Brief Statement for US Consumers

IMPORTANT SAFETY INFORMATION FOR PROMETRA DRUG DELIVERY SYSTEMS - BRIEF STATEMENT

Indications:
The Prometra® Programmable Infusion Pump System is indicated for intrathecal infusion of drug therapy, including: Infumorph ® (preservative free morphine sulfate sterile solution), preservative-free sterile 0.9% saline solution (Sodium Chloride Injection, USP), and baclofen (baclofen injection, intrathecal, 500-2000 mcg/mL). For Infumorph, the pump is indicated for use in adult populations of 22 years and older. For baclofen and 0.9% saline solution, the pump system is indicated for use in patient populations of 12 years and older (adolescents and adults).

Drug Information: See drug labeling for indications, contraindications, warnings, precautions, adverse reactions and under/over dose symptoms. Tell your doctor about any drug related signs or symptoms you may experience.

Contraindications: The Prometra pump system should not be implanted if: you have an infection (known or suspected); your body type cannot safely accommodate the pump size and weight; the pump cannot be implanted 1 inch below the skin; you have allergies to catheter or pump materials; you have had an intolerance to implanted devices in the past; your spinal column anatomy obstructs cerebrospinal fluid flow or prevents intrathecal drug delivery; you are deemed an unsuitable candidate after psychological evaluation; you have an occupation with exposure to high current industrial equipment, powerful magnets or transmitting towers; you require hyperbaric therapy.

Warnings: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH; THE PUMP MAY NEED TO HAVE AS MUCH AS 20ML OR 40ML OF DRUG REMOVED DEPENDING ON THE PUMP TYPE AND MODEL NUMBER. USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROMETRA II PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH. If an MRI is required, your doctor MUST empty your pump of all medication prior to the MRI. Your doctor should be familiar with approved drug intended for use with the implanted pump system, including dosing and symptoms related to and treatment for under- or over-dosing.

Precautions: Tell your doctor about any new neurological signs or overdose/withdrawal symptoms you may experience. Pain on injection may be early sign of infection. Seek immediate medical attention if you experience early signs of baclofen under-dose or withdrawal. In the pediatric population, care must be taken to select an appropriate location, taking into consideration available body mass, presence of ostomies, growth development, and comorbidities.

Adverse Events: The potential exists for serious complications. Adverse events include but are not limited to: pocket seroma/hematoma with or without infection, pump site skin erosion, pump rotation/migration/flipping or twisting, adverse reaction to pump materials, granuloma; infection in intrathecal space, including meningitis, nerve damage. Additional potential adverse events are included in the Patient Guide.

For full disclosure of contraindications, warnings, precautions, adverse events and MRI Instructions, please call Infusyn at 855-356-9665 and/or consult Infusyn website at Infusyn.com

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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