

## Instructions for Use: Menicon soft 72/Menisoft–mipafilcon A (72% water)

### Important

- Read the following instructions carefully before use and keep this document in a safe place for future reference.
- Always follow the instructions in this document and those of your eye care professional or practitioner for appropriate use of contact lenses and lens care products including lens cases.

### INTRODUCTION

- Menicon soft 72 is a green tinted soft hydrogel contact lens made of mipafilcon A with 72% water content. The sterile Menicon soft 72 is individually packaged in a blister case and immersed in saline solution.
- Menisoft is an aqua green tinted soft hydrogel contact lens made of mipafilcon A with 72% water content. The sterile Menisoft is individually packaged in a foil-sealed plastic container and immersed in saline solution.

### INDICATIONS

- Menicon soft 72 is intended for daily wear and correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic disease-free eyes.
- Menisoft is intended for daily wear and correction of refractive ametropia (myopia) in non-aphakic disease-free eyes.

### WEARING RESTRICTIONS

- Clean and disinfect the contact lenses after lens removal using the cleaning and disinfecting regimen recommended by your eye care professional or practitioner.
- Replace Menicon soft 72 yearly with fresh lenses.
- Replace Menisoft every month with fresh lenses.
- Be sure to consult your eye care professional or practitioner for the lens wearing schedule based on your individual needs. Always dispose of the contact lenses after the instructed wearing period. Wearing the contact lenses beyond the instructed wearing period increases the risk of eye problems.

### CONTRAINDICATIONS

Do not wear the contact lenses if you have any of the following conditions.

- Acute and subacute inflammation or infection of the anterior chamber of the eyes
- Any disease, injury, or abnormality that affects the cornea, the conjunctiva or eyelids
- Severe lacrimal secretion insufficiency (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may adversely affect the eyes by wearing contact lenses
- Allergic reactions that may be induced or exaggerated by wearing contact lenses and/or using lens care solutions
- Any active corneal infection
- Red or irritated eyes
- Incomplete corneal healing following eye surgery

### WARNINGS

Be aware of the following warnings pertaining to contact lens wear.

- Eye problems arising from wearing contact lenses and use of lens care products, such as corneal ulcers, can develop rapidly and lead to loss of vision. If you experience any discomfort in the eyes, excessive tearing, vision changes, redness in the eyes or other problems, immediately remove the lenses and consult your eye care professional or practitioner.

### PRECAUTIONS

- Handle the contact lenses with care (be careful not to drop them).
- Do not touch the contact lenses with your fingernails.
- Put in the contact lenses before applying cosmetics. Do not apply cosmetics, lotions, creams, or sprays while handling the contact lenses.
- Consult your eye care professional or practitioner before using any medicine in your eyes.
- If the contact lenses feel dry on your eyes, apply a few drops of the lubricating or rewetting solution (recommended by your eye care professional or practitioner) directly to the eyes and wait until the lenses can move freely on the eyes before removing them. If the discomfort still continues, immediately consult your eye care professional or practitioner.
- Avoid all harmful or irritating vapours and fumes while wearing the contact lenses.
- If any chemicals are splashed into the eyes, immediately flush the eyes with tap water, remove the contact lenses, and consult your eye care professional or practitioner, or visit a hospital emergency room.
- Consult your eye care professional or practitioner for instructions on wearing the contact lenses during sports or water activities, or for specific occupations.
- Do not sleep while still wearing the contact lenses.
- Follow-up visits are necessary to assure the continued health of your eyes.
- Consult your eye care professional or practitioner if you wish to change the lens type or parameters.
- Inform your medical doctor that you wear contact lenses.
- Store the contact lenses at room temperature. Do not allow the lenses to freeze.
- Consult your eye care professional or practitioner if you need to store the contact lenses for extended periods.
- If the contact lenses become dehydrated in a lens case, consult your eye care professional or practitioner.
- Do not share the contact lenses with other people.

### ADVERSE REACTIONS

If any of the following problems occur, immediately remove the contact lenses and examine them to be sure that they are free of any damage. If the contact lenses are not damaged, clean and disinfect the lenses before wearing them again. If the problem still continues, remove the lenses and seek prompt treatment. Serious eye damage may result such as infection, corneal ulcer, neovascularization, and iritis.

- Eye stinging, burning, itching, or any other pain in the eyes
- Continuous foreign body or scratching sensation
- Excessive tearing, unusual eye secretions, redness, reduced visual acuity, blurred vision, halos, photophobia, or dry eyes

If any serious incidents to the contact lenses occur, report it to the authorized representative and the competent authority.

### HANDLING THE CONTACT LENSES

- Always wash, rinse, and dry your hands thoroughly before handling the contact lenses.
- Do not wear the contact lenses if the blister cases or sterile packages have been opened or damaged, or if the expiration date has passed.
- Always handle the left and right contact lenses in the same sequence to avoid mixing up the lenses.

