

Relistor is used to treat constipation caused by opioids in adults with long-lasting (chronic) pain.

Help get your gut moving with Relistor



Learn how Relistor may help increase the number of bowel movements each week.

Indications

Relistor® (methylnaltrexone bromide) is a prescription medicine used to treat constipation in adults that is caused by prescription pain medicines called opioids.

- Relistor tablets and Relistor injection are 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

- Do not take Relistor if you have a bowel blockage (called an intestinal obstruction) or have a history of bowel blockage.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](#).

Links to: <https://www.relistor.com/pi>

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methylnaltrexone bromide
Tablets & Subcutaneous Injection

1. **Note to reviewers**
This is a digital rendition of the approved PRINT version (REL.0086.USA.21V3.0-Patient Brochure Update) [COMPASS Studio]

2. **Note to reviewers**
GLOBAL: Please see line has been adjusted throughout for digital use. [COMPASS Studio]

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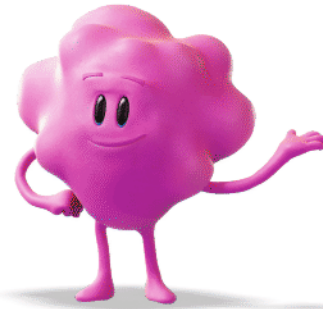
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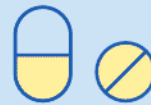
CHECK YOUR GUT

Opioid-induced constipation (OIC) is a different type of constipation that can be a side effect of taking opioid pain medicine



Opioid treatment can help relieve moderate to severe pain. Unfortunately, opioid use often comes with the undesired effect of constipation. If you're taking opioid pain medication and experiencing difficulty with bowel movements, you may have OIC.

OIC can last the entire time you continue taking your opioid medication. It is not likely to improve over time or with a change in opioid dose.



Some examples of opioids that can cause OIC include codeine, hydrocodone, morphine, oxycodone, fentanyl, and tramadol.

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YOU'RE NOT ALONE

Many people who take opioid pain medication may become constipated

~80% of patients taking oral opioid therapy and OTC laxatives reported still being constipated.

OIC symptoms can include



Reduced bowel movements (<3 per week in clinical studies)



Straining to have a bowel movement



Dry, hard stools



Sense of incomplete emptying of your bowels

OIC can impact your bowel routine.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](https://www.relistor.com/pi).

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RECONNECT WITH YOUR GUT



Like others suffering from OIC you may currently be trying to treat OIC symptoms with over-the-counter laxatives, diet changes, and exercise. The truth is, **OIC is a different type of constipation that may require a different kind of treatment.**

- OTC laxatives are intended for the treatment of occasional constipation, but are generally not meant for long-term use
- Some OTC laxatives should not be taken for longer than a week without consulting your healthcare provider

- Some common OTC laxatives include Miralax[®], Colace[®], and Senokot[®]

All trademarks are the properties of their respective owners.

Important Safety Information (continued)

- Relistor 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 and get emergency medical help right away.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](https://www.relistor.com/pi).

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CHECK IN WITH YOUR GUT

It's time to challenge your opioid-induced constipation (OIC) and your discomfort talking about it.

- Remember:
- Healthcare providers know that OIC is a real issue—they just might not know that you're suffering from it
 - When you let your healthcare provider know what you're experiencing, they can determine if prescription medication can help

Below is a guide to check off your answers. Answer it and use it as a tool to help discuss your OIC with your healthcare provider.

Points to discuss if it's your first visit

- 1 Are you taking opioid pain medications for long lasting (chronic) non-cancer pain?**
Here are some examples of opioids you may be taking: Codeine, Morphine, Tramadol, Hydrocodone, Oxycodone or Fentanyl.

Yes
 No
 I don't know


- 2 Since you've been taking opioid pain medication, have you noticed a reduction in the frequency or number of your bowel movements?**

Yes
 No


- 3 Since you've been taking opioid pain medication, how many bowel movements do you typically have each week?**

2 or less
 3+


- 4 Let's check other potential OIC symptoms. Have you been experiencing any or all of the following?**
Select all answers that apply.

