Doryx MPC® (doxycycline hyclate) – New Formulation Approval

- On May 20, 2016, the FDA approved Mayne Pharma’s Doryx MPC (doxycycline hyclate) delayed-release tablets, for the treatment of the rickettsial infections, sexually transmitted infections, respiratory tract infections, specific bacterial infections, ophthalmic infections, anthrax, including inhalations anthrax (post-exposure), alternative treatment for selected infections when penicillin is contraindicated, adjunctive therapy in acute intestinal amebiasis and severe acne, and prophylaxis of malaria.

  — To reduce the development of drug-resistant bacteria and maintain the effectiveness of doxycycline hyclate, Doryx MPC tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

- Doryx MPC will be available as 60 mg and 120 mg delayed-release tablets. Doryx MPC is a new formulation that incorporates a modified polymer coat designed to further retard the release of doxycycline in the acidic environment of the stomach.

- Doxycycline hyclate is also available as Doryx® and as generics in the following strengths: 50 mg, 75 mg, 100 mg, 150 mg, and 200 mg delayed-release tablets.

  — Doryx delayed-release tablets have the same indications as Doryx MPC.

- The recommended usual dose of Doryx MPC in adults and pediatric patients ≥ 45 kg is 240 mg orally on the first day of treatment (administered 120 mg every 12 hours) followed by a maintenance dose of 120 mg daily.

  — In the management of more severe infections (particularly chronic infections of the urinary tract), 120 mg every 12 hours is recommended.

- The recommended usual dose of Doryx MPC in pediatric patients weighing < 45 kg with severe or life threatening infections (e.g., anthrax) is 2.6 mg/kg every 12 hours.

  — For pediatric patients with less severe disease (> 8 years of age and weighing < 45 kg), the recommended dose is 5.3 mg/kg divided into two doses on the first day of treatment, followed by a maintenance dose of 2.6 mg/kg (given as a single daily dose or divided into twice daily doses).

- The dose of Doryx in adults and pediatric patients > 45 kg is 200 mg orally on the first day of treatment (administered 100 mg every 12 hours) followed by a maintenance dose of 100 mg daily. More severe infections should be treated with 100 mg every 12 hours.

- For pediatric patients with less severe disease (> 8 years of age and weighing ≤ 45 kg), the recommended Doryx dose is 4.4 mg/kg divided into two doses on the first day of treatment, followed by a maintenance dose of 2.2 mg/kg (given as a single daily dose or divided into two doses on subsequent days). For more severe infections, a dose up to 4.4 mg/kg may be used.

- Mayne Pharma’s launch plans for Doryx MPC are pending.