### Opening the blister case (for Menicon soft 72):

1. Open the blister case.
2. Find one contact lens in the blister case.
3. Carefully pick up the lens and examine it to be sure that it is free of any damage or foreign bodies.

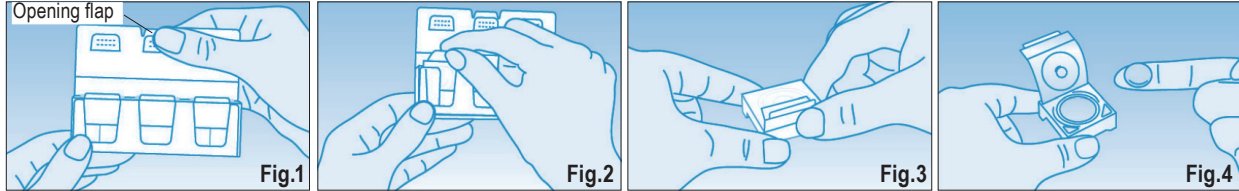
**Opening the multi-pack box (for Menisoft):**

Three containers are packed in a multi-pack box.

1. Pull up the opening flap to break the seal. (See Fig.1.)
2. Remove one container from the multi-pack box. (See Fig.2.)
  - To close the multi-pack box for storage, tuck in the flap.

**Opening the foil-sealed plastic container (for Menisoft):**

1. Remove the container foil to open the package. (See Fig.3.)
  - To minimize the possibility of sudden splash, stabilize the container on a tabletop and then open the package.
2. Find one contact lens with the concave side facing up in the container.
3. Carefully pick up the lens from the container and examine it to be sure that it is free of any damage or foreign bodies. (See Fig.4.)



**Putting in contact lenses:**

The general procedure for putting in contact lenses is described below. Consult your eye care professional or practitioner for more details as necessary.

1. Place the contact lens on the tip of the forefinger of your dominant hand with the concave side facing up.
  2. Check the profile of the lens to make sure it is not turned inside out.
  3. Hold your eyelids wide apart by pulling the upper lid with the forefinger of your non-dominant hand and the lower lid with the middle finger of your dominant hand.
  4. Slowly bring the lens up to your eye while looking straight ahead, and gently put the lens on the cornea.
    - Do not press the lens against your eye.
  5. Look down, release the upper lid first then the lower lid, and blink gently.
  6. Repeat this procedure for the other lens.
- If your vision is blurred after putting in the contact lenses:
    - If the contact lenses are not centred on the cornea:
      - Look into the mirror, and gently manipulate the edge of the lens to move it onto the cornea while opening your eye. Use finger pressure on the edge of the upper or lower lid until the lens is centred on the cornea.
    - If the contact lenses are centred on the cornea:
      - Remove the lenses. Possible causes are as follows.
        - The lens surface is dirty.
        - The lenses are on the wrong eyes.
        - The lenses have been put inside out onto the eyes.
  - If your vision is still blurred after clearing the problems mentioned above, remove the contact lenses and consult your eye care professional or practitioner.
  - If you feel significant discomfort while wearing the contact lenses, immediately remove the lenses and consult your eye care professional or practitioner.

**Removing contact lenses:**

1. Look upwards while keeping your head straight.
2. Pull down the lower lid with the middle finger of your non-dominant hand and place the forefinger of your dominant hand on the lower edge of the contact lens.
3. Slide the lens down to the lower white part of your eye.
4. Gently pinch the lens between the thumb and forefinger of your dominant hand.
5. Remove the lens.
6. Repeat this procedure for the other lens.

**CARE FOR THE CONTACT LENSES**

- Always use lens care products recommended by your eye care professional or practitioner. Never use care products for rigid gas permeable contact lenses.
- Do not use tap water for the care of the contact lenses and lens cases. Use of tap water increases the risk of microbial infection.
- Always use fresh unexpired lens care products.
- Do not alternate or mix lens care products unless indicated on the product instructions or recommended by your eye care professional or practitioner.
- Heat disinfection is not recommended for Menisoft.
- Store the contact lens completely immersed in storage solution when not in use.
- Clean and rinse the lens case with care products and allow it to air dry after each use. Replace lens cases at regular intervals.

**SYMBOLS USED ON THE PACKAGE**

<b>SYMBOL</b>		<b>LOT</b>		<b>STERILE</b>
<b>DEFINITION</b>	Consult Instructions for Use	Batch Code	Use by Date (Expiry Date)	Sterile Using Steam or Dry Heat
<b>SYMBOL</b>	<b>MD</b>	<b>UDI</b>		
<b>DEFINITION</b>	Medical Device	Unique Device Identifier	EU Importer	
<b>SYMBOL</b>	<b>DIA.</b>	<b>B.C.</b>	<b>P.</b>	<b>C.T.</b>
<b>DEFINITION</b>	Diameter	Base Curve	Dioptre (Lens power)	Centre Thickness

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