Dry, hard stools
 Straining to have a bowel movement
 Sense of incomplete emptying of your bowels
 None of the above
- 5 To relieve your constipation, have you tried any of the following methods? Select all answers that apply.**

Increase activity or exercise
 Fiber-rich foods
 Enemas
 Increased water intake
 Over-the-counter laxatives
 Prescription medicines
 None of the above










Track your bowel movements

1 How many times do you have a bowel movement each week? Any change in stool type (refer to the Bristol Stool chart below)?

Week of									
Frequency									
Stool type									

2 Any additional notes to share with your healthcare provider:

Bristol Stool Chart

<p>Type 1 Separate hard lumps, like nuts (hard to pass)</p> 	<p>Type 5 Soft blobs with clear-cut edges</p> 
<p>Type 2 Sausage-shaped but lumpy</p> 	<p>Type 6 Fluffy pieces with ragged edges, a mushy stool</p> 
<p>Type 3 Like a sausage but with cracks on the surface</p> 	<p>Type 7 Watery, no solid pieces. Entirely Liquid.</p> 
<p>Type 4 Like a sausage or snake, smooth and soft</p> 	<p>Types 1-2 indicate constipation, with 3 and 4 being the ideal stools (especially the latter), as they are easy to defecate while not containing any excess liquid, and 5, 6 and 7 tending towards diarrhea.</p>

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WHEN OIC SLOWS THINGS DOWN RELISTOR CAN GIVE A LITTLE PUSH WITHOUT AFFECTING YOUR CHRONIC OPIOID PAIN TREATMENT



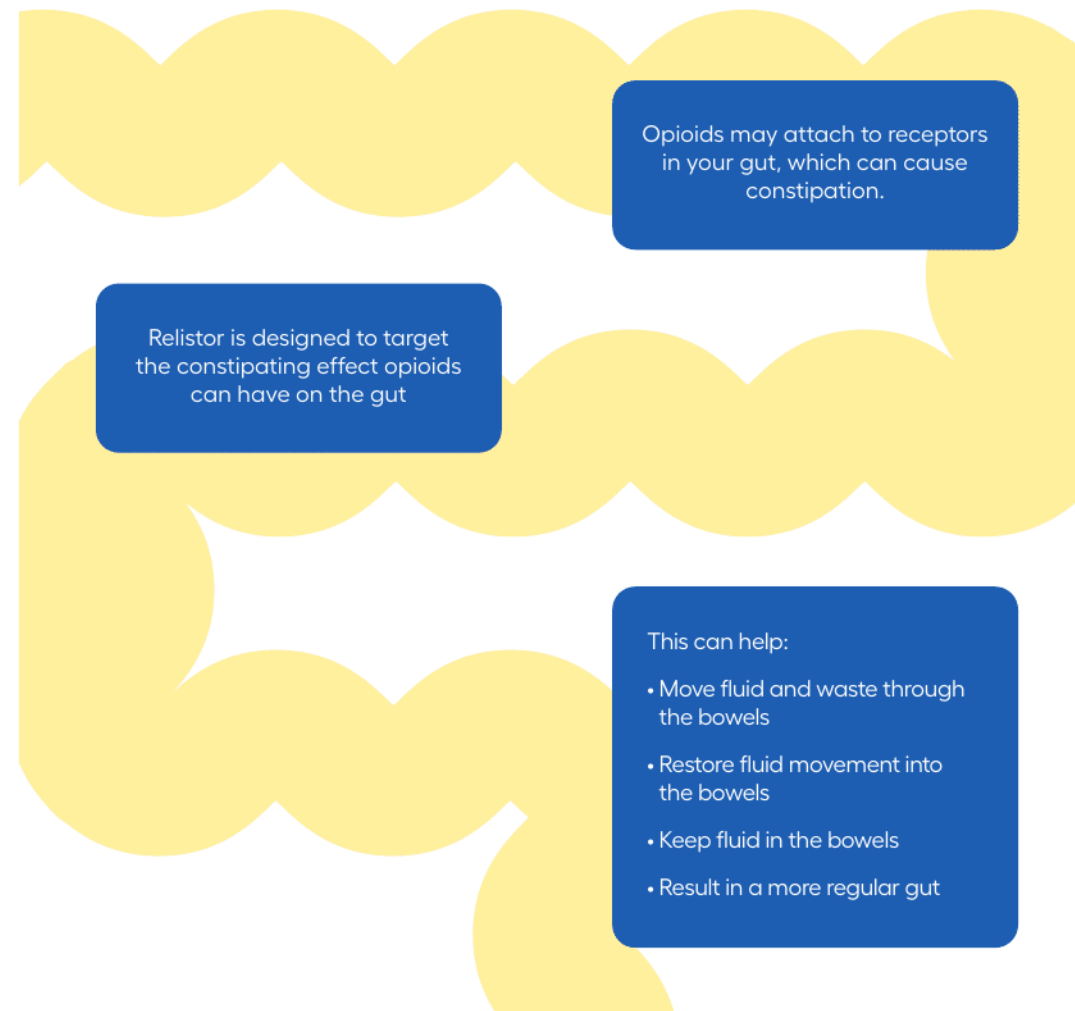
Relistor works differently from over-the-counter (OTC) laxatives. It's an FDA-approved prescription treatment specifically designed to target the constipating effect opioids have in the gut, without impacting opioid pain relief in the central nervous system. Tell your doctor if you experience any changes in your pain relief.

