Patients receiving opioids for less than 4 weeks may be less responsive to RELISTOR injection. 

**RELISTOR injection: The recommended dosage is 12 mg subcutaneously once daily.**

- In adults with OIC, the recommended dose is 450 mg orally once daily, and the average dose of RELISTOR injection is 12 mg subcutaneously once daily. 
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR. The use of RELISTOR injection is not recommended during pregnancy.

**ADVERSE REACTIONS**

**5.1 Gastrointestinal Perforation**
- When used in patients with OIC and chronic non-cancer pain receiving opioid analgesia, this study (Study 2) showed that the incidence of gastrointestinal perforation was 0.3% among patients receiving RELISTOR tablets, compared to 0.2% among patients in the placebo group.
- Adverse reactions occurring in at least 2% of patients receiving RELISTOR tablets 450 mg once daily included: abdominal distention (9%), nausea (8%), vomiting (7%), mouth dryness (7%), constipation (6%), diarrhea (6%), flatulence (7%), abdominal pain (7%), and headache (7%).

**5.2 Hepatic Impairment**
- The use of RELISTOR in patients with hepatic impairment may require a dosage adjustment. It is recommended that the dose of RELISTOR injection be reduced for patients with hepatic impairment (creatinine clearance greater than 60 mL/minute as estimated by Cockcroft-Gault).

**5.3 Opioid Withdrawal**
- Opioid withdrawal may occur with RELISTOR injection in patients who have been treated with opioids for an extended period. The symptoms and severity of opioid withdrawal vary with the duration of opioid therapy, the daily opioid dose, and the rate of withdrawal. In general, patients treated with higher daily opioid doses require more careful and protracted tapering. The symptoms of opioid withdrawal include: sweating, gooseflesh, chills, rhinorrhea, lacrimation, yawning, lacrimation, piloerection, tachycardia, hyperventilation, yawning, mydriasis, somnolence, irritability, and anorexia. The symptoms may begin within a few hours after the last opioid dose and may last for several days.

**5.9 Other**
- Symptoms of opioid withdrawal are not recommended if the patient is receiving a combination of opiates and benzodiazepines. If the patient is receiving a combination of opiates and benzodiazepines, the withdrawal symptoms are not expected to be severe.

For a detailed instructions on how to safely dispose of used needles and syringes, please refer to the section on “How to dispose of used needles and syringes.”

**13.1 How to Dispose of Used Needles and Syringes:**
- Patients should be instructed to dispose of used needles and syringes in a safe and secure manner to prevent needle-stick injuries. The needles should be placed in a rigid container that is compatible with the type of needle used. The container should be labeled with the word “sharps” and kept out of reach of children. The container should be disposed of in a secure and safe manner that is compatible with the type of needle used. The container should be disposed of in a secure and safe manner that is compatible with the type of needle used. The container should be disposed of in a secure and safe manner that is compatible with the type of needle used.

**13.2 How to Dispose of Used Syringes:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.3 How to Dispose of Used Oral Medications:**
- The use of RELISTOR tablets is not recommended during pregnancy. The use of RELISTOR tablets is not recommended during pregnancy.

**13.4 How to Dispose of Used Intravenous Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.5 How to Dispose of Used Parenteral Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.6 How to Dispose of Used Intranasal Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.7 How to Dispose of Used Topical Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.8 How to Dispose of Used Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.9 How to Dispose of Used Topical Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.10 How to Dispose of Used Topical Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.11 How to Dispose of Used Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.12 How to Dispose of Used Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.13 How to Dispose of Used Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.14 How to Dispose of Used Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.

**13.15 How to Dispose of Used Ocular Medications:**
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the opioid antagonist properties of RELISTOR injection. The use of RELISTOR injection is not recommended during pregnancy.