Indication

Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

Important Safety Information

• Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

Please see Full Prescribing Information in pocket.
# LASTING RELIEF THAT CAN START AS EARLY AS 2 WEEKS

Xiidra reduced symptoms of eye dryness at 2 weeks in 2 out of 4 studies, with improvements observed at 6 and 12 weeks in all 4 studies.

### Mean percent change from baseline in Eye Dryness Score (EDS) over 12 weeks

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Week 2</th>
<th>Week 6</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY 1</td>
<td>Xiidra</td>
<td>-1.5</td>
<td>-1.9</td>
<td>-2.2</td>
</tr>
<tr>
<td></td>
<td>Vehicle</td>
<td>-2.1</td>
<td>-2.0</td>
<td>-1.7</td>
</tr>
<tr>
<td>STUDY 2</td>
<td>Xiidra</td>
<td>-2.5</td>
<td>-2.3</td>
<td>-2.2</td>
</tr>
<tr>
<td></td>
<td>Vehicle</td>
<td>-2.6</td>
<td>-2.6</td>
<td>-2.4</td>
</tr>
<tr>
<td>STUDY 3</td>
<td>Xiidra</td>
<td>-2.5</td>
<td>-2.5</td>
<td>-2.5</td>
</tr>
<tr>
<td></td>
<td>Vehicle</td>
<td>-2.4</td>
<td>-2.3</td>
<td>-2.1</td>
</tr>
<tr>
<td>STUDY 4</td>
<td>Xiidra</td>
<td>-2.5</td>
<td>-2.5</td>
<td>-2.5</td>
</tr>
<tr>
<td></td>
<td>Vehicle</td>
<td>-2.4</td>
<td>-2.3</td>
<td>-2.1</td>
</tr>
</tbody>
</table>

Based on ANCOVA model adjusted for baseline value in Study 1, and ANCOVA model adjusted for baseline value and randomization stratification factors in Studies 2-4. All randomized and treated patients were included in the analysis and missing data were imputed using last-available data. In Study 1, one Xiidra-treated subject who did not have a baseline value was excluded from analysis.

*In some patients with continued daily use. One drop in each eye, twice daily (approximately 12 hours apart).†

Indicates relative difference compared to vehicle.

Pivotal trial data: The safety and efficacy of Xiidra were assessed in four 12-week, randomized, multicenter, double-masked, vehicle-controlled studies (N=2,133). Patients were dosed twice daily. Use of artificial tears was not allowed during the studies. The study end points included assessment of signs (based on Inferior Fluorescein Corneal Staining Score [ICSS] on a scale of 0.0 to 4.0) and symptoms. Eye dryness score was rated by patients using a visual analogue scale (0=none, 100=worst possible discomfort).

Effects on signs of dry eye disease: A larger reduction in ICSS favoring Xiidra was observed at 12 weeks.

### NOTABLE IMPROVEMENTS IN SIGNS OF DRY EYE DISEASE

In 3 out of 4 studies, a larger reduction in ICSS favoring Xiidra was observed at 12 weeks.

ICSS: 0=no staining, 1=few/rare punctate lesions, 2=discrete and countable lesions, 3=lesions too numerous to count, but not coalescent, 4=coalescent.

Mean Inferior fluorescein Corneal Staining Score (ICSS) over 12 weeks

Based on ANCOVA model adjusted for baseline value in Study 1, and ANCOVA model adjusted for baseline value and randomization stratification factors in Studies 2-4. All randomized and treated patients were included in the analysis and missing data were imputed using last-available data. In Study 2, one vehicle-treated subject who did not have a study eye designated was excluded from analysis.

Vehicle=placebo.

Effects on signs of dry eye disease: At day 84, a larger reduction in ICSS favoring Xiidra was observed in 3 of the 4 studies.

Important Safety Information (cont)

- In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discomfort, eye pruritus and sinusitis.

Please see Full Prescribing Information in pocket.
MAKE XIIDRA YOUR FIRST CHOICE

When artificial tears aren’t enough, consider prescribing Xiidra for appropriate patients\textsuperscript{1-3}

Xiidra can offer fast and lasting relief of symptoms and improvement in signs of dry eye disease\textsuperscript{3}

Xiidra is covered on 88\% of commercial plans, of which 66\% do not have restrictions\textsuperscript{4}

Important Safety Information (cont)

\begin{itemize}
\item Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.
\item Safety and efficacy in pediatric patients below the age of 17 years have not been established.
\end{itemize}

Please see Full Prescribing Information in pocket.


XIIDRA, the XIIDRA logo and ii are registered trademarks of Novartis AG.