Important Safety Information (continued)

- Stop using Relistor and call your healthcare provider if you get diarrhea that is severe or that does not go away during treatment with Relistor.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](#).

Links to: <https://www.relistor.com/pi>



Important Safety Information (continued)

- You may have symptoms of opioid withdrawal during treatment with Relistor including sweating, chills, diarrhea, stomach pain, anxiety, and yawning. Tell your healthcare provider if you have any of these symptoms.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](#).

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CHECK RELISTOR

For adult patients with OIC and long-lasting (chronic) non-cancer pain:

- ✓ Relistor may help increase the number of bowel movements you have each week.^{*,†,‡,§}
- ✓ Relistor may work within 4 hours.^{*,†,‡}
- ✓ Relistor is available in both tablets and injection.^{*,†,‡}

* Individual results may vary.

† Based on a clinical study of 401 adult patients with opioid-induced constipation (OIC) and long-lasting (chronic) non-cancer pain treated with Relistor tablets or placebo (sugar pill).

‡ Based on a clinical study of 312 adult patients with OIC and long-lasting (chronic) non-cancer pain treated with Relistor injection or placebo injection.

§ In clinical studies a spontaneous bowel movement was defined as a bowel movement without the use of a laxative in the previous 24 hours.

Visit [Relistor.com](https://www.relistor.com) to learn more on how to take Relistor.

Relistor is available as a tablet or subcutaneous injection. Talk to your healthcare provider about which option may be best for you.

Important Safety Information (continued)

- Tell your healthcare provider if you have kidney or liver problems.
- 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.

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For adult patients with OIC and advanced illness (eg, end-stage chronic obstructive pulmonary disease, or COPD; heart disease; Alzheimer's disease) or pain caused by active cancer and who need increases in their opioid dose for comfort care.

- ✓ Relistor injection may help increase the number of bowel movements you have each week.^{*,†,‡}
- ✓ Relistor injection may work within 4 hours.^{*,†}
- ✓ Some patients who have a bowel movement within 4 hours may do so within 30 minutes.^{*,†}

* Individual results may vary.

† Based on a clinical study of 133 adult patients with advanced illness and OIC treated with Relistor injection or placebo injection.

‡ In clinical studies a spontaneous bowel movement was defined as a bowel movement without the use of a laxative in the previous 24 hours.

Relistor injection is the only prescription medicine FDA-approved to treat OIC in adult patients with advanced illness and pain caused by active cancer and who need increases in their opioid dose for comfort care.

Important Safety Information (continued)

- Tell your healthcare provider if you are pregnant or plan to become pregnant. Taking Relistor 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.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](https://www.relistor.com/pi).

Links to: <https://www.relistor.com/pi>

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HOW TO TAKE RELISTOR TABLETS



Relistor tablets should be taken daily, as directed by your healthcare provider.



