SUMMARY OF PRODUCT CHARACTERISTICS
Sidopros 8D Capsules (Silodosin 8 mg / Dutasteride 0.5 mg)

1. NAME OF THE MEDICINAL PRODUCT
Sidopros 8D Capsules (Silodosin 8 mg / Dutasteride 0.5 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each hard gelatin capsule contains: Silodosin 8 mg and dutasteride USP 0.5 mg.

Excipients with known effect:
Contains lactose monohydrate. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Hard gelatin capsule.
Blue/white coloured, size-0 hard gelatin capsule containing white to off-white granular powder.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Sidopros 8D is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate. This product is not intended for use as an antihypertensive and is not approved for the prevention of prostate cancer.

4.2 Posology and method of administration
One capsule taken once daily after a meal. The capsule should be swallowed whole and not crushed, chewed or opened. Method: oral.

4.3 Contraindications
Silodosin
- 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 any excipient.

Dutasteride
- Pregnancy: Dutasteride inhibits development of external genitalia of the male foetus. Dutasteride may cause foetal harm when administered to a pregnant woman.
- Women of childbearing potential.
- Paediatric patients.
- Clinically significant hypersensitivity (serious skin reactions, angio-oedema) to dutasteride or other 5-alpha-reductase inhibitors.

4.4 Special warnings and precautions for use
Silodosin

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.

Dutasteride — Effects on PSA and prostate cancer detection

Dutasteride reduces serum PSA by approximately 50% within 3–6 months of treatment. To interpret serial PSA in men on dutasteride, a new PSA baseline should be established at least 3 months after starting treatment, with PSA monitored periodically thereafter. Any confirmed increase from the lowest PSA value while on dutasteride may signal prostate cancer and should be evaluated. PSA values should be doubled for comparison with normal values in untreated men when interpreting an isolated PSA value in a man treated with dutasteride for ≥3 months. The free-to-total PSA ratio remains constant under dutasteride; no adjustment to percent free PSA is necessary.

Increased risk of high-grade prostate cancer

An increased incidence of Gleason score 8–10 prostate cancer was observed in a 4-year trial (dutasteride 1.0% vs placebo 0.5%). 5-alpha-reductase inhibitors may increase the risk of development of high-grade prostate cancer. Whether the volume-reducing effect or trial-related factors influenced these results has not been established.

Exposure of women — risk to the male foetus

Dutasteride must not be handled by a woman who is pregnant or who could become pregnant. Dutasteride is absorbed through the skin and could result in unintended foetal exposure. If skin contact occurs, the contact area must be washed immediately with soap and water.

Blood donation

Men being treated with dutasteride must not donate blood until at least 6 months have passed following their last dose, to prevent administration of dutasteride to a pregnant female transfusion recipient.

Lactose content

This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Silodosin

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.

Dutasteride

CYP3A4/3A5 inhibitors (e.g. ritonavir):

Dutasteride is metabolised by CYP3A4 and CYP3A5. Use caution when prescribing to patients taking potent, chronic CYP3A4 enzyme inhibitors.

4.6 Fertility, pregnancy and lactation

Fertility

Silodosin: Possible effects on male fertility at exposures ≥2× MRHD in rats; reversible; clinical relevance unknown. Dutasteride: Clinical significance of dutasteride's effect on semen characteristics for an individual patient's fertility is not known.

Pregnancy

Sidopros 8D is contraindicated in women of childbearing potential and during pregnancy. Dutasteride may cause foetal harm (male foetal genital development); must not be used in pregnancy.

Breast-feeding

Contraindicated in women of childbearing potential, including nursing women. Not known whether dutasteride is excreted in human milk.

4.7 Effects on ability to drive and use machines

Postural hypotension (silodosin component) may occur. Patients should be cautioned about driving or operating machinery when initiating therapy.

4.8 Undesirable effects

Silodosin — Clinical trial adverse reactions

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)

Post-marketing silodosin: Toxic skin eruption, purpura, skin rash, pruritus, urticaria, jaundice, impaired hepatic function, allergic reactions including pharyngeal oedema.

Dutasteride — Clinical trial adverse reactions (monotherapy)

Adverse Reaction	Months 0–6 Dutasteride/Placebo	Months 7–12	Months 13–18	Months 19–24
Impotence	4.7% / 1.7%	1.4% / 1.5%	1.0% / 0.5%	0.8% / 0.9%
Decreased libido	3.0% / 1.4%	0.7% / 0.6%	0.3% / 0.2%	0.3% / 0.1%
Ejaculation disorders	1.4% / 0.5%	0.5% / 0.3%	0.5% / 0.1%	0.1% / 0.0%
Breast disorders (tenderness/enlargement)	0.5% / 0.2%	0.8% / 0.3%	1.1% / 0.3%	0.6% / 0.1%

Note: Sexual adverse reactions (impotence, decreased libido, ejaculation disorders) are associated with dutasteride treatment and may persist after treatment discontinuation.

