PROMETRA® II

For the Relief of Chronic Pain

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 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 your patients 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 patient's 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 your patients can enjoy more of the activities you love to do, including hot-tubbing!

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Visit **flowonix.com**
for more information and ask your doctor today
if Prometra II can help treat your chronic pain.

Brief Statement for US Health Care Professionals | PL-19589-02 | Issue date: November 2019

IMPORTANT SAFETY INFORMATION FOR PROMETRA DRUG DELIVERY SYSTEMS - BRIEF STATEMENT. Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure. Clinicians implanting, programming, accessing, or maintaining implanted programmable pumps must comply with the instructions for use. 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, dosage, administration, screening procedures and under/over dose symptoms and management. Patients should be informed of signs and symptoms that require medical attention. Contraindications: Implantation is contraindicated in the presence of infection; insufficient body size; incompatible spinal anatomy or obstruction of CSF flow; implant depth >2.5cm below skin; allergies to catheter or pump materials; intolerance to implanted devices; medical history of substance abuse deemed to prohibit intrathecal drug administration; occupations with exposure to high current industrial equipment, powerful magnets or transmitting towers; hyperbaric exposure. 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; Prometra System is MRI Conditional-consult the labeling for MRI information. Precautions: An inflammatory mass resulting in serious neurological impairment, including paralysis, may occur at tip of catheter. Monitor patients carefully for new neurological signs or symptoms. Monitor patients after pump and/or catheter implant or replacement for signs of underdose/overdose. Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion. Abrupt withdrawal of intrathecal baclofen may be life-threatening. Electromagnetic interference may interfere with Programmer telemetry during pump programming. Pain on injection may be early sign of infection. 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. For full prescribing information and 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.

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