Stop taking other laxatives before you start taking Relistor. You may resume laxatives after 3 days if needed.



Take three 150-mg tablets, for a total of 450 mg each day, in the morning. It is important to take Relistor as prescribed by your healthcare provider, which is usually for the duration of your opioid therapy. Your doctor may change your dose if you have kidney or liver problems.



Relistor should be taken at least 30 minutes before eating your first meal of the day. Do not eat food right before taking Relistor.



Take Relistor with water.

Even if you do not feel constipated, do not make changes to your medication schedule without talking to your healthcare provider.

Important Safety Information (continued)

- Taking Relistor while you are breastfeeding may cause opioid withdrawal in your baby. You should not breastfeed during treatment with Relistor. You and your healthcare provider should decide if you will take Relistor or breastfeed. You should not do both.
- Also, tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](https://www.relistor.com/pi).

Links to: <https://www.relistor.com/pi>

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HOW TO INJECT RELISTOR



Relistor subcutaneous injection should be taken as directed by your healthcare provider and should be kept at room temperature.

Relistor injection is injected under the skin of the upper arm, stomach-area (abdomen), or thigh. Do not inject at the same spot each time (rotate injection sites). Please see the Instructions for Use included in the accompanying full Prescribing Information



For adult OIC patients with long-lasting (chronic) non-cancer pain

- Inject one dose of Relistor subcutaneously every other day as needed.
- Stop taking other laxatives before you start treatment with Relistor. You may resume laxatives after 3 days if needed.



For adult OIC patients with advanced illness

- Inject one dose of Relistor subcutaneously every other day as needed.
- You should not inject more than 1 dose of Relistor in a 24-hour period.
- You may continue regular laxatives as directed.

Stop taking Relistor if you stop taking your prescription opioid pain medication. Tell your healthcare provider if your pain medication changes.

Important Safety Information (continued)

- In a clinical study, the most common side effects of Relistor tablets in people with long-lasting (chronic) pain that is not caused by cancer include: stomach-area (abdomen) pain, diarrhea, headache, swelling or a feeling of fullness or pressure in your abdomen, sweating, anxiety, muscle spasms, runny nose, and chills.

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ELIGIBLE PATIENTS MAY PAY AS LITTLE AS \$0 FOR RELISTOR WITH A CO-PAY CARD

100% of commercially insured patients are eligible to use the \$0 dollar co-pay card to fill their prescription.

SCAN THE
QR CODE BELOW
TO DOWNLOAD
AND ACTIVATE YOUR
CO-PAY SAVINGS
CARD.



If your healthcare provider has prescribed Relistor and you are an eligible commercially insured patient, you may benefit from a savings card and may pay as little as \$0 co-pay on your Relistor prescriptions.

Eligible patients can get a Relistor Instant Savings Card by calling 1-855-298-6939 or by visiting www.Relistor.com or scanning the QR code below. You will also receive refill reminders via text message.

Maximum benefits and other restrictions apply. Please see below for full eligibility criteria, terms, and conditions.



Links to: <https://www.relistor.com>

Eligibility Criteria, Terms and Conditions: This offer is only valid for patients with commercial insurance, including commercially-insured patients without coverage for Relistor. Patients without commercial insurance are not eligible. For eligible patients, Salix Pharmaceuticals will be responsible to pay your co-pay/out of pocket expense for each eligible prescription fill using this savings card, maximum benefits apply. Please call 1-855-202-3719 for more information. Patient is responsible for all additional costs and expenses after the maximum limit is reached. This savings card can be used up to 12 times before the expiration date. You must activate this coupon before using it by visiting www.Relistor.com, calling 1-855-202-3719, or texting SaveNow to 24109. Message and data rates may apply. The full terms can be viewed at Relistor.copaysavingsprogram.com/sms-terms. This offer is not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any federal, state, or other governmental programs, including, but not limited to, Medicare (including Medicare Advantage and Part A, B, and D plans), Medicaid, TRICARE, Veterans Administration or Department of Defense health coverage, CHAMPUS, the Puerto Rico Government Health Insurance Plan, or any other federal or state health care programs. This offer is only good in the USA at participating retail pharmacies. This offer cannot be redeemed at other locations, including government-subsidized clinics or facilities. This offer is not valid where otherwise prohibited, taxed, or otherwise restricted. Patient is responsible for reporting receipt of co-pay assistance to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the co-pay card, as may be required. This offer cannot be combined with other offers. This card has no cash value. No other purchase is necessary. This offer is nontransferable. No substitutions are permitted. This card is not health insurance. You understand and agree to comply with the terms and conditions of this offer as set forth above. Please see copay card for expiration date. Salix Pharmaceuticals reserves the right to rescind, revoke, or amend this offer at any time without notice.

