SUMMARY OF PRODUCT CHARACTERISTICS
Sidopros 8 Capsules (Silodosin 8 mg)

1. NAME OF THE MEDICINAL PRODUCT
Sidopros 8 Capsules (Silodosin 8 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each hard gelatin capsule contains 8 mg silodosin.

Excipients with known effect:
This medicinal product does not contain excipients with known effect at the stated dose.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Hard gelatin capsule.
Blue/white coloured, size-2 hard gelatin capsule containing white coloured powder.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Sidopros 8 is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult men.

4.2 Posology and method of administration
Recommended dose: 8 mg orally once daily with a meal. Renal impairment: contraindicated in severe (CrCl <30 ml/min); dose reduced to 4 mg once daily with a meal in moderate impairment (CrCl 30–50 ml/min); no adjustment in mild impairment (CrCl 50–80 ml/min). Hepatic impairment: no adjustment in mild or moderate impairment; contraindicated in severe impairment (Child-Pugh score ≥10). Paediatric: Not indicated for use below 18 years. Method: oral; swallow whole with a glass of water with a meal.

4.3 Contraindications
- Severe renal impairment (CrCl <30 ml/min).
- Severe hepatic impairment (Child-Pugh score ≥10).
- Concomitant administration with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir).
- Hypersensitivity to silodosin or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
Orthostatic hypotension
Postural hypotension, with or without symptoms (e.g. dizziness), may develop when beginning silodosin treatment. As with other alpha-blockers, there is potential for syncope. Patients should be cautioned about driving, operating machinery, or performing hazardous tasks when initiating therapy until they know how silodosin will affect them.

Renal impairment
Plasma concentrations (AUC and Cmax) of silodosin are approximately three times higher in subjects with moderate renal impairment; half-lives doubled. Dose should be reduced to 4 mg in patients with moderate renal impairment. Silodosin is contraindicated in severe renal impairment.

Hepatic impairment
Silodosin has not been tested in patients with severe hepatic impairment and is therefore contraindicated in those patients.

Intraoperative Floppy Iris Syndrome (IFIS)

IFIS has been observed during cataract surgery in some patients on or previously treated with alpha-1 blockers. Patients planning cataract surgery should advise their ophthalmologist that they are taking or have taken silodosin.

Carcinoma of the prostate

Carcinoma of the prostate and BPH cause many of the same symptoms and frequently co-exist. Patients should be examined prior to starting silodosin therapy to rule out carcinoma of the prostate.

4.5 Interaction with other medicinal products and other forms of interaction

Strong CYP3A4 inhibitors (ketoconazole, itraconazole, clarithromycin, ritonavir):

Concomitant use is contraindicated; causes 3.8-fold Cmax increase and 3.2-fold AUC increase.

Moderate CYP3A4 inhibitors (diltiazem, erythromycin, verapamil):

May increase silodosin concentrations. Exercise caution and monitor.

Strong P-gp inhibitors (ciclosporin):

Not recommended concomitantly; inhibition of P-gp may increase silodosin concentrations.

UGT2B7 inhibitors (probenecid, valproic acid, fluconazole):

May increase exposure to silodosin and its active glucuronide metabolite KMD-3213G.

Other alpha-blockers:

Do not use in combination; pharmacodynamic interactions expected.

PDE-5 inhibitors (sildenafil, tadalafil):

Greater number of positive orthostatic test results observed during co-administration. Exercise caution.

Antihypertensives:

Exercise caution; slightly higher incidence of dizziness and orthostatic hypotension reported.

Digoxin:

Concomitant silodosin and digoxin 0.25 mg/day did not significantly alter steady-state digoxin pharmacokinetics. No dose adjustment required.

Food:

Moderate-fat meal decreased silodosin Cmax by 18–43% and AUC by 4–49%. Must be taken with a meal.

4.6 Fertility, pregnancy and lactation

Silodosin is not indicated for use in women. Fertility: Possible effects on male fertility at exposures ≥2× MRHD in rats; reversible; clinical relevance unknown. Pregnancy: Not applicable. Breast-feeding: Not applicable.

4.7 Effects on ability to drive and use machines

Sidopros 8 may cause dizziness or symptoms related to postural hypotension. Patients should be cautioned about driving or operating machinery when initiating therapy or until they know how silodosin affects them.

