# **PACKAGE INSERT**

# THE ALBERTA LENS™SM2 (Sulfocon B)



Rigid
Gas Permeable Contact Lenses
For Daily Wear
With Ultraviolet Protection

# **IMPORTANT:**

Please read carefully and keep this information for future use.

# Spherical contact lenses for:

Nearsightedness (Myopia) Farsightedness (Hyperopia)

#### DESCRIPTION

The Alberta Lens™SM2 (Sulfocon B) rigid gas permeable contact lens is a hemispherical shell of approximately 8.0 mm to 10.0 mm chord diameter, 7.00 mm to 9.00 mm base curve and 0.05 mm to 0.6 mm center thickness. Powers -20.00 to +12.00 diopters.

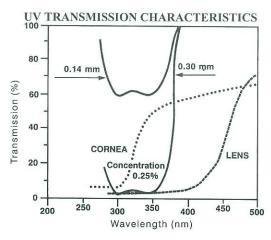
The Alberta Lens™SM2 is intended for daily wear. Your eye care practitioner can prescribe The Alberta Lens™SM2 in clear or tinted color for easy handling. The tinted lenses contain at least one or a combination of D&C #6 Green, D&C #2 Violet or D&C #10 Yellow. The ultraviolet absorber, TINUVIN P, has been integrated as an additive during the manufacturing process into The Alberta Lens™SM2 polymer matrix blocking up to 60-90% (depending on lens thickness) of light in the region of 290-360 nm.

# The physical properties of the lens are:

Oxygen Permeability*	45 x 10 <sup>-11</sup>	Dk at 35°C
Wetting Angle**	8.6	
(Sissel Technique)		
Hardness (ASTM-2240	80 - 85	
<ul> <li>modified D Scale)</li> </ul>		
Water Absorption	<2.0%	
Index of Refraction	1.4777 (n <sup>23</sup> D)	
Specific Gravity	1.16	
Light Transmittance	>90%	
(Absorbance Units/ln)		

\*(cm²/sec)(ml O₂/ml x mm Hg) Revised method of Irving Fatt, Ph.D.

<sup>\*\*</sup>Frank Holly, Ph.D., Sissel Drop Method.



7. Allergy to any ingredient in a solution which must be used to care for The Alberta Lens™SM2.

WARNINGS: UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eye wear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eye wear as directed.

#### **PRECAUTIONS**

Follow the instructions below to prevent damage to your eye(s) or lens(es):

- The Alberta Lens<sup>TM</sup>SM2 (Sulfocon B) rigid gas permeable contact lens should not be worn while sleeping, swimming or in the presence of noxious and irritating vapors or fumes.
- Before you leave your eye care practitioner's office, be able to properly remove your lens(es) or have someone else be able to remove your lens(es) for you.
- Always follow the recommended lens care system for The Alberta Lens™SM2 (Sulfocon B) lens(es). Use only the recommended lens care solutions and carefully follow recommended directions.
- Always use FRESH storage solution.
- Do not use saliva or anything other than the recommended solution to wet your lenses.
- Always keep the lens(es) completely immersed in the recommended storage solution when the lens(es) are not being worn.
- If your lens sticks (stops moving) on the eye, follow the recommended directions for freeing the lens. The lens must move freely on the eye for the continued health of the eye. If non-movement of the lens continues, immediately consult your eye care practitioner.
- Always wash and rinse your hands before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams or deodorants come into contact with your lenses or if the lenses are contaminated by infectious or non-infectious dirt.
- Avoid using aerosol products such as hair spray while wearing your lenses. If sprays are used, keep your eyes closed until the spray has settled.
- Never use tweezers or other pointed tools to remove your lenses from the lens container. Gently remove the lenses from their case.
- Do not use your fingernails to remove or touch the lenses.
- Always inform your doctor (health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require the use of eye

protection equipment or may require that you not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure ocular health.

Check with your eye care practitioner.

# ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

The following problems may occur:

- Eyes sting, burn or itch (irritation or allergic reaction);
- Comfort is less than when lens was first placed on eye;
- Feeling of something in the eye (foreign body, scratched area or abrasion);
- Excessive pain;
- Excessive watering (tearing) of the eye(s);
- Unusual eye secretions;
- Redness of the eye(s);
- Reduced sharpness of vision (poor visual acuity);
- Blurred vision, rainbows or halos around objects;
- Sensitivity to light (photophobia);

- Dry eyes.

If you notice any of the above, REMOVE YOUR LENS(ES)!

- If the discomfort or problem stops, then look closely at the lens(es).
- If the lens(es) is in any way damaged, <u>DO NOT PUT</u> the lens(es) back on your eye(s). Place the lens(es) in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash or other foreign body on it, or the problem stops and the appears undamaged, clean thoroughly, rinse and disinfect the lens(es); then reinsert them.
- If the problem continues, IMMEDIATELY remove your contact lens(es) and consult your eye care practitioner.

