



January 15, 2009

Medication Shortage Alert

MEDICATIONS: Metoprolol Succinate Extended-Release Tablets

DOSAGE FORMS: 25 mg, 50 mg, 100 mg, and 200 mg Extended-Release Tablets

ISSUE: On December 23, 2008 Ethex Corporation informed the FDA that they would voluntarily suspend all shipments of Metoprolol Succinate Extended-Release (ER) tablets (25 mg, 50 mg, 100 mg, and 200 mg). Ethex explained its action to be a precautionary measure that would allow review and enhancement of its manufacturing, quality, and efficiency systems. Ethex is keeping the FDA informed of its plans. Par Pharmaceuticals and Sandoz also manufacture metoprolol succinate ER tablets, and are currently experiencing shortages due to increased demand; Sandoz also has metoprolol ER tablets on back order due to a product recall in September 2008.

THE FOLLOWING PRODUCTS ARE AFFECTED BY THE CURRENT SHORTAGE:

Metoprolol succinate extended-release tablets, Ethex
100 mg, 100 unit-dose (NDC 58177-0368-11)
100 mg, 100s (NDC 58177-0368-04)
100 mg, 1000s (NDC 58177-0368-09)
200 mg, 100s (NDC 58177-0358-04)
200 mg, 1000s (NDC 58177-0358-09)

Metoprolol succinate extended release tablets, Par
25 mg, 100s (NDC 49884-0404-01)
50 mg, 100s (NDC 49884-0405-01)
100 mg, 100s (NDC 49884-0406-01)
200 mg, 100s (NDC 49884-0407-01)

Metoprolol succinate extended release tablets, Sandoz
25 mg, 100s (NDC 00185-0281-01)
25 mg, 1000s (NDC 00185-0281-10)
50 mg, 100s (NDC 00185-0282-01)
50 mg, 1000s (NDC 00185-0282-10)
100 mg, 100s (NDC 00185-0283-01)
100 mg, 1000s (NDC 00185-0283-10)
200 mg, 100s (NDC 00185-0284-01)
200 mg, 1000s (NDC 00185-0284-10)

ESTIMATED RESUPPLY DATES: Ethex and Sandoz will not estimate a release date for their products. Par has metoprolol extended release tablets available on allocation in 25 mg, 50 mg, 100 mg, and 200 mg strengths. Brand name Toprol XL®, from Astra-Zeneca, is currently available in all strengths.