Links to: <https://relistor.copaysavingsprogram.com/sms-terms>

Important Safety Information (continued)

- 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 include: stomach-area (abdomen) pain, nausea, diarrhea, sweating, hot flush, tremor, and chills.

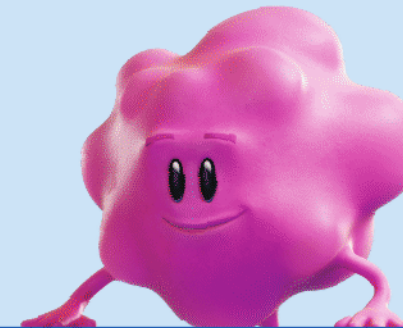
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Links to: <https://www.relistor.com/pi>

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YOUR RELISTOR SUMMARY

Relistor is specifically designed to target the constipating effect opioids have in the gut.



- ✓ Relistor may help increase the number of bowel movements you have each week.^{*,†,‡}
- ✓ Relistor may work within 4 hours.^{*,†,‡}
- ✓ Relistor is available in two different administration options for long-lasting (chronic) non-cancer pain patients.^{*,†,‡}

* Individual results may vary.

† Based on a clinical study of 401 adult patients with opioid-induced constipation (OIC) and long-lasting (chronic) non-cancer pain treated with Relistor tablets or placebo (sugar pill).

‡ Based on a clinical study of 312 adult patients with OIC and long-lasting (chronic) non-cancer pain treated with Relistor injection or placebo injection.

§ In clinical studies a spontaneous bowel movement was defined as a bowel movement without the use of a laxative in the previous 24 hours.

A more regular gut is closer than you think. Talk to your healthcare provider to find out how Relistor can help manage your OIC.

Important Safety Information (continued)

- In clinical studies, the most common side effects of Relistor injection in people receiving treatment for their advanced illness include: stomach-area (abdomen) pain, gas, nausea, dizziness, and diarrhea.

Please see full Important Safety Information on page 16 and full Prescribing Information, including Medication Guide, [here](#).

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications

Relistor® (methylnaltrexone bromide) is a prescription medicine used to treat constipation in adults that is caused by prescription pain medicines called opioids.

- Relistor tablets and Relistor injection are 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

- Do not take Relistor if you have a bowel blockage (called an intestinal obstruction) or have a history of bowel blockage.
- Relistor 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 and get emergency medical help right away.
- Stop using Relistor and call your healthcare provider if you get diarrhea that is severe or that does not go away during treatment with Relistor.
- You may have symptoms of opioid withdrawal during treatment with Relistor 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.
- Tell your healthcare provider if you have any stomach or bowel (intestine) 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 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.
- Taking Relistor while you are breastfeeding may cause opioid withdrawal in your baby. You should not breastfeed during treatment with Relistor. You and your healthcare provider should decide if you will take Relistor or breastfeed. You should not do both.
- 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 tablets in people with long-lasting (chronic) pain that is not caused by cancer include: stomach-area (abdomen) pain, diarrhea, headache, swelling or a feeling of fullness or pressure in your abdomen, sweating, anxiety, muscle spasms, runny nose, and chills.
- 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 include: 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 include: stomach-area (abdomen) pain, gas, nausea, dizziness, and diarrhea.

Links to: <https://www.fda.gov/safety/medwatch>

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

Please see full Prescribing Information, including Medication Guide, [here](#).

Links to: <https://www.relistor.com/pi>

Links to: <https://www.salixmc@dlss.com>

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PHARMACEUTICALS

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