PROMETRA® II

For the Relief of Spasticity

NOT ALL PUMPS ARE THE SAME

CONSISTENTLY ACCURATE

The Prometra II pump is consistently accurate to within 3% of your prescription, which means the amount of medication treating your spasticity will be the same from when the pump is full to when it's almost empty.

LONGER BATTERY LIFE

The Prometra II pump has a 10-year battery life, which means less replacement surgeries for you compared to other pumps on the market.

SAFE, RELIABLE PERFORMANCE

The Prometra II pump design provides safeguards to help your clinical team confidently refill your pump, and its motor-less design eliminates the concerns that other pumps have with stalling.

LIVE YOUR LIFE with FEWER RESTRICTIONS

The Prometra II pump is less affected by environmental conditions like altitude and temperature, which means you can have confidence at all times when performing activities of daily living.

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Visit **flowonix.com**
for more information and ask your doctor today
if Prometra II can help **redefine your potential**.

Brief Statement for US Consumers | PL-19701-02 | Issue date: November 2019

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). The pump is indicated for use in adult populations of 22 years and older. **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; 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; 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. **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. **Adverse Events:** 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 Flowonix at 855-356-9665 and/or consult Flowonix website at Flowonix.com. **Caution**: Federal Law (USA) restricts this device to sale by or on the order of a physician. FLOWONIX and PROMETRA are trademarks of Flowonix Medical, Inc.

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