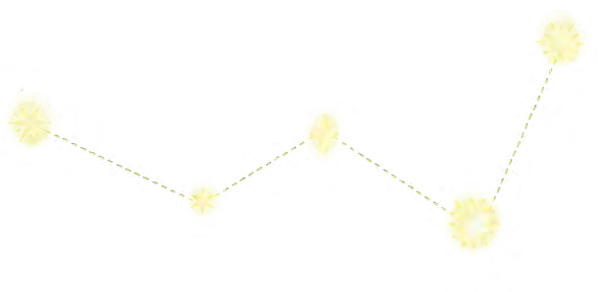
Menicon BLOOM™

WHITE PAPER ON

Menicon Bloom™

Myopia Control Management System

April 2022



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Introduction

The prevalence of myopia has increased in recent decades to affect approximately 30% of the world's population and it has been estimated to significantly increase to affect about 50% of the world's population by 2050 (**Figure 1**).[1] Of particular concern is that even relatively low degrees of myopia may be associated with an increased risk of sight-threatening ocular complications, with the risk increasing substantially with higher levels of myopia.[2–8] Concerned with the growing incidence of myopia and its health consequences worldwide, Menicon Co., Ltd. has dedicated significant resources to develop ***Menicon Bloom Myopia Control Management System***, a holistic approach for myopia control management. This system features ***Menicon Bloom Day***, an extended depth of focus daily disposable soft contact lens with CE-approval specifically for myopia progression control, and ***Menicon Bloom Night***, the first CE-approved orthokeratology contact lens for myopia control management in Europe. Accompanying these contact lens products are lens care solutions (i.e., ***Menicon Bloom Care*** and ***Menicon Bloom Progent*** for ***Menicon Bloom Night***) to ensure optimal hygiene and safety with the lenses. Also included are new digital tools (***Menicon Bloom Easyfit*** and ***Menicon Bloom App***) to help with the lens fitting and to enhance communications between the patient and the eye care professional for closer monitoring of each individual myopia control journey. Menicon was the first company in the world to offer both soft and orthokeratology contact lens devices specifically approved for myopia control in Europe within the context of a comprehensive treatment system. The rationale for the launch and the details of this myopia control management system are explained in this white paper.

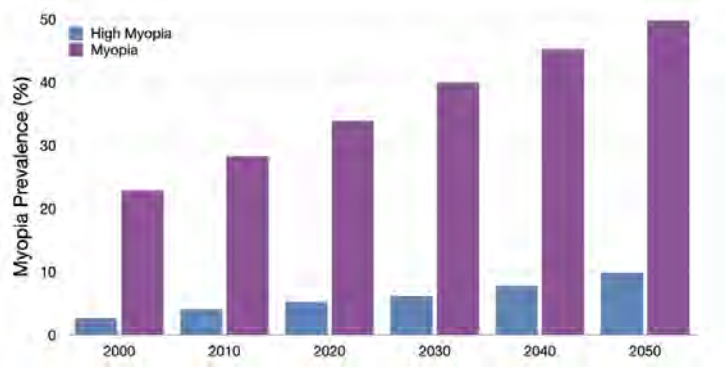

Figure 1. Graph showing the estimated prevalence of myopia (spherical equivalent refractive error ≤-0.50 D when ocular accommodation is relaxed) and high myopia (spherical equivalent refractive error ≤-6.00 D when ocular accommodation is relaxed) for each decade from 2000 through 2050. Data replotted from Holden et al.[1]

What Is Myopia?

Our understanding of myopia has increased substantially with the publication of a number of white papers providing global consensus on different aspects related to myopia in 2019[9–15] and more recent updates in 2021.[13,16–21] The International Myopia Institute has defined myopia, also known as near- or short-sightedness, as a *'refractive error in which rays of light entering the eye parallel to the optic axis are brought to a focus in front of the retina when ocular accommodation is relaxed. This usually results from the eyeball being too long from front to back, but can be caused by an overly curved cornea and/or a lens with increased optical power'* (**Figure 2**).[9] Myopia typically causes blurred distance vision while objects at near may appear clear. It normally develops during childhood and progresses until the mid to late teenage years, with younger children and females showing greater annual rates of myopia progression.[22,23]

