Miru

1day Menicon Flat Pack

PROFESSIONAL FITTING AND INFORMATION GUIDE

Miru 1day Menicon Flat Pack (hioxifilcon A) Daily Disposable Soft Contact Lens

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

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Description of Lens

The **Miru 1day Menicon Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lens is available as a single vision spherical lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The **Miru 1day Menicon Flat Pack** packaging system is designed to reduce lens handling by always presenting the lens 'convex' side up upon opening, which ensures correct lens orientation for proper eye insertion. The approximately 1 mm flat pack packaging system is easily opened and reinforces the single-use factor.

The non-ionic lens material (hioxifilcon A) is a random co-polymer of 2-hydroxyethyl methacrylate and glycerol methacrylate cross-linked with ethylene glycol dimethacrylate. It consists of 43% hioxifilcon A and 57% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint, color additive 'Reactive Blue #19', 21CFR part 73.3121. The United States Adopted Names Council (USAN) has adopted the (hioxifilcon A) name.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens. In its fully hydrated state the lens is approximately 57% water by weight. The physical properties of the lens are:

Refractive Index : 1.409 (ISO 18369-4:2006)
Light Transmission : 99% (ISO 18369-3:2006)
Surface Character : Hydrophilic
Water Content : 57% (ISO 18369-4:2006)
Oxygen Permeability at 34-36°C : 25.38 x 10^{-11} (cm^2 / sec) (mL O_2/mL×mm Hg),
(revised Fatt method)

The lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera with the following dimensions:

Chord Diameter:	14.2 mm
Center Thickness:	0.10 mm~0.20 mm
Base Curve:	8.6 mm
Powers:	+4.00 to +0.50 Diopters in 0.25 D increment -0.50 to -6.00 Diopters in 0.25 D increment -6.50 to -10.00 Diopters in 0.50 D increment

ACTIONS

In its hydrated state, the **Miru 1day Menicon Flat Pack**, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS

Intended Use:

The **Miru 1day Menicon Flat Pack** is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new lens.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **Miru 1day Menicon Flat Pack** when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients unable to follow the daily disposable lens care schedule.
- Advise patient not to wear **Miru 1day Menicon Flat Pack** while sleeping.

WARNINGS

Please reference Warnings in the Package Insert.

PRECAUTIONS

Please reference Precautions in the Package Insert.

ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended wearing schedule of **Miru 1day Menicon Flat Pack** should not be provided with this lens. All necessary precautions and warnings should be discussed and understood by the patient *(review Package Insert with the patient.)*

FITTING PROCEDURE

1. Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications).
- Collect and record baseline clinical information to which post-fitting examination results can be compared.
- Make ocular measurements for initial contact lens parameter selection.

2. Initial Lens Power Selection

1. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
2. Select the appropriate power lens and place the lens on the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.
3. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

a. To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
- Movement: The lens should provide discernible movement with:
  —Primary gaze blink
  —Upgaze blink
  —Upgaze lag
- Centration: The lens should provide full corneal coverage.

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.25 mm, lags downward about 1.0 to 1.5 mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens has settled on the eye (5-10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1-1.5 mm.

2. Characteristics of a Tight (Steep) Lens

A tight (steep) lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Loose (Flat) Lens

A loose (flat) lens sags more than 2.0 mm on upward gaze.

FOLLOW-UP CARE

1. Follow-up examinations are recommended by the eye care practitioner. They are necessary to ensure continued successful contact lens wear.
2. Prior to a follow up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and / or damage.
4. After the lens removal, conduct a thorough bio-microscopy examination.
   a. The presence of vertical corneal striate in the posterior central cornea and /or cornea neovascularization is indicative of excessive corneal edema.
   b. The presence of corneal staining and / or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and / or a poorly fitting lens.
   c. Papillary conjunctival changes may be indicative of an unclean and / or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the **Criteria of a Well-Fitted Lens** are not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

FOLLOW – UP EXAMINATIONS

- Within one week of lens dispensing
- After three weeks of lens wear
- After seven weeks of lens wear
- After each six month period of lens wear

MONOVISION FITTING GUIDELINES

1. Patient selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.50 diopters) in one eye may not be a good candidate for monovision with the **Miru 1day Menicon Flat Pack**.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

(1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
(2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 – Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 – Determine which eye will accept the added power with the latest reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Consideration

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is –2.50 diopters myopic in the right eye and –1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power
in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face of fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions has been completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight-ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the **Miru 1day Menicon Flat Pack** Patient Instructions.

LENS HANDLING (in-office cleaning)

Wash and rinse hands thoroughly, making certain that all soap residues have been rinsed away before drying with a lint-free towel. It is suggested to wet the lens while in the eye using wetting drops before removal. Always start with the right eye first in order to avoid mixing the lenses. When handling the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

To assure sterility each Flat Pack should not be opened until ready for use.
To open the Flat Pack, grasp both top and bottom foil tabs and peel them apart to fully expose the lens. Promptly pick up the lens with your fingers.

Miru 1day Menicon Flat Pack is not reused in diagnostic procedures.

CLEANING

The **Miru 1day Menicon Flat Pack** is designed as a daily disposable lens.
The lens is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a new lens.

Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times

RECCOMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to overwear the lens initially. It is important not to exceed the wearing schedule. Regular check ups, as determined by the eye care practitioner, are also extremely important. The maximum suggested wearing schedule for the **Miru 1day Menicon Flat Pack** is suggested below.

DAY	1	2	3	4	5	6 and after
HOURS	6	8	10	12	14	All waking hours

STUDIES HAVE NOT BEEN CONDUCTED TO SHOW THAT THE "Miru 1day Menicon Flat Pack" IS SAFE TO WEAR DURING SLEEP

REPLACEMENT SCHEDULE

The **Miru 1day Menicon Flat Pack** is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a new lens.

CARE FOR A STICKING(NON-MOVING) LENS

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, you should IMMEDIATELY consult the eye care practitioner.

REPORTING OF ADVERSE REACTIONS

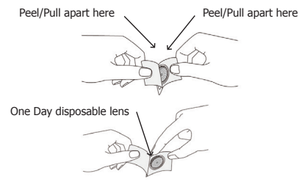
Practitioners should report any adverse reactions to **Miru 1day Menicon Flat Pack** within 5 days to the address below. Additional Package Inserts, Professional Fitting and Information Guides, and Patient Instructions are available from:

Menicon America, Inc.
Waltham, MA 02451
1-800-MENICON (1-800-636-4266)
information@menicon.com

HOW SUPPLIED/OPENED

Each lens is supplied sterile in a non-traditional packaging system, the Flat Pack, containing buffered saline solution. Each container is marked with base curve, dioptric power, diameter, Single Patient Use, Rx Symbol, Sterile Symbol, composition of the lens, manufacturing lot number and expiration date of the lens.

HOW TO OPEN



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