

LEARN HOW TO SAFELY AND ACCURATELY USE THE
RELISTOR PREFILLED SYRINGE BY FOLLOWING THIS GUIDE

How to get started with RELISTOR[®] (methyl**n**altrexone bromide) subcutaneous injection

12-mg injection*



*Use exactly as directed by your healthcare provider.

Also available in 8-mg injection

INDICATIONS

RELISTOR[®] (methyl**n**altrexone bromide) subcutaneous injection is a prescription medicine used to treat constipation in adults that is caused by prescription pain medicines called opioids.

- RELISTOR injection is used to treat constipation caused by opioids in adults with long-lasting (chronic) pain that is not caused by active cancer.
- RELISTOR injection is also used to treat constipation caused by opioids in adults with advanced illness or pain caused by active cancer and who need increases in their opioid dose for comfort care.

It is not known if RELISTOR is safe and effective in children.

IMPORTANT SAFETY INFORMATION - RELISTOR injection, for subcutaneous use

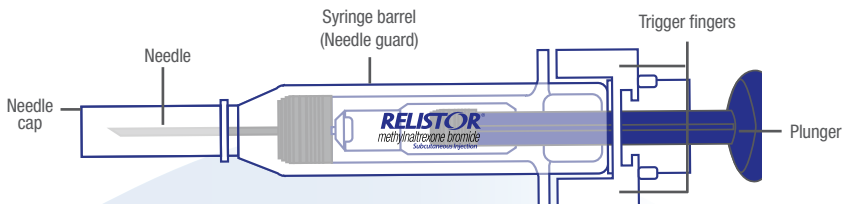
- Do not take RELISTOR injection if you have a bowel blockage (called an intestinal obstruction) or have a history of bowel blockage.
- RELISTOR injection can cause serious side effects such as a tear in your stomach or intestinal wall (perforation). Stomach pain that is severe can be a sign of a serious medical condition. If you get stomach pain that is severe, does not go away, or gets worse, stop taking RELISTOR injection and get emergency medical help right away.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including Medication Guide and Instructions for Use for RELISTOR injection.

RELISTOR[®]
methyl**n**altrexone bromide
Subcutaneous Injection

Step 1: Choose and prepare the injection site

Figure A

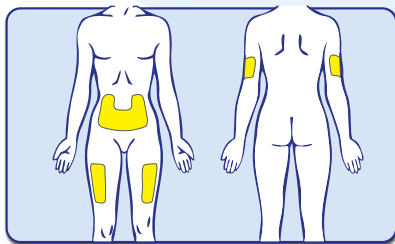


Supplies needed

RELISTOR prefilled syringe with attached needle, alcohol swab, cotton ball or gauze, adhesive bandage and puncture resistant container, such as an FDA-cleared sharps disposal container to dispose of used pre-filled syringes and needles.

Choose and prepare the injection site

Choose an injection site on your stomach area (abdomen), thighs, or upper arms. See the shaded areas in Figures B and C. Do not inject at the exact same spot each time (rotate injection sites). Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.



Figures B and C

- **(Figure B)** Abdomen or thigh—use these sites when injecting yourself or another person
- **(Figure C)** Upper arm—use this site only when injecting another person

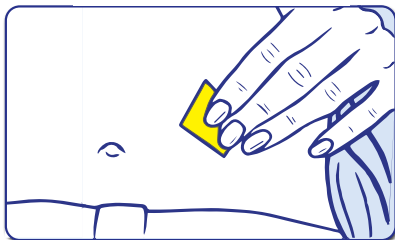


Figure D

Clean the injection site with an alcohol swab and let it air dry. Do not touch this area again before giving the injection.

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Step 2: Prepare the injection

Prepare the injection

- Choose a flat, clean, well-lit work surface
- Wash your hands with soap and water before preparing for the injection

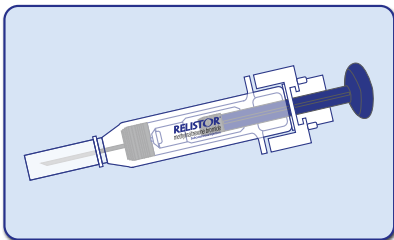


Figure E

- Look at the prefilled syringe of RELISTOR. Make sure that the dose prescribed by your healthcare provider matches the dose on the prefilled syringe label. Look at the plunger rod of the syringe. If the dose prescribed by your healthcare provider is 8 mg, the plunger rod will be yellow; if the prescribed dose is 12 mg, the plunger rod of the syringe will be dark blue
- The liquid in the prefilled syringe should be colorless to pale yellow, and should not have any particles in it. Do not use the prefilled syringe if it looks discolored, cloudy, or has any particles

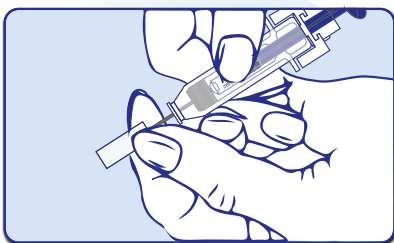


Figure F

Use one hand to firmly hold the barrel of the prefilled syringe. Use your other hand to pull the needle cap straight off. Do not touch the needle or allow it to touch anything.

IMPORTANT SAFETY INFORMATION - RELISTOR injection, for subcutaneous use (cont'd)

- Stop using RELISTOR injection and call your healthcare provider if you get diarrhea that is severe or that does not go away during treatment with RELISTOR injection.
- You may have symptoms of opioid withdrawal during treatment with RELISTOR injection including sweating, chills, diarrhea, stomach pain, anxiety, and yawning. Tell your healthcare provider if you have any of these symptoms.
- Tell your healthcare provider if you have kidney or liver problems.

