



# New Device Approvals

## Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens - P990018

*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

Product Name: Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens  
Manufacturer: Menicon U.S.A., Inc.  
Address: 333 West Pontiac Way, Clovis, CA 936120-5613  
Approval Date: July 11, 2000  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990018a.pdf>

What is it? This is a rigid gas permeable contact lens used for the correction of nearsightedness (myopia), farsightedness (hyperopia), and astigmatism (blurring of vision). Gas permeable contact lenses are made of materials that allow oxygen to reach the clear front surface (cornea) of the eye. This flow of oxygen contributes to the health and comfort of the eye.

How does it work? When placed on the eye, the lens focuses light onto the retina (back surface of the eye) at an angle that can correct for nearsightedness, farsightedness, and astigmatism.

When is it used? You can wear the lens for one day during waking hours. You may also wear them for 1 to 7 days. Once you remove them, the lenses must be cleaned and disinfected.

What will it accomplish? The lens corrects refractive error such as nearsightedness, farsightedness, presbyopia (both near and far correction are needed) and or astigmatism (blurring of vision). The gas permeable materials the lenses are made of allow oxygen flow (also called oxygen permeability or Dk) that helps maintain the eye's health and comfort.

When should it not be used? The lens should not be used if you have an inflammation or infection of the eye or if you have any eye disease or injury that affects your cornea, conjunctiva or eyelids.

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p990018.html>

(Updated 5/15/01)