

# Alphagra® 100mg

GENERIC NAME  
Sildenafil Citratel

CHEMICAL NAME  
1-{[3-(6,7-Dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl}-4-methylpiperazine citrate

MOLECULAR FORMULA  
C<sub>22</sub>H<sub>30</sub>N<sub>6</sub>O<sub>4</sub>S • C<sub>6</sub>H<sub>8</sub>O<sub>7</sub>

MOLECULAR WEIGHT  
666.7

PROPRIETARY NAME: Alphagra®  
DOSAGE FORM: 100mg Sildenafil tablet for oral administration

COMPOSITION  
Alphagra 100 mg: Each tablet contains sildenafil citrate equivalent to 100 mg sildenafil.

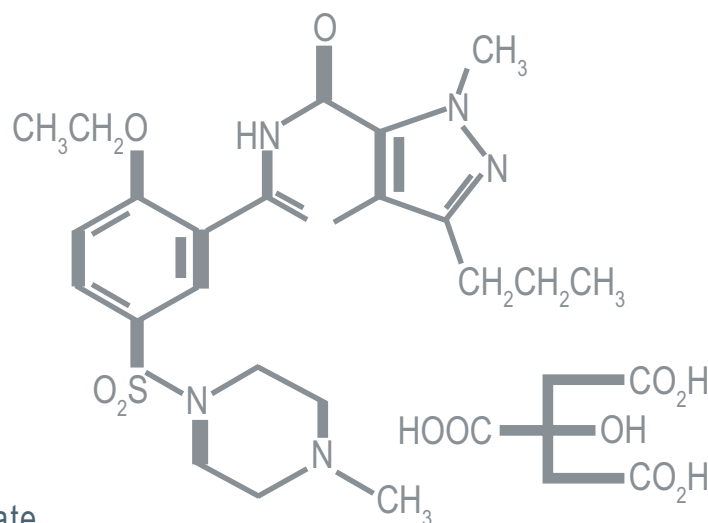
PHARMACOLOGICAL CLASSIFICATION  
Vasodilators – peripheral, Phosphodiesterase type 5 inhibitor

PHARMACOLOGICAL ACTION:  
Alphagra is selective inhibitor of cyclic guanosine monophosphate specific phosphodiesterase type 5 (PDE-5) Enzyme. The physiologic mechanism of erection of penis involves the release of “NO” in the human corpus cavemosum during sexual stimulation. “NO” then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (c-GMP) producing smooth muscle relaxation and increased blood flow. In the absence of sexual stimulation, Alphagra is not effective when administered at its therapeutic doses.

PHARMACOKINETICS:  
Sildenafil citrate tablet is rapidly absorbed after oral administration with about 40% absolute bioavailability. Their pharmacokinetics is dose-proportional over the recommended dose range. Peak plasma concentrations are achieved within 30 to 120 minutes of oral dosing in fasting state. It is eliminated predominantly by hepatic metabolism (mainly cytochrome P450 3A4) and is converted into an active metabolite with properties similar to parent, sildenafil. Both sildenafil and its N-desmethyl metabolite have half-life ( $t_{1/2}$ ) of 4 hours and approximately 96% bound to the plasma proteins. The elimination is mainly in the form of faeces (approximately 80% of administered oral dose) and to the lesser extent in the urine (approximately 13% of administered oral dose).



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**INDICATIONS:** Alphagra is indicated in the treatment of male impotency disorders such as Erectyl dysfunction.

## ADVERSE EFFECTS:

The following adverse effects were reported on oral administration:

Headache, flushing, dyspepsia, respiratory tract infection, nasal-congestion, urinary tract infection, abnormal vision, retinal vascular disease, photosensitivity, ocular burning, redness, swelling, vitreous detachment/traction, increased intraocular pressure, depression, diarrhoea, dizziness, rash, back pain, arthralgia, tachycardia, palpitation, angina pectoris, migraine, hypotension, postural hypotension, myocardial infarction, chest pain, allergic reactions.

## CONTRA-INDICATIONS:

- Alphagra® should not used in patients with known hypersensitivity to sildenafil or any one of the tablet excipients.
- Contraindicated in patients who concurrently or intermittently using organic nitrates in any form  
Alphagra is contraindicated in infant, children, pregnancy and lactating mothers

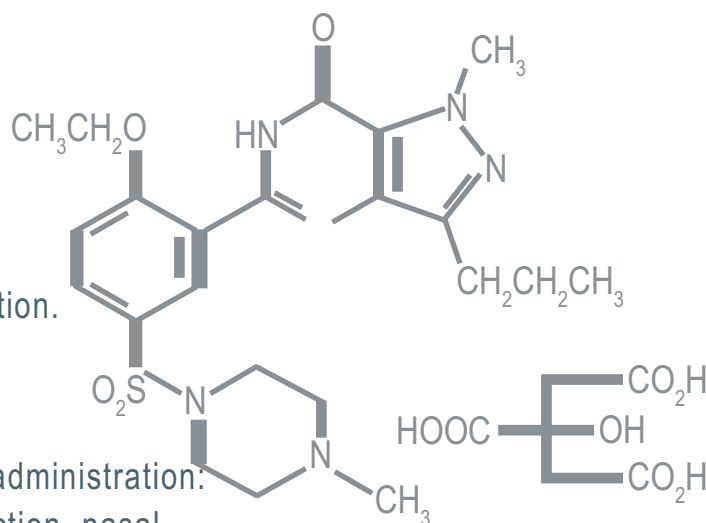
## WARNINGS AND PRECAUTIONS:

Use with caution in patients with sever hepatic and renal impairment (25mg is recommended).