When any of the above symptoms occur, a serious condition such as an infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. Seek professional identification of the problem immediately and prompt treatment to avoid serious eye damage which may include corneal scarring, opacification, blindness or loss of eye.

All contact lens wearers must see their eye care practitioner as directed.

#### FITTING

Conventional methods of fitting contact lenses apply to The Alberta Lens™SM2 (Sulfocon B) rigid gas permeable contact lens. For a detailed description of the fitting technique refer to the Fitting Guide for The Alberta Lens™SM2 (Sulfocon B) contact lens. The Fitting Guide is available from Progressive Optical Research Ltd.

### WEARING SCHEDULE:

The wearing schedule should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

# WEARING SCHEDULE FOR NAIVE EYES

(Those with no previous experience with rigid contact lenses)

DAY	HOURS
1	3
2	4
3	5
4	6
5	7
6	8
7	10
8	11
8 9	12
10	all waking hours

# WEARING SCHEDULE FOR CURRENT WEARERS OF RIGID CONTACT LENSES

DAY	HOURS	
1	7	
2	8	
3	9	
4	10	
5	11	
6	12	
7	all waking hours	

DO NOT SLEEP while wearing The Alberta Lens™ SM2 (Sulfocon B) rigid gas permeable contact lens. Studies have not been completed to show that The Alberta Lens™SM2 (Sulfocon B) contact lens is safe to wear during sleep.

#### LENS CARE

Always wash and rinse your hands before handling your contact lenses.

Follow these basic instructions for general lens care to clean, rinse and condition your lenses:

- Never use heat (thermal) lens care systems.
- Carefully read your Patient Care Guide for lens care details.
- The Alberta Lens™SM2 (Sulfocon B) rigid gas permeable contact lenses must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface and disinfection is necessary in a chemical (not heat) disinfection solution for a minimum of four (4) hours. Follow the directions included with the solutions
- DO NOT USE THESE SOLUTIONS WITH HEAT. Such use can damage your lens. The Alberta Lens™SM2 (Sulfocon B) rigid gas permeable contact lens <u>cannot</u> be heat (thermally) disinfected.
- After removing the lenses from soaking in the lens storage case, rinse briefly in fresh conditioning solution, if desired, and insert.
- After you remove your lenses from the lens storage case, empty and rinse your lens storage case and allow it to dry. When you next use the case, refill it with fresh conditioning solution.
- Do not use saliva or anything other than the recommended solution to wet your lens(es).

Always keep the lenses completely immersed in conditioning solution when the lenses are not being worn.

#### WETTING AND REWETTING

If your lens feels dry on the eye or becomes uncomfortable, remove the lens and condition it by rubbing several drops of conditioning solution on both surfaces and reinsert - OR - instill one to three drops of a conditioning solution into the eye while the lens is on the eye as recommended by your eye care practitioner. The lens must move freely on the eye for the continued health of the eye. If dryness or discomfort continues, remove lens and immediately consult your eye care practitioner.

## CARE FOR A STICKING LENS

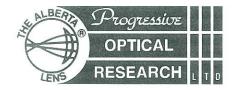
If the lens sticks (stops moving) on the eye, apply a few drops of conditioning solution. Wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, immediately consult your eye care practitioner.

## HOW SUPPLIED

Each lens is supplied in an individual plastic case and sealed within a pouch. The case is labelled with the base curve, dioptric power, diameter and center thickness of the lens, lot number, expiration date and color of the lens.

**CAUTION:** 

Federal law (U.S.A.) prohibits dispensing without a prescription.



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<u>CORNEA</u>-Human cornea from a 24-year old person as described in Lerman, S., <u>Radiant Energy and the Eye</u>, MacMillan, New York, 1980, p.58.

<u>CRYSTALLINE LENS</u>-Human crystalline lens from a 25-year old person as described in Waxler, M., Hitchins, V.M., <u>Optical Radiation and Visual Health</u>, CRC Press, Boca Raton, Florida, 1986, p.19, figure 5.

NOTE: Long Term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

#### ACTIONS

When placed on the human cornea, The Alberta Lens™ SM2 (Sulfocon B) rigid gas permeable contact lens acts as a refracting medium to focus light upon the retina to improve visual acuity.

### **INDICATIONS (USES)**

The Alberta Lens™SM2 (Sulfocon B) rigid gas permeable contact lens is indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who may exhibit astigmatism of 3.00 diopters (D) or less that does not interfere with visual acuity.

# CONTRAINDICATIONS (REASONS NOT TO USE)

The Alberta Lens™SM2 (Sulfocon B) rigid gas permeable contact lenses are contraindicated by the presence of any of the following conditions:

- 1. Acute or subacute inflammation of the anterior segment of the eye.
- 2. Eye disease in which wearing the lenses adversely affects the eye.
- 3. Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity) except that which is temporarily produced by previous PMMA or soft wear use.
- 5. Systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Active corneal infection, including bacterial, fungal or viral infection.