Myopia is one of the most common refractive errors and a major cause of vision impairment worldwide.[1,24] The prevalence of myopia in young adolescents has been increasing in recent decades to about 30% in industrialized societies of the West and epidemic levels of over 90% in some parts of Far East Asia.[1,25–30] Globally, it is recognized as a significant public health concern associated with increased ocular-related morbidity, considerable healthcare costs, indirect costs such as lost productivity and reduced quality of life.[2,8,9,24,31–34] Of particular concern is the association of increasing levels of myopia with a higher risk of

potentially blinding ocular pathologies such as glaucoma, myopic maculopathy, and vitreous and retinal detachments.[2–8] Furthermore, high myopia has also been found to contribute to a general degradation of quality of life due to psychological, cosmetic and practical reasons.[35]

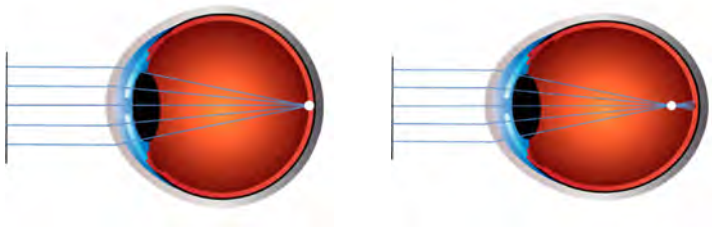

Figure 2. The image on the left shows the refractive status of an emmetropic eye where light rays entering the eye focus on the retina, whereas the image on the right represents a myopic eye where light rays entering the eye focus in front of the retina causing blurred distance vision.

What Causes Myopia?

The underlying cause behind the onset and progression of myopia is believed to be a combination of genetic and environmental factors.[11] Risk factors include ethnicity, number of myopic parents, time engaged in close work, lack of time spent outdoors, and country and location (i.e., urban/rural) of residency.[10,20,36–43]

Pathology of Myopia

Traditionally, myopia has been broadly perceived, apart from a very small minority of high myopes, as simply an optically correctable inconvenience.[44] However, the perception that 'physiological myopia' as just an 'optical inconvenience' has changed over the last two decades as increasing scientific evidence has established a clear link between increasing levels of myopia and an increased risk of a wide range of ocular pathologies, with even low levels of myopia carrying an increased risk of potentially blinding ocular complications.[2–8,45] Pathologic myopia is a major cause of irreversible visual impairment worldwide[53–57] and conditions such as myopic maculopathy and high myopia-associated optic neuropathy are already among the most frequent causes of irreversible vision loss and blindness in East Asia.[46–48] A recent systematic review and meta-analysis of studies determined that low, moderate, and high myopia were all associated with increased risks of myopic macular degeneration (MMD), retinal detachment (RD), posterior subcapsular cataract (PSC), nuclear cataract (NC), open angle glaucoma (OAG), and blindness.[45] The risk of visual impairment was strongly related to longer axial length, higher degree of myopia, and age older than 60 years (**Table 1**). Although high myopia carries the highest risk of complications and visual impairment, low and moderate myopia also have considerable risks (**Table 1**). These estimates should alert policy makers and health care professionals to make myopia a priority for prevention and treatment.

		Degree of Myopia		
		Low	Moderate	High
Ocular complication	MMD	13.57 [6.18–29.79]	72.74 [33.18–159.48]	845.08 [230.05–3104.34]
	RD	3.15 [1.92–5.17]	8.74 [7.28–10.50]	12.62 [6.65–23.94]
	PSC	1.56 [1.32–1.84]	2.55 [1.98–3.28]	4.55 [2.66–7.75]
	NC	1.79 [1.08–2.97]	2.39 [1.03–5.55]	2.87 [1.43–5.73]
	OAG	1.59 [1.33–1.91]	2.92 [1.89–4.52]	2.92 [1.89–4.52]
	Blindness	1.71 [1.07–2.74]	5.54 [3.12–9.85]	87.63 [34.50–222.58]

