Slow myopia progression.[1] Protect their future.*

ryjunea®

0.1mg/ml atropine sulfate
eye drops, solution

The first and only approved low-dose atropine, proven to slow progression of paediatric myopia.[1,2]

Ryjunea® is indicated for slowing the progression of myopia in paediatric patients. Treatment may be initiated in children aged 3–14 years with a progression rate of 0.5 D or more per year and a severity of -0.5 D to -6.0 D.[1]

*From sight-threatening complications. Each dioptre lost through myopia increases the risk of: myopic maculopathy (58%), retinal detachment (30%), posterior subcapsular cataract (21%) and open-angle glaucoma (20%).[3]

The individual in this image is a model and not an actual patient.

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This material is intended for healthcare professionals in the United Kingdom only.
QR code for the prescribing information is located on the back page.
Ryjunea® has a dosage of 0.1mg/ml, referred to as 0.01% concentration throughout. D: dioptre.

Santen

Meet Sofia:
A 6-year-old girl with myopia

- Sofia wants to be a helicopter pilot
- Both her parents have high myopia*
- Sofia is currently wearing single-vision glasses
- **Over 1 year, Sofia's myopia has progressed a further –0.75 D**

Clinical characteristics:

Myopia	–2.25 D
Astigmatism	1.25 D
Anisometropia	0.75 D
BCVA Snellen†	20/32

Hypothetical patient case. The individual in this image is a model and not an actual patient.

THE CHOICES WE MAKE TODAY, CAN SHAPE THE FUTURE FOR CHILDREN TOMORROW[3]

*High myopia is classified as a spherical equivalent refractive error of ≤–6.0 D when ocular accommodation is relaxed.[4]
†After correction.
BCVA: best-corrected visual acuity; D: dioptre.

Ryjunea® is the first and only approved LDA, proven to slow progression of paediatric myopia[1,2]

Ryjunea® is supported by STAR,* currently the largest and longest RCT of atropine for myopia control in a predominantly White population[2†]

Efficacy[2]

- Clinically proven to slow myopia progression[2*]
- Primary endpoint statistically significant reduction in APR over 2 years compared with vehicle[2]

Novel formulation[2]

D2O offers:

- Enhanced stability and optimised pH[2]
- Increased bioavailability and an extended shelf life[2]

Acceptable safety profile[2]

- Long-term safety over 24 months[2]
- Only 0.7% of patients discontinued treatment due to TEAEs[2]

Convenience[1,2]

Ryjunea® can fit into the everyday lives of children with:

- Just one drop in each eye nightly[1]
- High compliance rates[2]

RYJUNEA®: YOUR CLINICALLY PROVEN SOLUTION TO SLOW PROGRESSION IN PAEDIATRIC MYOPIA[1,2]

*A randomised, double-masked, vehicle-controlled, Phase III clinical trial conducted over 48 months at 47 clinical sites across Europe and the USA. In total, 847 children aged 3–14 years were included, with a range of SE values between -0.5 D and -6.0 D.[2]

†In total, 68.5% (580/847) were White.[2]

Until now, efficacy has predominantly been demonstrated through studies conducted in Asian populations using compounded LDA, which can lead to issues with quality, stability and consistency.[2,5]

APR: annual progression rate; D: dioptre; D2O: Deuterium oxide; LDA: low-dose atropine; RCT: randomised controlled trial; SE: spherical equivalent; TEAE: treatment-emergent adverse event.

Ryjunea® is clinically proven to slow progression in paediatric myopia[2]*

PRIMARY ENDPOINT

Ryjunea® demonstrated a statistically significant reduction in the mean APR of myopia vs. vehicle[2]

