






# Mediflex® 1 Day Extra (ocufilcon D) Soft Contact Lens

## Package Inserts

**IMPORTANT:** Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

### SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION
	Caution: this device to sale by or on the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat

### DESCRIPTION

**Mediflex® 1 Day Extra** (ocufilcon D) Soft Contact Lenses are made from a material containing 55% water and 45% ocufilcon D, a random copolymer of 2-hydroxyethylmethacrylate and methacrylic acid. The lenses have a tint (VAT Blue 6) which is added to make the lens more visible for handling.

Lenses parameters for **Myopia/Hyperopia**:

- Diameter: 12.0mm to 18.0mm
- Basic Curve: 6.50mm to 12.80mm
- Center Thickness: 0.025 mm to 0.40 mm (varies with power)
- Powers: -20.00D to +20.00D

Lenses parameters for **Astigmatism**:

- Diameter: 14.5mm
- Basic Curve: 8.7mm
- Center Thickness: 0.0745 mm to 0.178 mm (varies with power)
- Powers: -20.00D to +20.00D
- Cylinder: -0.25D to -10.00D
- Axis: 0° to 180° in 10° increments

The physical/optical properties of the lens are:

- Refractive Index: 1.41
- Light Transmittance: 97%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability (Dk) (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/mlxmmHg) at 35°C (Fatt method): 19.6×10<sup>-11</sup>
- Lens Color: Light Blue
- Wearing Schedule: Daily Wear
- Replacement Schedule: Daily Disposable

### ACTIONS

When placed on the cornea in its hydrated state, the **Mediflex® 1 Day Extra** (ocufilcon D) Soft Contact Lens acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

### INDICATIONS FOR USE

**Mediflex® 1 Day Extra** (ocufilcon D) ASPHERE Soft Contact

lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from - 20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

**Mediflex® 1 Day Extra (ocufilcon D) TORIC** Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

### CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use the **Mediflex® 1 Day Extra** (ocufilcon D) lens 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.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution, which is to be used to care for any **Mediflex® 1 Day Extra** (ocufilcon D) lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

### WARNINGS

**Patients should be advised of the following warnings pertaining to contact lens wear:**

#### **PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCER AND LEAD TO LOSS OF VISION.**

It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case.

You should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect your lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean your lenses.

- You should fill your lens case with fresh solution every time you store your lenses, and never "top-off" or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case. You should not expose or store your lenses in or rinse your lens case with any water, such as tap, bottled or distilled, or with any non-sterile solution. Clean, rinse and air-dry your lens case each time you remove

your lenses. In order to permit excess solution to drain, you can flip over your lens case while air drying. Replace your lens case frequently, depending upon your hygiene habits.

- The result of a study<sup>1</sup> indicate the following:
  - a. The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.
  - b. The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users are 10 to 15 times greater than among daily wear users.
  - c. When daily users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.
  - d. The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
  - e. The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.
  - f. If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Practitioner. It is recommended that contact lens wears see their Eye Care Practitioner routinely as directed.

<sup>1</sup>NewEnglandJournalofMedicine, September 21, 1989; 321(12), pp. 773-783

## PRECAUTIONS

### Special Precautions for Eye Care Practitioners

- Due to the small numbers of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommend solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical lens care system. Use of a heat care system can damage the **Mediflex® 1 Day Extra** (ocufilcon D) Soft Contact Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep lens completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage lenses and reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Carefully follow the handling, insertion, removal, cleaning, and wearing instructions in the Patient Instructions for **Mediflex® 1 Day Extra** (ocufilcon D) soft contact lenses and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing the lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Always discard disposable lenses after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

**ADVERSE REACTIONS**

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove the lenses.**
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect both lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner.**
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

**FITTING**

Conventional methods of fitting contact lenses apply to all **Mediflex® 1 Day Extra** (ocufilcon D) soft contact lenses.

**WEARING SCHEDULE**

**The wearing and replacement schedules should be determined by the eye care practitioner.** Patients tend to over-wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

It's recommended that all **Mediflex® 1 Day Extra** (ocufilcon D) lenses be discarded and replaced with a new lens on a frequent replacement basis. The eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

DAILY WEAR: (less than 24 hours, while awake). The maximum suggested wearing time is:

Day	1	2	3	4	5	6
Hour	6	8	10	12	14	All waking hours

**LENS CARE DIRECTIONS**

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting. Do not put lenses in the mouth.
- The patient should always have a spare pair of lenses at all times.

**CARE FOR A DRIED OUT (DEHYDRATED) LENS**

If any **Mediflex® 1 Day Extra** (ocufilcon D) lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

**CARE FOR A STICKING (NONMOVING) LENS**

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 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 more than 5 minutes, the patient should immediately consult the eye care practitioner.

**EMERGENCIES**

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

**FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**HOW SUPPLIED**

Each lens is supplied sterile in a blister containing buffered saline solution. The blister is labeled with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

**DO NOT USE IF THE BLISTER IS BROKEN OR THE SEAL HAS BEEN DAMAGED.**

**REPORTING OF ADVERSE REACTIONS**

All serious adverse experiences and adverse reactions observed in patients wearing any **Mediflex® 1 Day Extra** (ocufilcon D) soft contact lens or experienced with the lenses should be reported.

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