MEDICATION GUIDE

Tofacitinib (toe-fa-sye-ti-nib) Oral Solution

What is the most important information I should know about tofacitinib oral solution?

Tofacitinib oral solution may cause serious side effects including:

1. Serious infections. Tofacitinib oral solution is a medicine that affect your immune system. Tofacitinib oral solution can lower the ability of your immune system to fight infections. Some people can have serious infections while taking tofacitinib oral solution, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting tofacitinib oral solution and during treatment.
- Your healthcare provider should monitor you closely for signs and symptoms of TB infection during treatment with tofacitinib oral solution.

You should not start taking tofacitinib oral solution if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).

Before starting tofacitinib oral solution, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:
    - fever, sweating, or chills
    - cough
    - blood in phlegm
    - warm, red, or painful skin or sores on your body
    - burning when you urinate or urinating more often than normal
    - muscle aches
    - shortness of breath
    - weight loss
    - diarrhea or stomach pain
    - feeling very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may happen or become more severe if you take tofacitinib oral solution. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B or C.

After starting tofacitinib oral solution, call your healthcare provider right away if you have any symptoms of an infection. Tofacitinib oral solution can make you more likely to get infections or make worse any infection that you have.

After starting tofacitinib oral solution, call your healthcare provider right away if you, your partner, or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes because these may be symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking XELJANZ 5 mg or 10 mg twice daily.

3. Cancer and immune system problems. Tofacitinib oral solution may increase your risk of certain cancers by changing the way your immune system works.

- Lymphoma and other cancers including skin cancers can happen in people taking tofacitinib oral solution. People taking XELJANZ 5 mg twice daily or XELJANZ 10 mg twice daily have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker. Tell your healthcare provider if you have ever had any type of cancer.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking XELJANZ 5 mg or 10 mg twice daily, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking tofacitinib oral solution, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech

5. Blood clots in the lungs, veins of the legs or arms, and arteries. Blood clots in the lungs (pulmonary embolism, PE), veins of the legs (deep vein thrombosis, DVT) and arteries (arterial thrombosis) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking XELJANZ 5 mg or 10 mg twice daily. Blood clots in the lungs have also happened in people with ulcerative colitis. Some people have died from these blood clots.

- Stop taking tofacitinib oral solution and tell your healthcare provider right away if you develop signs and symptoms of a blood clot, such as sudden shortness of breath or difficulty breathing, chest pain, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm.

6. Tears (perforation) in the stomach or intestines.

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking tofacitinib oral solution can get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Tell your healthcare provider right away if you have fever and stomach-area pain that does not go away, and a change in your bowel habits.

7. Allergic reactions.

- Symptoms such as swelling of your lips, tongue, or throat, or hives (raised, red patches of skin that are often very itchy) that may mean you are having an allergic reaction have been seen in people taking XELJANZ. Some of these reactions were serious. If any of these symptoms occur while you are taking tofacitinib oral solution, stop tofacitinib oral solution and call your healthcare provider right away.

8. Low blood sugar (hypoglycemia) in people with diabetes. If you have diabetes, your healthcare provider may tell you to check your blood sugar (glucose) more often during treatment with tofacitinib oral solution. Call your healthcare provider if you have any problems with low blood sugar.

9. Changes in certain laboratory test results. Your healthcare provider should do blood tests before you start taking tofacitinib oral solution and while you take tofacitinib oral solution to check for the following side effects:

- **changes in lymphocyte counts.** Lymphocytes are white blood cells that help the body fight off infections.
- **low neutrophil counts.** Neutrophils are white blood cells that help the body fight off infections.
- **low red blood cell count.** This may mean that you have anemia, which may make you feel weak and tired.

Your healthcare provider should routinely check certain liver tests. You should not take tofacitinib oral solution if your lymphocyte count, neutrophil count, or red blood cell count is too low or your liver tests are too high. Your healthcare provider may stop your tofacitinib oral solution treatment for a period of time if needed because of changes in these blood test results.
You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests to check your cholesterol levels 4 to 8 weeks after you start taking tofacitinib oral solution, and as needed after that. Normal cholesterol levels are important to good heart health.

See "**What are the possible side effects of tofacitinib oral solution?**" for more information about side effects.

What is tofacitinib oral solution?

- Tofacitinib oral solution is a prescription medicine called a Janus kinase (JAK) inhibitor.
- Tofacitinib oral solution is used to treat children 2 years of age and older with active psoriatic arthritis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.
- Tofacitinib oral solution is used to treat children 2 years of age and older with active polyarticular course juvenile arthritis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.