Table 1. Summary of the results of a systematic review and meta-analysis that determined the risk between degree of myopia, assessed in terms of spherical equivalent refractive error (SER), and myopic macular degeneration (MMD), retinal detachment (RD), posterior subcapsular cataract (PSC), nuclear cataract (NC), open angle glaucoma (OAG), and blindness. Low myopia (i.e., SER < −0.5 to > −3.00 D), moderate myopia (i.e., SER ≤ −3.00 to > −6.00 D), high myopia (i.e., ≤ −6.00 D). Risks are reported in terms of odds ratios [95% confidence intervals]. The risks for blindness are reported in participants aged >60 years. Data drawn from Haarman et al. 2020.[45]

The Health & Social Impacts of Myopia

Globally, uncorrected refractive errors represent a major cause of vision loss, particularly in developing countries, and refractive errors have been listed as one of the five priority conditions in the World Health Organizations 'Vision 2020'.[49] Myopia has a tremendous impact on individuals and society due to its lifetime of direct health expenditure, potential pathological manifestations and indirect costs such as lost productivity and reduced quality of life,[34] even in developed countries where the majority of myopes have normal visual acuity with the appropriate optical correction.[2]

The prevalence of myopia is high and rising worldwide with consequences spanning from childhood to late adult life. Recent evidence reveals that the prevalence of high myopia is growing at a faster rate than the prevalence of overall myopia.[34] This is in conjunction with rising rates of serious blinding complications associated with high myopia, notably myopic macular degeneration. Myopic maculopathy, a condition associated with significant risks of visual loss[2] and measurable reductions in quality of life,[50] is the most obvious link between myopia and ocular pathology. Quality of life is adversely affected by uncorrected myopia, high myopia, and complications of high myopia,[35,51] with high levels of myopia being associated with an impact on quality of life comparable with keratoconus.[35]

Currently, the global costs related to direct health expenditure and lost productivity as a result of myopia are in the range of several hundred billion dollars annually.[34] Unless the current trajectory for the rising prevalence of myopia and high myopia is lowered, the costs will continue to grow.

Mitigating the Risks Associated With Increased Levels of Myopia

Population growth and ageing, along with urnbanization, behavioural and lifestyle changes, is expected to dramatically increase the number of people with eye conditions, vision impairment and blindness in the coming decades.[126] Given the clear link between increasing levels of myopia as a result of an elongation of the eye and the increased risks of developing ocular pathology in the ageing eye, strategies aimed at reducing myopia and the axial elongation of the eye are likely to reduce the risk of suffering from a wide range of sight-threatening complications (**Table 1**).[17,45] Studies have estimated that the benefits of reducing the axial elongation of the eye of myopic pediatric patients as a result of contact lens wear outweigh the risks associated with the wear of contact lenses.[52,53] It has been recently estimated that between 4 and 7 patients with a mean age of 12 years need to receive myopia control treatment with contact lenses to prevent 5 years of visual impairment (assuming a mean life expectancy of 82 years), while fewer than 1 in 38 will experience a loss of vision as a result of suffering from microbial keratitis due to myopia control contact lens wear.[53] Measurement of myopia progression, especially axial elongation, is key to assessing the effectiveness of strategies aimed at reducing eye growth and, in turn, the potential to mitigate the risk of future ocular pathology in the aging eye. It has been reported that the greatest impact on eye growth and myopia progression occurs when treatment is started early and sustained over a longer period. Early intervention provides an opportunity to accumulate treatment effects over more years during which the eye would be growing, resulting in a greater total treatment benefit.[54]

Shifting the trajectory of myopia requires a coordinated global effort and success has already been demonstrated with some optical, environmental, and pharmaceutical strategies to prevent the onset and/or effectively slow the progression of myopia.[34] An early and appropriate intervention mitigates the risks and consequences related to uncorrected vision. More importantly, it can reduce the risk of the eye progressing to higher levels of myopia and have a positive impact on reducing the public health burden.

How Can Myopia Be Detected and Controlled?