29.5%

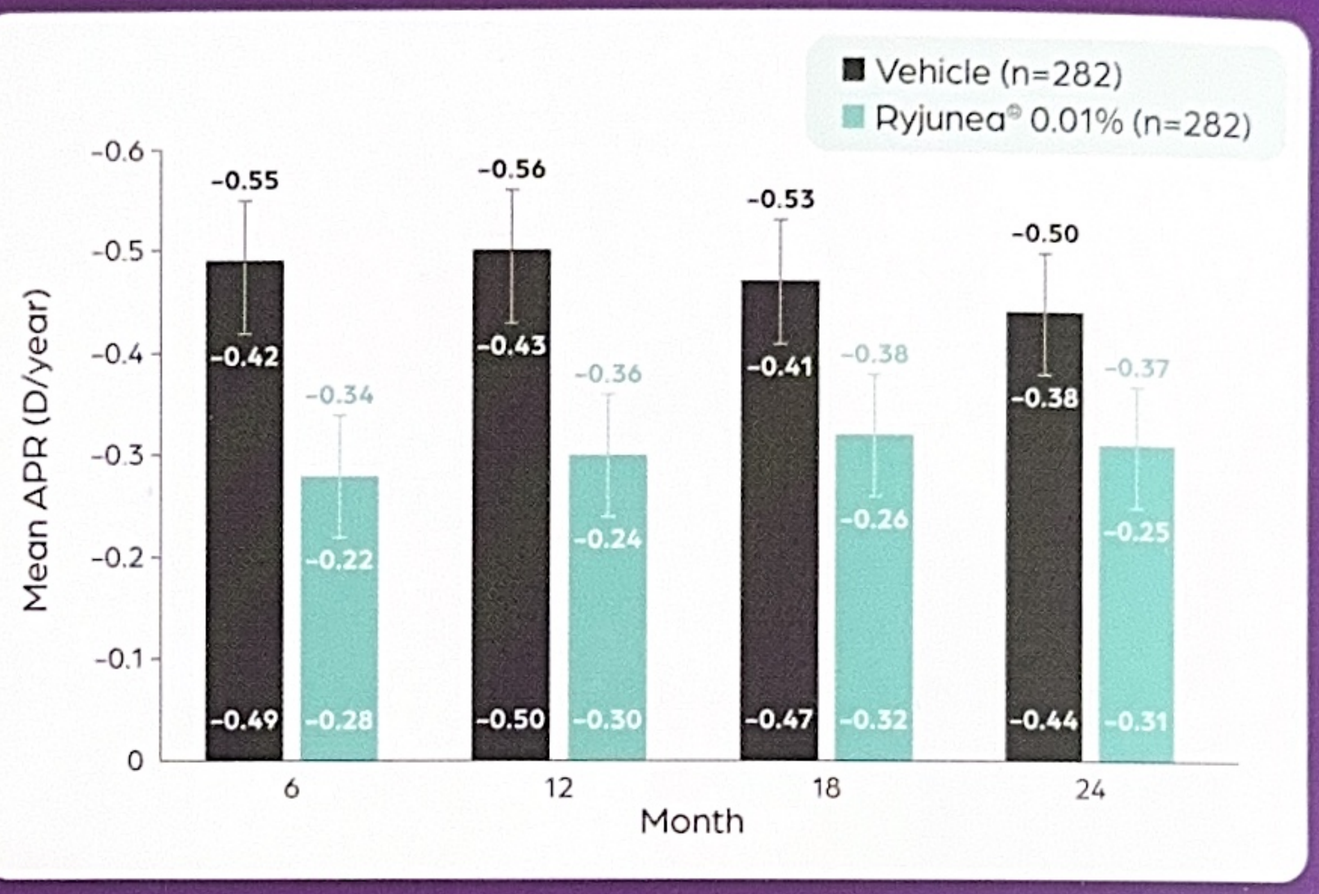
reduction in mean APR of myopia with Ryjunea® vs. vehicle at 24 months

(P=0.0003)[2]

Treatment difference:[2]

–0.13 D

(95% CI: 0.06–0.20)[2]



PRIMARY ENDPOINT (SUBGROUP)

Ryjunea® significantly reduced the mean APR of myopia **in children with progression of –0.5 D/year or worse vs. vehicle[2]**