It is not known if tofacitinib oral solution is safe and effective in people with Hepatitis B or C.
Tofacitinib oral solution is not recommended for people with severe liver problems. It is not known if tofacitinib oral solution is safe and effective in children for treatment other than active polyarticular course juvenile arthritis and psoriatic arthritis.

What should I tell my healthcare provider before taking tofacitinib oral solution?
Before taking tofacitinib oral solution, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection. See "**What is the most important information I should know about tofacitinib oral solution?**"
- are a current or past smoker.
- have had any type of cancer.
- have had a heart attack, other heart problems or stroke.
- have had blood clots in the veins of your legs, arms, or lungs, or clots in the arteries in the past.
- have liver problems.
- have kidney problems.
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines.
- have diabetes.
- have had a reaction to tofacitinib or any of the ingredients in tofacitinib oral solution.

- have recently received or are scheduled to receive a vaccine. People who take tofacitinib oral solution should not receive live vaccines. People taking tofacitinib oral solution can receive non-live vaccines.
- plan to become pregnant or are pregnant. Tofacitinib oral solution may affect the ability of females to get pregnant. It is not known if this will change after stopping tofacitinib oral solution. It is not known if tofacitinib oral solution will harm an unborn baby.
- plan to breastfeed or are breastfeeding. You and your healthcare provider should decide if you will take tofacitinib oral solution or breastfeed. You should not do both. After you stop your treatment with tofacitinib oral solution do not start breastfeeding again until:
  - 18 hours after your last dose of tofacitinib oral solution

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tofacitinib oral solution and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- any other medicines to treat your psoriatic arthritis or polyarticular course juvenile arthritis. You should not take tocilizumab (Actemra), etanercept (Enbrel), adalimumab (Humira), infliximab (Remicade), rituximab (Rituxan), abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), ustekinumab (Stelara), secukinumab (Cosentyx), vedolizumab (Entyvio), ixekizumab (Taltz), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking tofacitinib oral solution. Taking tofacitinib oral solution with these medicines may increase your risk of infection.
- medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take tofacitinib oral solution?

Take tofacitinib oral solution exactly as your healthcare provider tells you to take it.

- Take tofacitinib oral solution 2 times a day with or without food.
- If you take too much tofacitinib oral solution, call your healthcare provider or go to the nearest hospital emergency room right away.
- For the treatment of psoriatic arthritis, take tofacitinib oral solution in combination with methotrexate, sulfasalazine or leflunomide as instructed by your healthcare provider.
- XELJANZ XR (extended-release tablets) should not be used instead of tofacitinib oral solution.

What are the possible side effects of tofacitinib oral solution? Tofacitinib oral solution may cause serious side effects, including:

- See "**What is the most important information I should know about tofacitinib oral solution?**"
- **Hepatitis B or C activation infection** in people who carry the virus in their blood. If you are a carrier of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while you use tofacitinib oral solution. Your healthcare provider may do blood tests before you start treatment with tofacitinib oral solution and while you are taking tofacitinib oral solution. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B or C infection:
  - feel very tired
  - little or no appetite
  - clay-colored bowel movements
  - chills
  - muscle aches
  - skin rash
  - skin or eyes look yellow
  - vomiting
  - fevers
  - stomach discomfort
  - dark urine

Common side effects of tofacitinib oral solution in children with polyarticular course juvenile arthritis and psoriatic arthritis include:

- upper respiratory tract infections (common cold, sinus infections)
- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- headache
- fever
- nausea
- vomiting
- acne

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all the possible side effects of tofacitinib oral solution. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Sun Pharmaceutical Industries, Inc. at 1-800-818-4555.

How should I store tofacitinib oral solution?

- Store tofacitinib oral solution at room temperature, 20º to 25ºC (68º to 77ºF); excursions permitted to 15° to 30°C (59° to 86°F) in the original bottle and carton to protect from light.
- Safely throw away tofacitinib oral solution that is out of date or no longer needed. Use tofacitinib oral solution within 60 days of opening the bottle. Throw away (discard) remaining oral solution after 60 days.

Keep tofacitinib oral solution and all medicines out of the reach of children.

General information about the safe and effective use of tofacitinib oral solution.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use tofacitinib oral solution for a condition for which it was not prescribed. Do not give tofacitinib oral solution to other people, even if they have the same symptoms you have. It may harm them.
This Medication Guide summarizes the most important information about tofacitinib oral solution. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about tofacitinib oral solution that is written for health professionals.