4.8 Undesirable effects

Tabulated list of adverse reactions from clinical trials (2 placebo-controlled 12-week studies, N=466 silodosin vs N=457 placebo)

Adverse Reaction	Silodosin N=466 n (%)	Placebo N=457 n (%)
Retrograde ejaculation	131 (28.1)	4 (0.9)
Dizziness	15 (3.2)	5 (1.1)
Diarrhoea	12 (2.6)	6 (1.3)
Orthostatic hypotension	12 (2.6)	7 (1.5)
Headache	11 (2.4)	4 (0.9)
Nasopharyngitis	11 (2.4)	10 (2.2)
Nasal congestion	10 (2.1)	1 (0.2)

Additional adverse reactions reported at 1–2% (more frequent than placebo): insomnia, PSA increased, sinusitis, abdominal pain, asthenia, rhinorrhoea. One case of syncope (patient also on prazosin) and one case of priapism were reported. One case of IFIS reported in a 9-month open-label safety study.

Post-marketing adverse reactions (frequency not known)

Skin and subcutaneous tissue disorders: Toxic skin eruption, purpura, skin rash, pruritus, urticaria.

Hepatobiliary disorders: Jaundice, impaired hepatic function with increased transaminase values.

Immune system disorders: Allergic-type reactions including swollen tongue and pharyngeal oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Dose-limiting adverse event in studies (up to 48 mg/day in healthy males): postural hypotension. If hypotension occurs, support cardiovascular system. Maintain patient in the supine position; IV fluid if needed; vasopressors if required. Monitor renal function. Dialysis is unlikely to be beneficial (97% protein-bound).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alpha-adrenoreceptor antagonists. ATC code: G04CA04.

Silodosin is a selective antagonist of post-synaptic alpha-1A adrenoreceptors located in the human prostate, bladder base, bladder neck, prostatic capsule, and prostatic urethra. Blockade relaxes smooth muscle in these tissues, resulting in improvement in urine flow and reduction in BPH symptoms. Silodosin binds with high affinity to the alpha-1A subtype and does not prolong the QT interval at therapeutic or supratherapeutic doses.

5.2 Pharmacokinetic properties

Silodosin: Pharmacokinetics are linear from 0.1 to 24 mg/day. Absorption: Absolute bioavailability ~32%; Tmax ~2–3 h. Food decreases Cmax by 18–43% and AUC by 4–49%; must be taken with a meal. Distribution: Vd 49.5 L; 97% protein-bound. Metabolism: Extensive via glucuronidation (UGT2B7), alcohol/aldehyde dehydrogenase and CYP3A4. Active glucuronide metabolite KMD-3213G has T½ ~24 h and AUC ~4× parent compound. Excretion: 33.5% in urine, 54.9% in faeces (radioactivity, 10 days). Plasma clearance (IV) ~10 L/h.

5.3 Preclinical safety data

Silodosin: Thyroid follicular cell tumours in male rats at 150 mg/kg/day (TSH-mediated via altered T4 levels; did not alter TSH/T4 in clinical trials; relevance to humans not known). Mammary adenocarcinomas in female mice at ≥150 mg/kg/day (prolactin-mediated; elevated prolactin not observed in clinical trials; relevance to humans not known). No mutagenic or genotoxic potential in standard assays (weakly positive CHL chromosome aberration at high cytotoxic concentrations only). Male rat fertility effects at ≥20 mg/kg/day (≥2× MRHE; reversible after 2-week recovery). Female rat estrus cycle changes at 20 mg/kg/day; no effect on fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the hard gelatin capsule:

No.	Excipient	Specification
1	Sodium lauryl sulphate	BP
2	Mannitol	BP
3	Pregelatinized starch	USP
4	Magnesium stearate	BP
5	E.H.G. capsules blue/white size "2"	IH

6.2 Incompatibilities

None known.

6.3 Shelf life
24 months (2 years).

6.4 Special precautions for storage
Do not store above 30°C. Protect from direct sunlight. Keep all medicines out of reach and sight of children.

6.5 Nature and contents of container
Blister pack of 3 × 10 capsules in a unit box with literature insert. Pack size: 30 capsules.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
Dawa Limited
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O. Box 16633-00620, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
H2025/CTD11913/24471

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