Avoid use in patients with preexisting cardiovascular diseases such as myocardial infarction, stroke or life threatening arrhythmias, patients with retinitis pigmentosa, patients with brief history of blood pressure complications, patients with unstable angina and cardiac failure in whom sexual activity is inadvisable.



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In the event of an erection that persists longer than 4 hours, the patient should concerned physician. If priapism (painful erections greater than 6 hours in duration) is not treated immediately, penile tissue damage and permanent loss of potency could result.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:  
Dizziness, altered vision, and exercise caution before driving, operating hazardous machinery or performing hazardous tasks.

## DRUG INTERACTIONS:

- Non-specific beta blockers, Loop and potassium sparing diuretics enhances the efficacy of sildenafil citrate
- Concomitant administration of sildenafil 100 mg with amlodipine 5 or 10 mg in hypertensive patients lead to a mean additional blood pressure reduction of 8mm Hg systolic and 7 mm Hg diastolic. Thus, no interaction seen with amlodipine.
- Concurrent administration CYP3A4 inducers, such as rifampicin, will decrease plasma levels of sildenafil.
- Concurrent administration with cytochrome P450 (CYP3A4) inhibitors like erythromycin, ketoconazole, itraconazole and nonspecific CYP inhibitor like cimetidine are likely to increased plasma levels of sildenafil and reduce sildenafil clearance however, there was no increased incidence of adverse events in these patients.

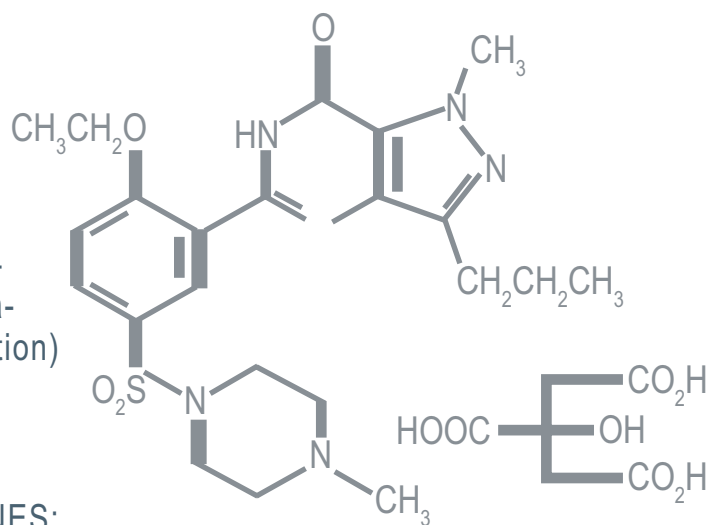
## OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In studies with healthy volunteers, of single doses up to 800 mg, adverse events were similar to those seen at lower doses

But incidence rates were increased.



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In cases of overdose, supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil citrate is highly bound to plasma proteins (96%) and not eliminated in urine.

## IDENTIFICATION:

ALPHAGRA 100 mg: The tablets are blue film coated diamond-shaped tablets.

## PRESENTATION

Pack of four tablets in a blister. Each blister is packed in an individual carton with a leaflet.

## DOSAGE AND DIRECTIONS FOR USE

- Oral Administration.

Adults :

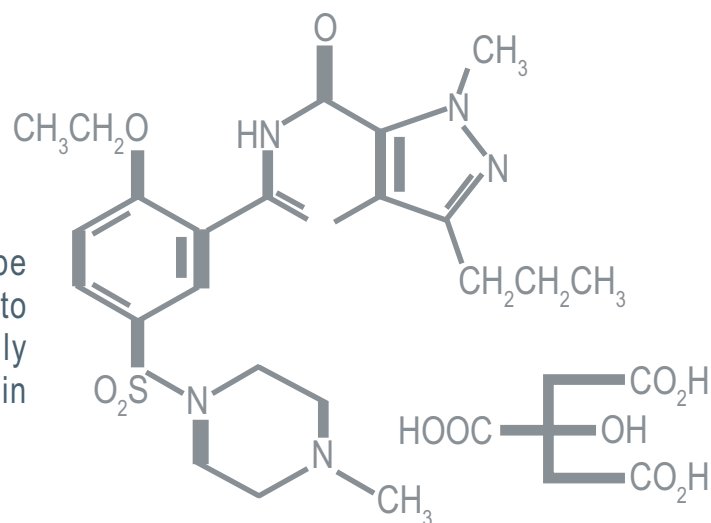
- The recommended starting dose is 50 mg, taken approximately one hour before sexual activity.
- The maximum recommended dose is 100 mg in once daily.
- Elderly and in Patients with Impaired Renal or Hepatic Function a starting dose of 50 mg may be considered.
- Children: Should not be given

## STORAGE

Store in cool and dry place. Protect from light  
KEEP OUT OF REACH OF CHILDREN.



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## MARKETED BY:

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