38%

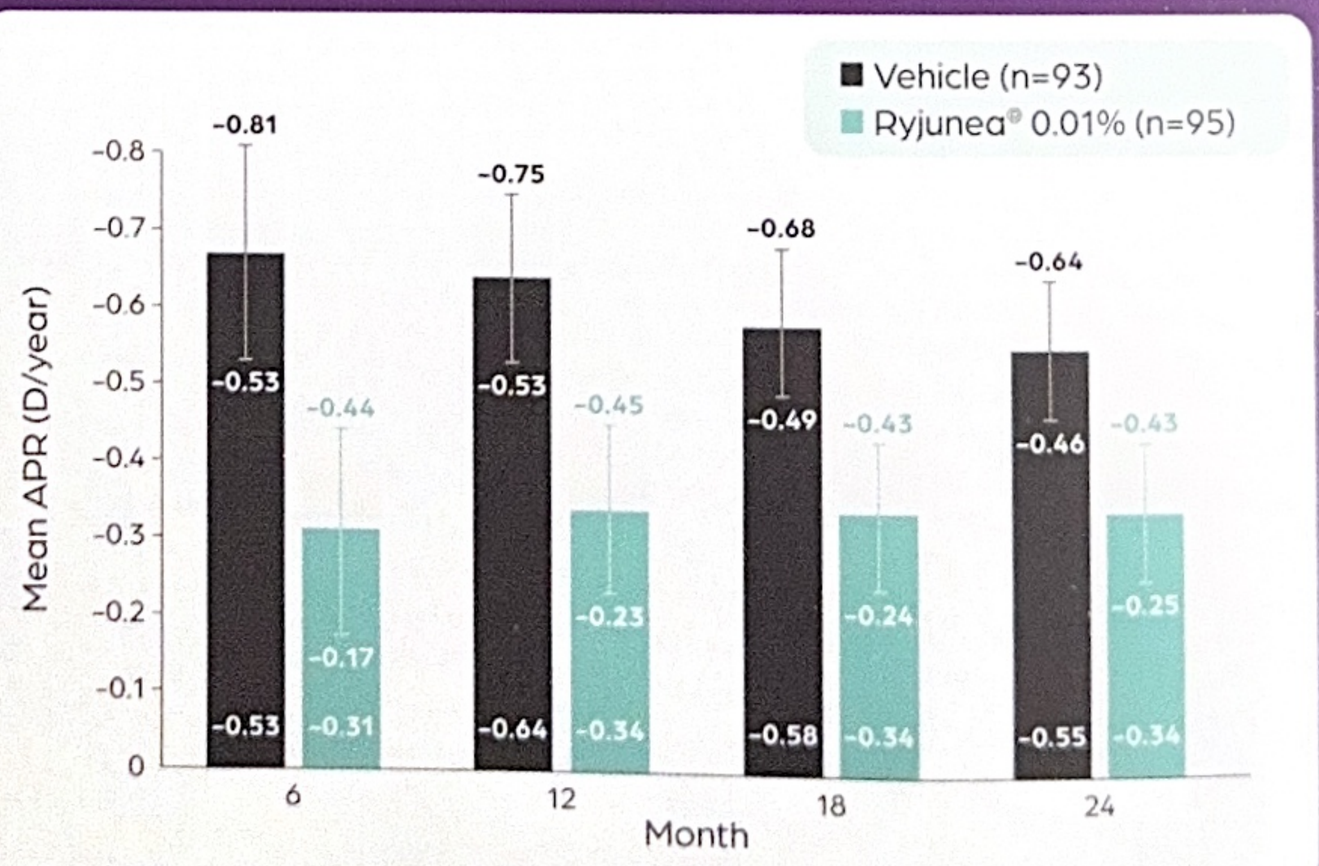
reduction in mean APR of myopia with Ryjunea® vs. vehicle at 24 months

(P<0.0001)[2]

Treatment difference:[2]

–0.21 D

(95% CI: 0.102, 0.306)[1]

