Update: FDA Approves Label Warning for Soy Allergy in Mint-Flavored Nicorette Lozenges

Content Update for Chapter 47, “Tobacco Cessation.”  
Posted July 1, 2015.

The Food and Drug Administration (FDA) has granted “Prior Approval” of a Supplemental New Drug Application for amended labeling of mint-flavored Nicorette (nicotine polacrilex) 2 mg and 4 mg lozenges.¹ Language specific to soya allergy has been added to the Warnings section of the Drug Facts Label. This warning means anyone with a soy allergy should avoid using this particular product. Fortunately, other safe and effective nicotine replacement products are available for these individuals.

Take home messages/patient education considerations:
1. Compared with other food allergies, the incidence of soy allergy is low²; however, it is important to encourage anyone with any food allergy to read all product labels carefully—now including the mint-flavored Nicorette lozenges.
2. Whenever possible, engage patients and customers in a conversation regarding the value and potential risks of using nicotine replacement products.
3. Remind all patients and customers to read the Drug Facts Label closely for all over-the-counter products.

Reference

Other resources for soy and food allergy information: