U NOVARTIS

Hypertension Patient Case - Jillian Image



Image



• Meet Jillian*

• Why EXFORGE?

Meet Jillian*

Age: 52

BMI: 31

Medical History:

- Hypertension diagnosed 1 year ago
- Obstructive sleep apnoea (on CPAP)
- Family history of cardiovascular disease
- Pre-diabetes

Current antihypertensive medications:

• DIOVAN (valsartan 160 mg)

At current clinic visit:

• **BP:** 156/98 mmHg

Image



Background:

- Works as a night-shift nurse
- Reports fatigue and poor sleep due to shift work, compounded by sleep apnoea
- Struggles with diet and consistent physical exercise due to her work schedule
- Sometimes misses evening medication dose, particularly while working night shift, or when her routine is disrupted
- Expresses that she is "trying her best" and is frustrated that her BP remains uncontrolled

Image

Jillian* is experiencing both clinical and practical challenges to achieving BP control

Her current profile meets several indicators for therapy escalation:

- Persistent high BP (>140/90 mmHg) despite periods of adherance to monotherapy
- Multiple cardiovascular risk factors including obesity, pre-diabetes and family history
- Target organ involvement risk, with sleep apnoea potentially contributing to BP dysregulation
- Suboptimal adherence related to work lifestyle and dosing complexity, undermining control
- Lifestyle limitations preventing reliable self-management, making simplicity of treatment an important consideration

Jillian's* treatment was escalated to EXFORGE (amlodipine/valsartan)

— a once-daily, single-pill combination.

• Meet Jillian*

• Why EXFORGE?

EXFORGE addresses Jillian's* challenges to BP control

Image



Proven efficacy^{2,3}

Clinical data shows people like Jillian* achieving BP control[†] at 16 weeks^{‡#a2,3}

Image



Dual mechanism of action^{2,3}

Targets both vascular resistance and RAAS pathway, improving BP control^{‡‡} in people like Jillian* where monotherapy has failed^{a2,3}

Image



Once-daily dosing²

Supports simplified regimens for people like Jillian* with adherence and lifestyle challenges

 † BP control: <140/90 mmHg or <130/80 mmHg for diabetics 3 † 72.7% of patients on EXFORGE 5/160 mg (±HCTZ) (95% CI 68.6–76.9) 3 $^{\#}$ 74.8% of patients on EXFORGE 10/160 mg (±HCTZ) (95% CI 70.8–78.9) 3

Image



Generally well tolerated with lower incidences of oedema.§b4

§Of the 863 patients with oedema at baseline, 73.2% had mild oedema, 25.0% had moderate oedema, and 1.7% had severe oedema.⁴
After 12 weeks of treatment, 89.9% of oedema cases were considered mild, 8.8% were moderate, and 1.3% were severe.⁴

Footnotes and References

DIOVAN: In placebo-controlled trials in patients with hypertension (n=2,542) treated with DIOVAN (10–320 mg), the overall incidence of AEs was comparable with that of placebo. ⁵ AEs with an incidence of $\geq 1\%$ irrespective of causal association with DIOVAN: headache, dizziness, viral infection, upper respiratory tract infection, coughing, rhinitis, sinusitis, pharyngitis, diarrhoea, abdominal pain, nausea, fatigue, back pain, arthralgia. ⁵

EXFORGE: In five controlled clinical studies including patients (n=2,613) treated with

EXFORGE, AEs with an incidence of $\geq 1\%$ were: nasopharyngitis, influenza, headache, oedema, pitting oedema, facial oedema, oedema peripheral, fatigue, flushing, asthenia, hot flush.²

^a EX-FAST: Randomised, double-blind, multicentre study in patients with BP uncontrolled on monotherapy who were switched directly to amlodipine/valsartan 5/160 mg (n=443) or 10/160 mg (n=451). If BP was uncontrolled at week 8 (BP ≥140/90 mmHg or ≥130/80 mmHg in diabetics), open-label HCTZ 12.5 mg was added.³ If BP remained uncontrolled at week 12, HCTZ dose was increased to 25 mg (patients with controlled BP at week 8 but not at week 12 received HCTZ 12.5 mg).³ Primary efficacy endpoint was the proportion of patients with BP control (mean BP <140/90 mmHg in non-diabetic patients and <130/80 mmHg in diabetic patients) at the study endpoint (week 16). Peripheral oedema was the most frequent drug-related AE and led to discontinuation in 10 patients (2.3%) in the EXFORGE 5/160 mg group and in 41 patients (9.1%) treated with amlodipine/valsartan 10/160 mg.³

^b Prospective, open-label, post-marketing surveillance study evaluating efficacy and safety of single-pill combination of amlodipine and valsartan in adults (n=8,336) with arterial hypertension (systolic BP >140 mmHg and/or diastolic BP >90 mmHg) in realworld clinical practice.⁴ Single-pill combination (SPC) amlodipine/valsartan 5/80, 5/160, or 10/160 mg once daily was prescribed and patients were observed over a 3-month period (12 weeks).⁴ The reason for prescription of SPC amlodipine/valsartan was specified for 8,287 patients: 43.4% were non-responders to previous monotherapy, 42.9% were non-responders to previous combination therapy, 9.6% could not tolerate previous therapy.⁴

Abbreviations: BP, blood pressure; **CPAP,** continuous positive airway pressure; **HCTZ,** hydrochlorothiazide; **RAAS,** Renin-Angiotensin-Aldosterone System; **SPC,** single pill combination.

References

- 1. McEvoy JW et al. Eur Heart J. 2024; 45(38): 3912-4018.
- 2. EXFORGE (amlodipine/valsartan) Australian approved Product Information.
- 3. Allemann Y et al. J Clin Hypertens (Greenwich). 2008; 10(3):185-94.
- 4. Karpov Y et al. Adv Ther 2012; 29: 134-147.
- 5. DIOVAN (valsartan) Australian approved Product Information.

DIOVAN PBS Information: General benefit. This product is listed on the PBS as an angiotensin II antagonist.

EXFORGE PBS Information: Restricted benefit. Hypertension in a patient who is not adequately controlled with either an angiotensin II antagonist OR a dihydropyridine calcium channel blocker.

For DIOVAN prescribing information, please click here.

For EXFORGE prescribing information, please click here.

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