

# PIL of Avala Tablet range for NPD.

Size: 125 mm x 250 mm

## Avala<sup>TM</sup> (Avanafil) Tablet

## آوالا

### COMPOSITION:

#### Avala Tablet 50 mg:

Each tablet contains:

Avanafil ..... 50 mg.

Product Specs.: Innovator

#### Avala Tablet 100 mg:

Each tablet contains:

Avanafil ..... 100 mg.

Product Specs.: Innovator

### CLINICAL PARTICULARS:

#### Therapeutic Indications:

Avanafil is indicated for the treatment of erectile dysfunction in adult men.

#### Posology and Method of Administration:

The recommended starting dose is 100 mg taken as needed approximately 15 to 30 minutes before sexual activity.

The dose may be reduced to 50 mg based on individual efficacy and tolerability.

The maximum dosing frequency is once daily.

Avanafil may be taken with or without food.

Sexual stimulation is required for efficacy.

### CONTRAINDICATIONS:

- Hypersensitivity to avanafil or any excipient.
- Concomitant use with nitrates or nitric oxide donors.
- Use with guanylate cyclase stimulators.
- Severe hepatic or renal impairment.
- Patients in whom sexual activity is inadvisable.

### SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

- Cardiovascular status should be assessed before initiation.
- Caution in patients with penile deformities or risk of priapism.
- Discontinue use in case of sudden visual loss.
- Use cautiously in patients with bleeding disorders.

### INTERACTION WITH OTHER MEDICINAL PRODUCTS:

- Contraindicated with nitrates.
- Caution with alpha blockers.
- Strong CYP3A4 inhibitors not recommended.
- Concomitant PDE5 inhibitors not recommended.

### FERTILITY PREGNANCY AND LACTATION:

- Not indicated for use in women.
- No evidence of impaired fertility.

#### Effects on Ability to Drive and Use Machines:

May cause dizziness or visual disturbances.

### UNDESIRABLE EFFECTS:

- Common adverse reactions include headache flushing nasal congestion and back pain.
- Uncommon reactions include dizziness nausea hypotension and palpitations.
- Rare adverse reactions include priapism sudden hearing loss and sudden visual loss.

### PHARMACOLOGICAL PROPERTIES:

#### Pharmacodynamic Properties:

Avanafil is a phosphodiesterase type 5 inhibitor enhancing nitric oxide mediated vasodilation in penile tissue.

#### Pharmacokinetic Properties:

- Rapid absorption with peak concentrations within 30 to 45 minutes.
- Primarily metabolized by CYP3A4.
- Terminal half life approximately 5 hours.

### INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

### PRESENTATION:

Avala Tablet 50 mg : Pack of 1 x 10 tablets.  
Avala Tablet 100 mg : Pack of 1 x 10 tablets.

Manufactured by:

Medizan Laboratories (Pvt.) Ltd.

Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:



Marketed by:  
CCL Pharmaceuticals (Pvt.) Ltd.  
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

ہدایات:  
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔  
گرمی، دھوپ اور نمی سے بچائیں۔  
بچوں کی پہنچ سے دور رکھیں۔  
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