Qualified eye care professionals can diagnose myopia through an eye examination. Myopia has historically been managed via correction of the refractive error with optical interventions. Spectacles are the easiest and most popular method of correcting refractive myopia followed by contact lenses.[55–57] Refractive surgery, which permanently changes the shape of the cornea, is usually indicated in early adulthood for patients with stable and relatively low myopia. Whilst all these strategies employ optical mechanisms

designed to correct a patient's refractive state by focusing light on the retina to improve distance vision, these remedies are not intended to control myopia progression. On the contrary, in some cases these optical devices may exacerbate the progression of myopia.[10,15,58] There is evidence indicating myopia can be mitigated by having children spend more time outdoors and through the use of specialized optical devices and medicines.[10,15] There is strong scientific evidence from case reports, retrospective studies, prospective clinical trials, systematic reviews and meta-analyses that center-distance multifocal soft contact lens wear and overnight orthokeratology contact lens wear are effective treatment options for myopia control in children and young adults.[10,15,58–61] Currently, there are several treatment options that have official regulatory approval for myopia control.[14]

Menicon Bloom Myopia Control Management System – How Does It Work?

The ***Menicon Bloom Myopia Control Management System*** was carefully developed to provide eye care professionals worldwide with a variety of high quality, officially approved (i.e., on-label) tools to address the myopia epidemic. This myopia control management system encompasses both soft and orthokeratology contact lens devices, which can be conveniently worn either during the day or night (***Menicon Bloom Day*** and ***Menicon Bloom Night***, respectively), thus making it one of the most comprehensive regulatory approved myopia care therapies available today. Menicon also believes that communication is a key factor to success with a long term myopia control treatment which is why the ***Menicon Bloom Myopia Control Management System*** also includes new, innovative digital tools called ***Menicon Bloom Easyfit*** and the ***Menicon Bloom App***.

Inspired by advanced camera optics, ***Menicon Bloom Day*** exclusive design uses extended depth of focus technology to provide a smooth transition in refractive power from a central zone that provides sharp distance vision to a peripheral zone that generates relative plus power. The gradual and continuous change in lens power from the center to the periphery of the lens has been carefully engineered to impose myopic defocus on the peripheral retina. This provides a putative stimulus to slow eye growth, while preventing simultaneous image formation on the retina and allowing for sharp, crisp vision at all distances (**Figure 3**).[62–64] ***Menicon Bloom Day*** features one universal lens design for optimal fit efficiency. The ***Menicon Bloom Day*** higher active add power of up to +3.00D has been designed to create significant peripheral myopic defocus that provides clinically relevant levels of myopia control efficacy compared to other center-distance multifocal contact lens designs.[10,59,63,65] Add powers of +3.00D or more have been shown to create a significant relative myopic shift in peripheral refraction relative to central refraction.[66] Through this unique extended depth of focus technology, ***Menicon Bloom Day*** daily disposable soft (i.e., etafilcon A) contact lenses are indicated for daily wear for the correction of refractive myopia and myopia progression control. The lens may be worn by persons who exhibit astigmatism of up to 1.00D that does not interfere with visual acuity although higher amounts of cylinder may be considered individually.

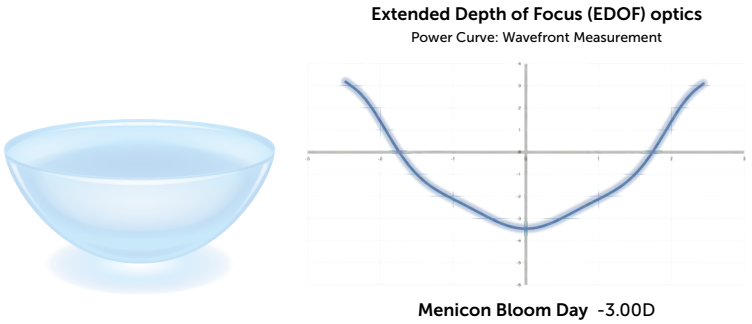

Figure 3. Menicon Bloom Day exclusive design for myopia progression control featuring extended depth of focus technology.

