



## Xiidra®\* Product Fact Sheet

### What is Xiidra and who is it for?

Xiidra (lifitegrast ophthalmic solution 5%) is a prescription eye drop approved in Canada indicated for the treatment of the signs and symptoms of dry eye disease.<sup>1</sup> Safety and efficacy in pediatric patients younger than 17 years of age have not been established.<sup>2</sup>

Xiidra contains the active ingredient lifitegrast, and is a sterile, preservative-free, twice-daily prescription eye drop.<sup>3</sup>

### More about the signs and symptoms of dry eye disease

Eye care professionals can diagnose dry eye disease based on patient reported symptoms as well as signs which can be evaluated through various tests and patient questionnaires.<sup>4</sup>

Patient-reported symptoms vary, but are most commonly associated with eye dryness, and overall eye discomfort, and may also include a feeling of stinging or burning in the eyes, or episodes of fluctuating blurry vision<sup>5</sup> and excess tearing.<sup>6</sup>

### How does Xiidra work?

Xiidra works by blocking the interaction between two types of proteins that can cause inflammation in dry eye disease.<sup>7</sup>

### What clinical data supported the approval of Xiidra?

- The approval of Xiidra is based on the largest clinical program for an investigational-stage dry eye disease candidate to date with more than 2,500 patients.<sup>8</sup> The program consists of five randomized, placebo-controlled clinical trials and includes one Phase 2 study, three Phase 3 efficacy and safety studies (OPUS-1, OPUS-2 and OPUS-3), and one long-term Phase 3 safety study (SONATA).
- A numeric reduction in patient-reported eye dryness score (EDS) favouring Xiidra was seen in all four safety and efficacy studies at week six and week 12 (the week six results were not part of the primary or key secondary analyses in three studies). In two clinical trials, symptom improvement was noted at two, six and 12 weeks.<sup>9</sup>

### What role does Xiidra play in the treatment of dry eye disease?

Xiidra is the first new treatment option in seven years<sup>10</sup> for eye care professionals to consider for patients diagnosed with dry eye disease. Patients with dry eye disease who used Xiidra saw symptom improvement as little as two weeks in two of four studies.<sup>11</sup>

### Important Safety Information

The most common side effects of Xiidra include irritation where the drops are applied to the eyes and altered taste sensation (dysgeusia).<sup>12</sup> To help avoid eye injury or contamination of the solution, do not touch the container tip to your eye or any surface. If you wear contact lenses, remove them before using Xiidra and wait for at least 15 minutes before placing them back in your eyes.<sup>13</sup>

Xiidra is contraindicated in patients who are hypersensitive to the drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Product Monograph.



You are encouraged to report negative side effects of prescription drugs to Health Canada. You can [report online](#) or call 1-866-234-2345 (toll-free).

For additional information, visit [shirecanada.com](http://shirecanada.com) for the full Prescribing Information including Patient Information.

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## References

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- <sup>1</sup> Xiidra product monograph. December 22, 2017.
- <sup>2</sup> Xiidra product monograph. December 22, 2017.
- <sup>3</sup> Xiidra product monograph. December 22, 2017.
- <sup>4</sup> Canadian Ophthalmological Society. Dry eyes. <http://www.cos-sco.ca/vision-health-information/conditions-disorders-treatments/corneal-diseases/dry-eyes/>. Accessed December 14, 2017.
- <sup>5</sup> Gayton, J. (2009). "Etiology, prevalence, and treatment of dry eye disease". Clinical Ophthalmology. 3: 405–412.
- <sup>6</sup> Canadian Ophthalmological Society. Dry eyes. <http://www.cos-sco.ca/vision-health-information/conditions-disorders-treatments/corneal-diseases/dry-eyes/>. Accessed December 14, 2017.
- <sup>7</sup> Xiidra product monograph. December 22, 2017.
- <sup>8</sup> Xiidra product monograph. December 22, 2017.
- <sup>9</sup> Xiidra product monograph. December 22, 2017.
- <sup>10</sup> Health Canada. <https://health-products.canada.ca/dpd-bdpp/dispatch-repartition.do>. Restasis DIN #02355655. Accessed December 15, 2017.
- <sup>11</sup> Xiidra product monograph. December 22, 2017.
- <sup>12</sup> Xiidra product monograph. December 22, 2017.
- <sup>13</sup> Xiidra product monograph. December 22, 2017.