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Subcutaneous Injection

Step 3: Inject RELISTOR

Inject RELISTOR

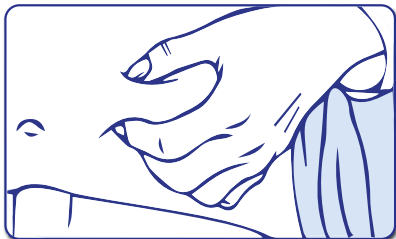


Figure G

Use one hand to pinch the skin around the injection site.

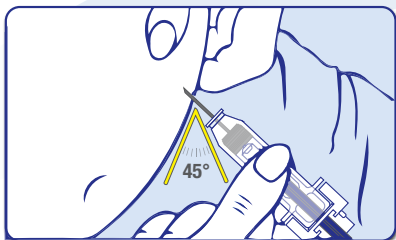


Figure H

Use your other hand to hold the prefilled syringe. Insert the full length of the needle into the skin at a 45-degree angle with a quick “dart-like” motion.

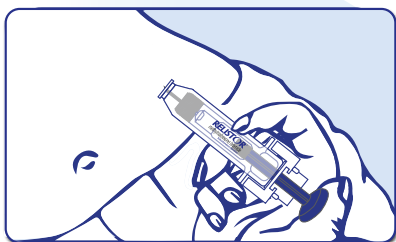


Figure I

Let go of the skin and slowly push the plunger in with your thumb until the prefilled syringe is empty. This will release the needle guard (safety device).

IMPORTANT SAFETY INFORMATION - RELISTOR injection, for subcutaneous use (cont'd)

- Tell your healthcare provider if you have any stomach or bowel (intestines) problems, including stomach ulcer, Crohn's disease, diverticulitis, cancer of the stomach or bowel, or Ogilvie's syndrome.
- Tell your healthcare provider if you are pregnant or plan to become pregnant. Taking RELISTOR injection during pregnancy may cause opioid withdrawal symptoms in your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with RELISTOR injection.
- Taking RELISTOR injection while you are breastfeeding may cause opioid withdrawal in your baby. You should not breastfeed during treatment with RELISTOR injection. You and your healthcare provider should decide if you will take RELISTOR injection or breastfeed. You should not do both.

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Step 3: Inject RELISTOR (cont'd)

Inject RELISTOR (cont'd)

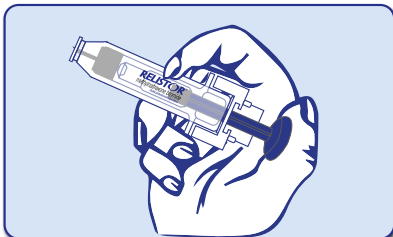


Figure J

Continue to hold pressure on the plunger with your thumb and quickly pull the needle out of the skin. Be careful to keep the needle at the same angle as it was inserted. Remove your thumb from the plunger to allow the protective sleeve to cover the needle. There may be a little bleeding at the injection site.

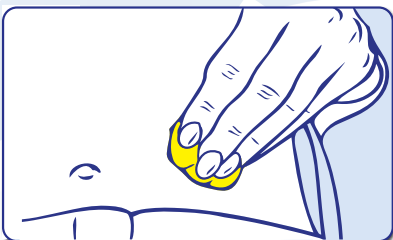


Figure K

Hold a cotton ball or gauze over the injection site. Do not rub the injection site. Apply an adhesive bandage to the injection site if needed.

Disposing of supplies

Do not reuse the prefilled syringe and attached needle. To avoid needle-stick injuries, do not recap used needles. Put your used prefilled syringes and attached needles in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash.** If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- Upright and stable during use
- Leak-resistant
- Properly labeled to warn of hazardous waste inside the container

There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, visit www.fda.gov/safesharpsdisposal.

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Important information

- **Do not** use a RELISTOR prefilled syringe and attached needle more than once, even if there is medicine left in the syringe
- Safely throw away RELISTOR prefilled syringes and attached needle after use (refer to “Disposing of supplies” in Step 3)
- To avoid needle-stick injuries, **do not** recap used needles
- Avoid touching the trigger fingers of the RELISTOR prefilled syringe to keep from activating the needle guard (safety device) too soon. The needle guard is activated by pressure from the plunger on the trigger fingers

How to store RELISTOR

- Store prefilled syringes at room temperature—68°F to 77°F (20°C to 25°C)
- Do not freeze
- Keep away from light until ready to use
- Keep out of reach of children

Please see the Instructions for Use – Pre-filled Syringe in the accompanying full Prescribing Information.

For more information visit www.RELISTOR.com

IMPORTANT SAFETY INFORMATION - RELISTOR injection, for subcutaneous use (cont'd)

- Also, tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- In a clinical study, the most common side effects of RELISTOR injection in people with long-lasting (chronic) pain that is not caused by cancer were: stomach-area (abdomen) pain, nausea, diarrhea, sweating, hot flush, tremor, and chills.
- In clinical studies, the most common side effects of RELISTOR injection in people receiving treatment for their advanced illness were: stomach-area (abdomen) pain, gas, nausea, dizziness, and diarrhea.

You are encouraged to report side effects of prescription drugs to FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For product information, adverse event reports, and product complaint reports, please contact:

Salix Product Information Call Center

Phone: 1-800-321-4576

Fax: 1-510-595-8183

Email: salixmc@dlss.com

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