Menicon Bloom Night therapy involves the overnight wear of a specially designed orthokeratology contact lens manufactured in hyper oxygen permeable Menicon Z material that ensures optimal corneal oxygenation for comfortable and safe contact lens wear.[67–71] The treatment temporarily changes the

shape of the cornea by flattening and steepening the central and mid-peripheral corneal curvatures, respectively. These corneal changes occur overnight and reduce refractive error, thus eliminating the need to wear contact lenses throughout the waking hours after lenses are removed.[72] The new corneal shape provides a particular optical path for incoming light that counters the ocular growth response associated with myopia development (**Figure 4**).[59] Studies conducted with ***Menicon Bloom Night*** lenses have found significant changes in high-order ocular aberrations,[73,74] with the increase in positive spherical aberration induced by the wear of these lenses[75] presumably being responsible for its well-established effectiveness in reducing the axial elongation of the eye.[76–78] Through this mechanism, ***Menicon Bloom Night*** is indicated for the correction of refractive myopia and for control of myopia when prescribed and managed by a qualified eye care professional. ***Menicon Bloom Night*** myopia control therapy is currently available in two different contact lens designs: ***Menicon Bloom Night*** and ***Menicon Bloom Night*** Toric. Both lens designs can correct up to -4.00D of myopia, with ***Menicon Bloom Night*** Toric providing additional options for correcting higher levels of corneal and refractive astigmatism.

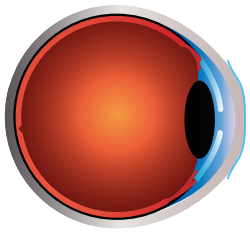

Figure 4. Menicon Bloom Night innovative orthokeratology contact lens design for myopia control fitted on an eye. Upon lens removal, the treatment provides a new corneal shape that counters the ocular growth response associated with myopia development.

The recommended care solution for ***Menicon Bloom Night*** contact lenses is ***Menicon Bloom Care***, a multipurpose solution with a demonstrated wide spectrum of disinfection against pathogenic microorganisms.[79–81] The solution comes in a unique bottle shape and material for improved handling by children. ***Menicon Bloom Care*** is also manufactured with significantly less plastic consistent with Menicon's commitment towards sustainable development goals (https://www.menicon.com/corporate/sdg/). Additionally, to ensure safe and comfortable lens wear the use of ***Menicon Bloom Progent***, an outstanding protein remover, disinfectant and intensive cleaner,[82] is recommended in combination with ***Menicon Bloom Care***.

Menicon Bloom Easyfit is Menicon's user-friendly, cloud-based lens fitting and monitoring tool for eye care professionals. It facilitates the collection of the patient's myopia-related information and the calculation of the most suitable ***Menicon Bloom*** lens for each individual eye. The different workflows displayed with each patient visit guides the eye care professional through the examination process and helps to ensure the most important clinical information is evaluated at each visit. The information is retained and maintained on the software for easy continuity of treatment and understanding of treatment history. The software also includes a myopia monitoring feature -the myopia prognosis chart- that helps the practitioner effectively track and manage their patient's treatment with both ***Menicon Bloom Night*** and ***Menicon Bloom Day***.

The ***Menicon Bloom App*** is a unique, intuitive mobile phone application created specifically to enhance communication between the patient and eye care professional. It was designed to help support and guide the patient through their myopia journey by providing regular touchpoints with them. The ***Menicon Bloom App*** helps foster the correct behavioural patterns related to compliance by asking patients about their experiences with the lenses and providing tips for improvement. Eye care professionals can check their patients' responses to the ***Menicon Bloom App*** on ***Menicon Bloom Easyfit*** so they can be alerted to any issues the patient may be facing prior to their next appointment. The ***Menicon Bloom App*** can also be used to facilitate direct communications between the patient and eye care professional or practice to help address any questions the patient may have.

Is Menicon Bloom Efficacious, Safe & Acceptable?

Comprehensive scientific evidence collected over the years has supportted the efficacy, safety and acceptance of ***Menicon Bloom Day*** and ***Menicon Bloom Night*** as succesful treatment options for myopia control management. The latter has been independently confirmed by notified bodies in Europe ultimately granting the treatments CE-approval for the specific indication of myopia control.