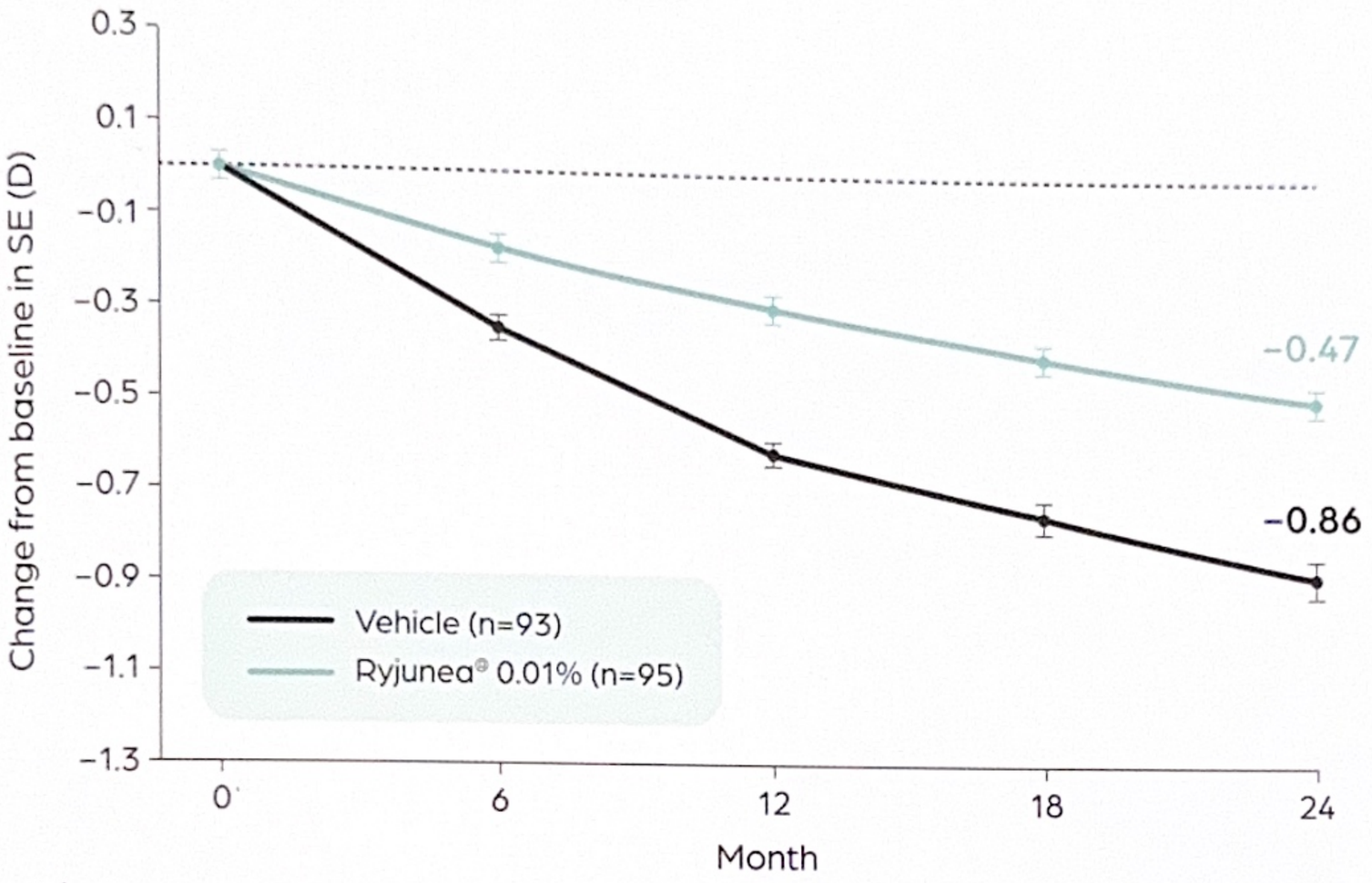


*The primary endpoint was the difference in the mean APR of myopia through 24 months between treatment and vehicle in the FAS. Measured by cycloplegic autorefraction; APR is defined as the negative change in SE (averaged over both eyes) from baseline divided by the number of days since baseline × 365.25.[2]

APR: annual progression rate; CI: confidence interval; D: dioptre; FAS: full analysis set; SE: spherical equivalent.

EXPLORATORY ENDPOINT

Ryjunea® reduced the mean change from baseline in SE **in children with a progression rate of –0.5 D/year or worse vs. vehicle**[1]



Number of subjects:					
Ryjunea 0.01%	95	82	85	85	82
Vehicle	93	85	87	81	76

45%

reduction in mean change in SE with Ryjunea® vs. vehicle at 24 months

(P=0.0001)[2]

Treatment difference:[2]

–0.39 D

(95% CI: 0.19–0.59)[2]

CI: confidence interval; D: dioptre; SE: spherical equivalent.

Ryjunea® contains the novel excipient D2O to enhance stability and consistency[2]

- LDA formulations are known to be intrinsically unstable and susceptible to hydrolysis[2,5]
- Compounded LDA shows considerable variation in potency and stability because of differences in formulation, storage conditions and handling practices[5,6]

Instead of purified water, Ryjunea® includes the excipient D2O in its formulation to:[2]

Enhance chemical stability
by reducing its degradation by hydrolysis[2]

Optimise pH
at a more stable value,[2,7,8*] with a system that is closer to the physiological pH of the precorneal tear film[2]

Extend shelf life[2†]
without requiring any special storage conditions[1]

Increase ophthalmic bioavailability[2]
which may allow for less frequent dosing[9]

*It is well established that the stability is enhanced if maintained at low pH values.[7,8] The pH of Ryjunea® is 5.4.[1]
†Ryjunea® can be stored for up to 2 years unopened, and for up to 4 weeks after first opening.[1]
D2O: deuterium oxide; LDA: low-dose atropine.

Ryjunea® offers an acceptable safety profile for the long term (24 months)[2]

Discontinuation rates were similar between groups and **remained low after 24 months** – with only 0.7% receiving Ryjunea® stopping treatment due to TEAEs[2*]

Overall rates of TEAEs were similar between Ryjunea® and the H2O-based vehicle[2]

	Vehicle (n=282) n(%)	Ryjunea® (0.01%) (n=282) n(%)
Any TEAE	183 (64.9)	173 (61.3)
Non-ocular TEAEs	134 (47.5)	111 (39.4)
Ocular TEAEs	113 (40.1)	121 (42.9)
Serious TEAEs	5 (1.8)	4 (1.4)

The most common TEAEs with Ryjunea® were photophobia (24.1%), headache (10.6%), blurred vision (10.3%) and instillation-site irritation (6.7%)[2]

Ocular TEAEs were mostly mild in severity – with **no serious** treatment-related events reported[2]

*Any TEAE leading to discontinuation occurred in 0.7% of participants receiving Ryjunea® and 0.7% of participants receiving vehicle.[2]
TEAE: treatment-emergent adverse event.

DON'T DELAY – SLOW PAEDIATRIC MYOPIA PROGRESSION WITH RYJUNEA®[1,2]

Scan the QR code to access the full Ryjunea® prescribing information

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References

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