】** 24 months

**【Operative Norm】** 《Chinese Pharmacopoeia》 2015 Edition, First Expanded Edition

**【Approval No.】** SFDA Approval No. H20041232

**【Manufacturer】**

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