Efficacy

A retrospective case series analysis from 10 practice locations in the US, which analyzed data from 32 patients (ages 6–19 years), has shown ***Menicon Bloom Day*** substantially slows myopia progression in children.[83] A follow-up retrospective analysis involving 15 practice locations in the US, which analyzed data from 192 patients who wore ***Menicon Bloom Day*** lenses for about 6 years, further supported the efficacy of this unique myopia control lens in slowing myopia progression.[84] Additionally, this unique extended depth of focus contact lens has also shown to correct peripheral hyperopia, the putative stimulus responsible for myopia progression,[85] and improve amplitude and lag of accommodation by 1.00D and 0.50D, respectively.[86]

Several peer-reviewed studies specifically conducted with ***Menicon Bloom Night*** for myopia control treatment have demonstrated significant levels of efficacy,[76–78] even following long periods of contact lens wear.[87]

Safety

Like any other treatment, contact lens wear can be associated with the development of adverse events and complications. However, recent large studies, including systematic reviews and meta-analyses, have demonstrated ***Menicon Bloom Day*** and ***Menicon Bloom Night*** type contact lenses, if fitted correctly by an eye care professional according to the manufacturer's instructions, are safe to use in pediatric populations.[88–92]

A review of nine prospective studies specifically conducted in children 7 to 19 years old wearing soft contact lenses, which collectively represents 1800 patient years of wear, reported the incidence of corneal infiltrative events in children to be no higher than that found in adults. The incidence was found to be markedly lower in the youngest age range of 8 to 11 years in comparison with adults.[91] A more recent data analysis from six randomized myopia control trials conducted with daily disposable hydrogel (i.e., etafilcon A) contact lenses in 581 myopic children (aged 7 to 15 years at baseline) reported no significant or serious ocular adverse events, including corneal infections or serious corneal infiltrative events indicating daily disposable etafilcon A hydrogel contact lenses are safe for use in children.[92] All together, these results support the safety of ***Menicon Bloom Day*** daily disposable soft contact lenses for the purposes of myopia progression control in children.

Specific studies performed with ***Menicon Bloom Night*** for myopia control management have shown that the complications associated with the use of the device are typically not considered to be serious; are similar to those reported with other contact lens types; and can be managed straightforwardly in clinical practice.[76,78,93] Additionally, post-marketing surveillance and complaint trend data from the manufacturer as well as potential adverse events reported with ***Menicon Bloom Night*** orthokeratology contact lenses in external databases have been reviewed. Analysis of all this data has provided conclusive evidence supporting ***Menicon Bloom Night*** as a safe, viable myopia control treatment option.[94]

Acceptance

The fitting of contact lenses on children and young adolescents has received resistance by eye care professionals worldwide over the years. This is likely related to perceptions related to decreased capacity for minors to care for contact lenses, more fitting and training time, and inferior risk-to-benefit ratio compared to adults. The latter might explain why children and teenagers with refractive errors have

traditionally been corrected with spectacles, despite reports of successful contact lens wear in minors with different types of contact lenses, including soft, rigid gas-permeable and orthokeratology contact lenses.[95–101] More specifically, many studies have shown that minors are fully capable of using and caring for soft and orthokeratology contact lenses.[76,77,87,98,102–107] Studies have also shown that certain soft and orthokeratology contact lenses are becoming popular forms of optical correction and myopia control management for children and young adolescents.[55,56,108,109] The use of contact lenses has been found to dramatically improve how children and teenagers feel about their appearance and participation in activities, leading to greater satisfaction with their refractive error correction.[97,101] ***Menicon Bloom Day*** has been shown to perform comparably to a single vision spherical lens by providing excellent distance, intermediate and near vision at high and low contrasts, with subjective overall vision rated remarkably high.[86] Additionally, ***Menicon Bloom Day*** provided stereoacuity identical to that found with the spherical soft contact lens and a slight improvement in reading rates for smaller text.[86] Similarly, ***Menicon Bloom Night*** therapy has shown to be well-accepted by parents and to improve children' overall vision, far distance vision, symptoms, appearance, satisfaction, activities, academic performance, handling and peer perceptions in comparison to single vision spectacle lens wear.[110]

Collectively, the above studies indicate that the benefits of prescribing ***Menicon Bloom Myopia Control Management System*** to children with progressive myopia would outweigh the potential risks associated with the treatment. ***Menicon Bloom Day*** and ***Menicon Bloom Night*** have met the highest standards of safety, efficacy and quality required to grant the treatments CE approval for myopia progression control management in Europe. As such, if used correctly in accordance with the instructions for use, ***Menicon Bloom Day*** and ***Menicon Bloom Night*** provide excellent benefits for myopia control with very limited risks in children.[52,53]

Choosing the Right Treatment for Your Patient

In implementing a myopia management strategy, it is important to choose the right treatment type for your patient while also considering the best time to start and stop treatment. Research indicates that lower levels of hypermetropia at a young age is a strong risk factor for future myopia development.[111,112] Furthermore, the major factor contributing to faster myopia progression is younger age at myopia onset, with this factor being independent of gender, ethnicity, school, time spent reading and parental myopia.[10] Myopia progresses at much faster rates in children compared to teenagers, with faster progression rates typically being observed in children between 7 to 12 years of age,[113] thus supporting the need for earlier intervention with ***Menicon Bloom Myopia Control Management System*** in myopic children.[114] To maximize the myopia control effect and minimize potential rebound effects,[115] eye care professionals are recommended to continue myopia control treatment until myopia progression stabilizes, which has been reported to occur sometime between 16 to 21 years of age in early-onset myopes.[116]

Certified eye care professionals on ***Menicon Bloom Myopia Control Management System*** can conveniently choose between ***Menicon Bloom Day*** and ***Menicon Bloom Night*** for myopia control management depending on the child's refractive and biometric status as well as on visual, handling and lifestyle demands.

How & Who Can Prescribe Menicon Bloom Day & Night?

Menicon Bloom Day features one universal, easy-to-fit lens design for optimal fit efficiency that provides an 88% initial on-eye fitting success rate.[117] The fitting of ***Menicon Bloom Night*** is optimized by the use of a corneal topographer in conjunction with ***Menicon Bloom Easyfit*** software and it has demonstrated a 90% first fit success rate in children.[118] Additionally, ***Menicon Bloom App*** has been developed to enhance the monitoring and communication process between eye care professionals and patients.

Menicon Bloom Myopia Control Management System is only available for certified eye care professionals.

Why CE Approval Matters

Marketing a medical device in Europe requires a marketing authorization ('product license') for specified indications under specified conditions (e.g., target population, indication, specific use), regulated by the country's medicines and health care products regulatory agency.[119,120] This process is employed to ensure that medical products meet the highest standards of safety, efficacy and quality before being issued a marketing authorization, which allows the medical device to become available to the general public. In Europe, products that hold a marketing authorization are designated a 'CE' marking. Prescribing a licensed product outside the approved scope of use is called 'off-label' prescribing. An example of off-label prescribing occurs when a regular soft multifocal contact lens, which has an indication for vision correction for patients >40 years who experience reading difficulties, is fitted for myopia control purposes to a child where both the indication (i.e., reading difficulties vs. reducing myopia progression) and target group (i.e., adults vs. children) are different from those for which the product has been approved for. Similarly, off-label prescribing also occurs when an orthokeratology contact lens, which is approved for the correction of manifest myopia in adults, is prescribed for reducing myopia progression in children, where again both the indication (i.e., correcting manifest myopia vs. reducing myopia progression) and target group (i.e., adults vs. children) are different from those for which the product has been approved for. When prescribing a treatment for myopia control, the eye care professional should ideally start by considering all on-label products that may be available and only contemplate off-label prescribing if there are no on-label options or if approved products are not effective or appropriate.[14] In off-label prescribing, the patient must be adequately informed about the lack of product authorization and the possible existence of unknown risks.[121–125] Parents and legal guardians should be informed of all options and associated risks in order to decide whether the child should be treated with a tested and approved on-label treatment or with an off-label treatment that might give a successful result, but has unknown risks.

With the official marketing authorization for myopia control management, ***Menicon Bloom Day*** and ***Menicon Bloom Night*** have met the highest standards of safety, efficacy and quality required to grant the treatment CE approval for myopia control management in Europe. With such approval, eye care professionals can now have peace of mind with the on-label prescription of this myopia control therapy.

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