Combination with alpha-blocker: Ejaculation disorders occurred significantly more in subjects receiving combination therapy (11%) compared with dutasteride monotherapy (2%) or tamsulosin monotherapy (4%).

Dutasteride — Post-marketing adverse reactions

Immune system: Hypersensitivity reactions including rash, pruritus, urticaria, localised oedema, serious skin reactions, and angio-oedema. Neoplasms: Male breast cancer. Psychiatric: Depressed mood. Reproductive system and breast disorders: Testicular pain and testicular swelling.

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

Silodosin: If hypotension occurs, support cardiovascular system (supine position, IV fluids, vasopressors). Monitor renal function. Dialysis unlikely to help (97% protein-bound). Dutasteride: No specific antidote. Symptomatic and supportive treatment. Consider long half-life (~5 weeks) when planning duration of monitoring.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The symptoms associated with BPH are related to bladder outlet obstruction comprising static (prostate size) and dynamic (smooth muscle tone) components. Silodosin addresses the dynamic component; dutasteride addresses the static component.

Silodosin (ATC: G04CA04): Selective alpha-1A adrenoreceptor antagonist. Relaxes smooth muscle in prostate, bladder neck and prostatic urethra, improving urine flow and reducing BPH symptoms. Does not prolong QT interval.

Dutasteride (ATC: G04CB02): Competitive and specific inhibitor of both type 1 and type 2 5-alpha-reductase isoenzymes. Inhibits conversion of testosterone to dihydrotestosterone (DHT), the androgen primarily responsible for prostatic enlargement. Dutasteride does not bind to the human androgen receptor.

5.2 Pharmacokinetic properties

Silodosin: Linear pharmacokinetics. Absolute bioavailability ~32%; Tmax ~2–3 h. Food decreases Cmax by 18–43% and AUC by 4–49%; must be taken with a meal. Vd 49.5 L; 97% protein-bound. Extensively metabolised via glucuronidation (UGT2B7; active metabolite KMD-3213G with T½ ~24 h and AUC ~4× parent compound), alcohol/aldehyde dehydrogenase, and CYP3A4. Excreted 33.5% in urine, 54.9% in faeces.

Dutasteride: Tmax 2–3 h. Absolute bioavailability ~60% (range 40–94%). When administered with food, Cmax reduced by 10–15% (no clinical significance). Large Vd (300–500 L); highly protein-bound (albumin 99.0%, alpha-1-acid glycoprotein 96.6%). Semen concentrations averaged 3.4 ng/ml after 12 months. Extensively metabolised by CYP3A4 and CYP3A5. Excreted mainly in faeces (~5% as unchanged dutasteride, ~40% as metabolites). Terminal elimination T½ ~5 weeks at steady state. Serum concentrations remain detectable (>0.1 ng/ml) for up to 4–6 months after discontinuation.

5.3 Preclinical safety data

Silodosin: Thyroid follicular cell tumours in male rats (TSH-mediated; not seen in clinical trials). Mammary adenocarcinomas in female mice (prolactin-mediated; elevated prolactin not observed in clinical trials). No mutagenic or genotoxic potential in standard assays. Reversible male fertility effects at ≥2× MRHD.

Dutasteride: Leydig cell adenomas in rat testes at 135× MRHD. Benign hepatocellular adenomas in female mice at 290× MRHD. Reversible male fertility effects at ≥0.1× MRHD (dose-and time-dependent). Feminisation of male foetuses at ≥2.5 mg/kg/day in rats. No genotoxic potential. Reversible CNS toxicity in rats and dogs at exposures 315–425× clinical exposure.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the hard gelatin capsule:

No.	Excipient	Specification
1	Lactose monohydrate (excipient with known effect)	BP
2	Microcrystalline cellulose (PH-102)	USP
3	Crospovidone (Polyplasdone XL-10)	IH
4	Isopropyl alcohol	BP
5	Dichloromethane (methylene dichloride)	BP
6	Magnesium stearate	BP
7	Mannitol	BP
8	Pregelatinized starch	USP
9	Sodium lauryl sulphate	BP
10	E.H.G capsule blue/white size "0"	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/CTD12087/25081

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