What are the ingredients in tofacitinib oral solution?
Active ingredient: tofacitinib citrate
Inactive ingredients: grape flavor (natural), hydrochloric acid, L-lactic acid, purified water, sodium benzoate, sodium hydroxide, sucralose and xylitol. Grape flavor (natural) contains propylene glycol and natural flavor.

Manufactured by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

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XELJANZ/XELJANZ XR is a registered trademark of Pfizer Inc.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: October 2026

INSTRUCTIONS FOR USE

Tofacitinib (toe-fa-sye-ti-nib) Oral Solution

Read this Instructions for Use before you start taking tofacitinib oral solution and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

Important information about measuring tofacitinib oral solution:

Always use the oral dosing syringe that comes with tofacitinib oral solution to measure and take your prescribed dose. Ask your healthcare provider or pharmacist to show you how to measure your prescribed dose if you are not sure.

How should I store tofacitinib oral solution?

- Store tofacitinib oral solution at room temperature, 20º to 25ºC (68º to 77ºF); excursions permitted to 15° to 30°C (59° to 86°F).
- Always store tofacitinib oral solution in the original bottle and carton to protect from light.

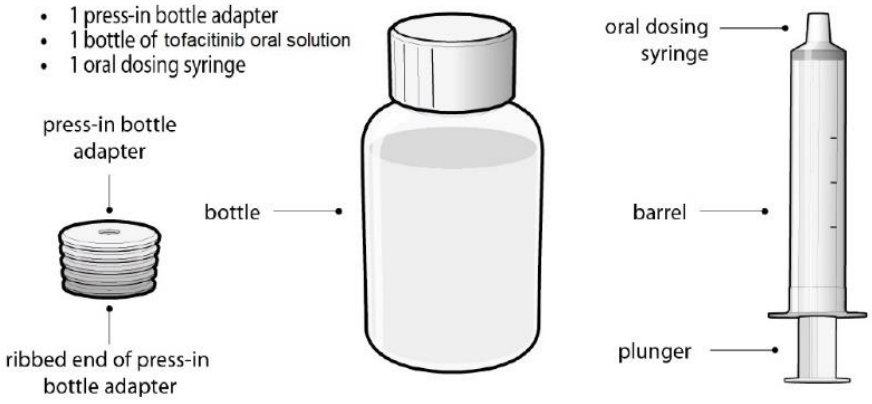
Keep tofacitinib and all medicines out of the reach of children.

Use tofacitinib oral solution within 60 days of opening the bottle. Throw away (discard) remaining tofacitinib oral solution after 60 days.

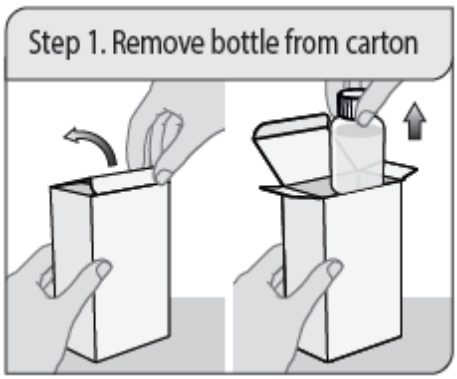
To help you remember when to throw away your bottle of tofacitinib oral solution, you can write the date when you first start to use it on the carton and below:
Date of first use ____ / ____ / ____.

Before each use:
Wash your hands with soap and water and place the items from the carton on a clean, flat surface.

Each carton of tofacitinib oral solution contains:

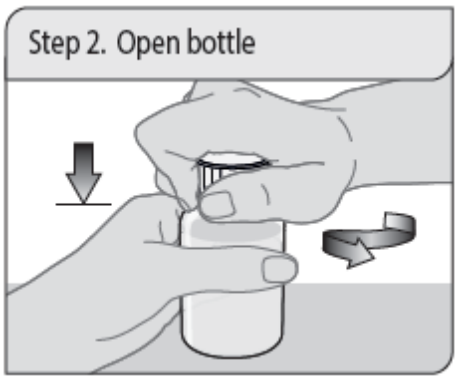


Step 1. Remove bottle from carton



Open the carton and remove the bottle of tofacitinib oral solution.

