Menicon BLOOM™

White paper on

Menicon Bloom™ Myopia Control Management System

May 2019

For journalist use

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Introduction

Menicon Co., Ltd. is concerned with the growing incidence of myopia and its health consequences worldwide, and has thus dedicated significant resources to develop the Menicon Bloom Myopia Control Management System, a holistic approach for myopia control management. This system features the initial introduction of Menicon Bloom Night, the first and only CE-approved orthokeratology contact lens for myopia control management. The CE approval also allows Menicon to prepare regulatory submissions to launch Menicon Bloom Night in additional countries, including Australia, New Zealand, Hong Kong, Singapore, Malaysia and others. The rationale for the launch and the details of this myopia care therapy are explained in this white paper.

What Is Myopia?

Myopia, also known as near- or short-sightedness, is the most common refractive error and the major cause of vision impairment worldwide (1, 2). Globally, it is recognized as a significant public health concern associated with increased ocular-related morbidity and considerable healthcare costs (3-6). It affects approximately 30% of the world's population and its prevalence has been forecast to affect about 50% of the world's population by 2050 (1). 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, 7-12).

Myopia is a condition in which incoming light focuses in front of, rather than on, the retina as a result of the eye being too long for its refractive power (Figure 1) (6). This causes blurred distance vision while objects at near may appear clear. Myopia normally develops during childhood and progresses until the mid to late teenage years (13, 14), with younger children and females showing greater annual rates of myopia progression (15).

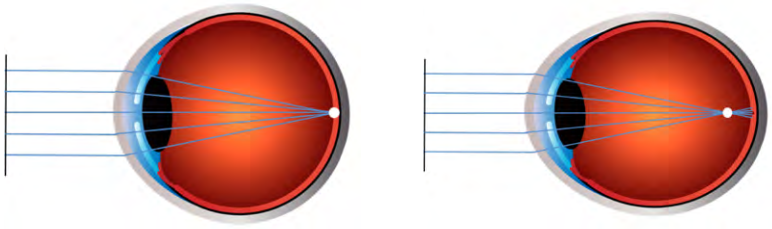

Figure 1. The image on the left shows the refractive status of an emmetropic eye where light rays entering the eye focus on the retina, whereas the image on the right represents a myopic eye where light rays entering the eye focus in front of the retina causing blurred distance vision.

What Causes Myopia?

The underlying cause behind the onset and progression of myopia is believed to be a combination of genetic and environmental factors (16). 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 (17-25). 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 (5, 26-30). Furthermore, high myopia has also been found to contribute to a general degradation of quality of life due to psychological, cosmetic and practical reasons (31).

How Can Myopia Be Detected?

Qualified eye care professionals can diagnose myopia through an eye examination. Whilst the refractive state of myopic individuals can be successfully corrected to achieve acceptable distance vision by conventional spectacles or contact lenses, these remedies are not intended to control myopia progression. On the contrary, in some cases these optical devices may exacerbate the progression of myopia (25, 32, 33). 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 (25, 33).

There is strong scientific evidence from case reports, retrospective studies, prospective clinical trials and meta-analyses that overnight orthokeratology contact lens wear is a successful treatment option for myopia control in children and young adults (32, 34, 35). There is also growing evidence on the long-term efficacy of overnight orthokeratology for myopia control (36-39). However, there are currently very limited treatment options that have official regulatory approval for myopia control (40).

How Does Menicon Bloom Night Work?

Menicon Bloom Night therapy involves the overnight wear of a specially designed orthokeratology contact lens manufactured in hyper oxygen permeable Menicon Z material to ensure optimal corneal oxygenation for safe and comfortable lens wear (41-45). 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 (46). The new corneal shape also provides a particular optical path for incoming light that counters the ocular growth response associated with myopia development (47).

Menicon Bloom Night is indicated for the correction of refractive myopia and for the 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 types 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.

Is Menicon Bloom Night Safe and Effective?

Menicon Bloom Night contact lenses have been reviewed and validated via numerous comprehensive, peer-reviewed studies related to myopia control management. These studies provide conclusive support for the safety and efficacy of this treatment for myopia control management (37, 48-59).

Safety

Like any other treatment, Menicon Bloom Night can be associated with the development of adverse events and complications. However, recent large studies, including meta-analyses and systematic reviews, have demonstrated that 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 younger populations (60-62). 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 (50, 52, 53). 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 (63).

Effectiveness

Several peer-reviewed studies specifically conducted with Menicon Bloom Night for myopia control treatment have demonstrated significant levels of efficacy (50, 51, 53). Furthermore, recent results demonstrate the successful long-term efficacy of Menicon Bloom Night at reducing myopia progression in children (37). All together, these studies have provided consistent evidence supporting the efficacy of the treatment for myopia control management.

With the accumulation of long-term and comprehensive scientific evidence over the years, Menicon Bloom Night has met the highest standards of safety, efficacy and quality required to grant the treatment CE approval for myopia control management in Europe. Menicon Bloom Night, if used correctly in accordance with the instructions for use, provides excellent benefits with very limited risks.

How Well is Menicon Bloom Night Accepted?
Menicon Bloom Night therapy has shown to be well-accepted by parents and to improve children's self-esteem in terms of physical appearance, participation in activities, academic performance and peer perception (55).

How & Who Can Fit Menicon Bloom Night?
The fitting of Menicon Bloom Night is optimized by the use of a corneal topographer to precisely measure corneal shape, in conjunction with Easyfit software, a sophisticated, user-friendly tool which accurately guides the eye care professional through the fitting process. Additionally, a specially designed mobile phone application, Menicon's Virtual Doctor, has been developed to enhance the monitoring and communication process between eye care professionals and patients. Menicon Bloom Night 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 European Medical Agency (64, 65). This process is employed to ensure that medical products meet the highest standards of safety, efficacy and quality before being issued a marketing authorization. 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 an orthokeratology contact lens, which is approved for the correction of manifest myopia in adults, is prescribed for reducing myopia progression in children, where 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 (40). In off-label prescribing, the patient must be adequately informed about the lack of product authorization and the possible existence of unknown risks (66-70). 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 Night has 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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