



Canada Innovation

October 27, 2011

To all COPAXONE[®] patients

Subject: Important Information for Canadian COPAXONE[®] Users – the use of soap and water added as an alternative for preparation of injection sites.

We are pleased to inform you that soap and water can be used as a safe alternative to prepare your injection sites prior to injection. We received approval from Health Canada to update the Copaxone product information leaflet to include this option.

Since the alcohol preps recall of last January, Teva has endeavored to find replacement sterile alcohol preps. Unfortunately, there are no sterile alcohol preps approved and marketed in Canada, so we are unable to resume providing them.

The product information leaflet included in your Copaxone carton will be updated in the next few months to reflect the addition of soap and water as a skin preparation alternative. Please note that you can either follow the directions currently in the box, **OR** you can use soap and water to prepare the injection site, which may have already been recommended to you by a healthcare professional.

Please continue to use your COPAXONE[®] daily as prescribed by your health care professional.

As always, Shared Solutions[®] is here for you. Please call us at 1-800-283-0034 with any questions and we will be happy to help!

You will find enclosed an updated Copaxone Product Information document reflecting the approved use of soap and water to prepare your injection sites.

Your Shared Solutions Team

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Indication

COPAXONE[®] is indicated for the treatment of ambulatory patients with Relapsing Remitting Multiple Sclerosis (RRMS) to decrease the frequency of clinical exacerbations; to reduce the number and volume of active brain lesions identified on Magnetic Resonance Imaging (MRI) scans.

COPAXONE[®] is indicated for the treatment of patients who have experienced a single demyelinating event, accompanied by abnormal MRI scans, and are considered to be at risk of developing Clinically Definite MS (after alternative diagnoses are excluded), to delay the onset of definite MS, to decrease the number and volume of active brain lesions and overall disease burden (as identified by MRI scans).

Important safety information about COPAXONE[®]

The most common side effects of COPAXONE[®] are injection site reactions, such as redness, pain, swelling, itching, or a lump at the site of injection. A permanent indentation under the skin at the injection site may occur, due to a local destruction of fat tissue. Be sure to follow proper injection technique and inform your doctor of any skin changes. Some people report a short-term reaction right after injecting COPAXONE[®]. This reaction can involve flushing (feeling of warmth and/or redness), chest tightness or pain with heart palpitations, anxiety, and trouble breathing. Keep in mind that these symptoms generally appear within minutes of an injection, last about 15 minutes, and go away by themselves without further problems. If symptoms become severe, call the emergency phone number in your area. Do not give yourself any more injections until your doctor tells you to begin again.

You are encouraged to report adverse events or side effects to Health Canada through the Canada Vigilance Program. For more information, contact Canada Vigilance at www.healthcanada.gc.ca/medeffect or at 866-234-2345 (toll-free telephone).

The Shared Solutions[®] Team

