

# SILDENAFIL

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## SILDORA

50 mg Film-Coated Tablet  
100 mg Film-Coated Tablet  
Urological

### FORMULATION:

Each film-coated tablet contains:  
Sildenafil (as citrate), EP .....50 mg / 100mg

### MECHANISM OF ACTION:

Sildenafil citrate is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5), the enzyme that is responsible for degradation of cGMP. Apart from the presence of this enzyme in the corpus cavernosum of the penis, PDE5 is also present in the pulmonary vasculature. Sildenafil, therefore, increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with pulmonary arterial hypertension this can lead to vasodilation of the pulmonary vascular bed and, to a lesser degree, vasodilatation in the systemic circulation.

### INDICATIONS:

Sildenafil citrate is a phosphodiesterase type-5 inhibitor used in the management of erectile dysfunction.

### DOSE AND ADMINISTRATION:

Sildenafil citrate tablets are for oral administration.

**Adults:** The recommended dose is 50 mg, taken as needed approximately one hour before sexual activity. Based on efficacy and toleration, the dose may be increased to 100 mg or decreased to 25 mg. The maximum recommended dose is 100 mg. The maximum recommended dosing frequency is once per day.

### ADVERSE EFFECTS:

Serious cardiovascular events, including myocardial infarction, sudden cardiac death, ventricular arrhythmia, Headache, flushing, dizziness, hypotension, angina pectoris, face edema, photosensitivity reaction, shock, dyspepsia, vomiting, dry mouth, arthritis, neuropathy, depression, insomnia, nasal congestion, and asthma,

### PRECAUTIONS:

Caution is required in patients with hepatic or severe renal impairment, and dosage reduction of sildenafil may be necessary. Care is also needed in patients with anatomical deformation of the penis or haematological disorders that may predispose them to priapism. Patients who experience dizziness or visual disturbances should not drive or operate machinery.

### CONTRA-INDICATIONS:

Sildenafil citrate is not indicated for use in women.

Use of Sildenafil citrate is contraindicated in patients with a known hypersensitivity to any component of the tablet. Consistent with its known effects on the nitric oxide/cGMP pathway, Sildenafil citrate was shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitric oxide donors or nitrates in any form is therefore contraindicated.

### WARNINGS:

There is a potential for cardiac risk of sexual activity in patients with pre-existing cardiovascular disease.

Therefore, treatments for erectile dysfunction, including Sildenafil citrate, should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status.

Patients who have suffered a myocardial

infarction, stroke, or life-threatening arrhythmia within the last months;  
Patients with resting hypotension (BP <90/50) or hypertension (BP >170/110);  
Patients with cardiac failure or coronary artery disease causing unstable angina;  
Patients with retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases).

### DRUG INTERACTIONS:

#### Effects of other drugs on Sildenafil citrate

Cimetidine (800 mg), may cause increased plasma sildenafil concentrations when co-administered with Sildenafil citrate to healthy volunteers.

When sildenafil clearance is co-administered with CYP3A4 inhibitors (such as itraconazole, ketoconazole, erythromycin, and cimetidine), there is reduction in sildenafil clearance

Single doses of antacid (magnesium hydroxide/aluminium hydroxide) have no effect on the bioavailability of Sildenafil citrate

#### Effects of Sildenafil citrate on other medicines

No significant interactions were shown with tolbutamide (250 mg) or warfarin (40 mg), both of which are metabolised by CYP2C9.

Sildenafil citrate was shown to potentiate the hypotensive effect of acute and chronic nitrates. Therefore, use of nitrates or nitric oxide donors with Sildenafil citrate is contraindicated.

### OVER DOSAGE:

Adverse events were similar to those seen at lower doses.

In cases of overdose, supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil is highly bound to plasma proteins and not eliminated in the urine.

### STORAGE:

Store at temperatures not exceeding 30°C.

**CAUTION:** Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

### PRESENTATION:

50mg & 100mg Film-Coated Tablet Alu-PVC blister pack of 4's, box of 4 tablets.

**For suspected adverse drug reaction, report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph).**

Regn No: DR-XY 39730 - 50mg  
Regn No: DR-XY 39729 - 100mg

### Date of First Authorization :

**Sildora-50** : July 6, 2011

**Sildora-100** : July 6, 2011

### Date of Revision :

27 December 2023



Manufactured by:

**SYNMEC** Laboratories

SP-3-5 A and C, RIICO Industrial Area Keshwana, Kotputli, Jaipur, Rajasthan-303108, India

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**ONE PHARMA**

**ONE PHARMA MARKETING INC.**  
L51, B21, Abel Nosce St., BF Resort Village, Talon II, Las Piñas City, Metro Manila