Step 2. Open bottle

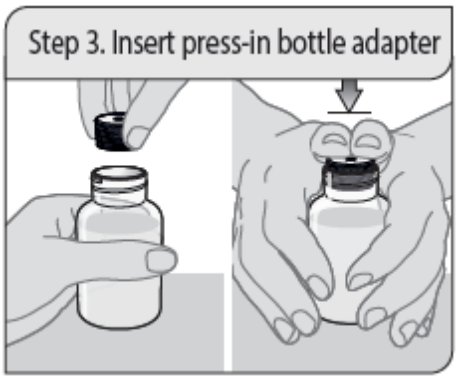


Open the bottle by pushing down on the child-resistant cap and turning it to the left (counter-clockwise) as shown. Remove the seal off the top of the bottle (first time only).

Do not throw away the child-resistant cap.

Note: The bottle does not need to be shaken before use.

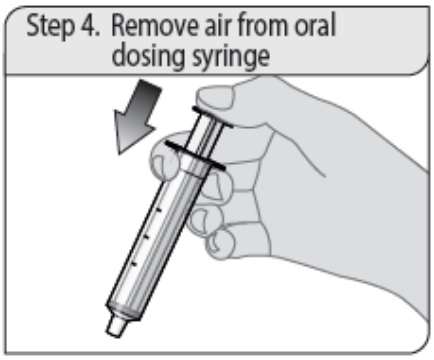
Step 3. Insert press-in bottle adapter (first time only)



Remove the press-in bottle adapter and oral dosing syringe from the plastic overwrap. With the bottle on a flat surface, push the ribbed end of the press-in bottle adapter all the way into the neck of the bottle with your thumbs while holding the bottle firmly.

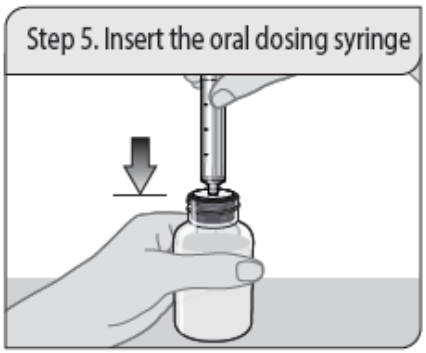
Note: Do not remove the press-in bottle adapter from the bottle after it is inserted.

Step 4. Remove air from oral dosing syringe



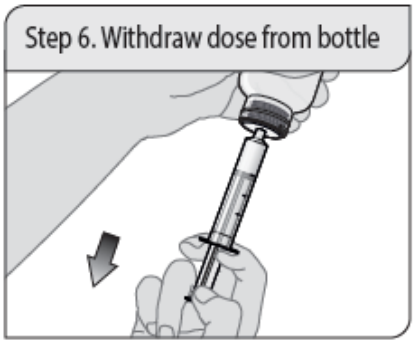
Push the oral dosing syringe plunger all the way down to the tip of the syringe barrel to remove excess air.

Step 5. Insert the oral dosing syringe



Insert the oral dosing syringe tip into the upright bottle through the opening of the press-in bottle adapter until it is firmly in place.

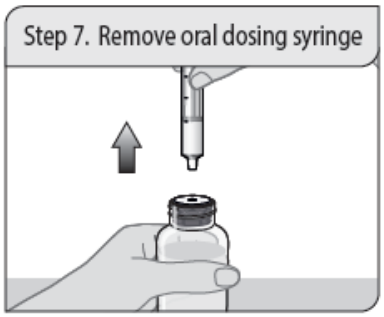
Step 6. Withdraw dose from bottle



With the oral dosing syringe in place, turn the bottle upside down. Pull down on the plunger until the bottom of the plunger is even with the markings on the oral dosing syringe for your prescribed dose of oral solution.

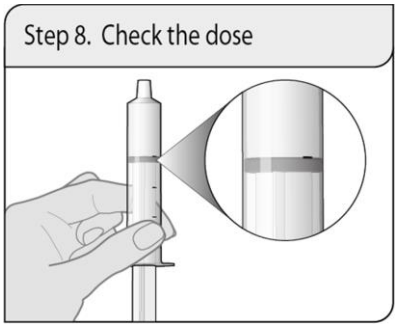
If you see air bubbles in the oral dosing syringe, fully push the plunger in so that the oral solution flows back into the bottle. Then withdraw your prescribed dose of oral solution.

Step 7. Remove oral dosing syringe



Turn the bottle upright and place the bottle on a flat surface. Remove the oral dosing syringe from the press-in bottle adapter and bottle by pulling straight up on the oral dosing syringe barrel.

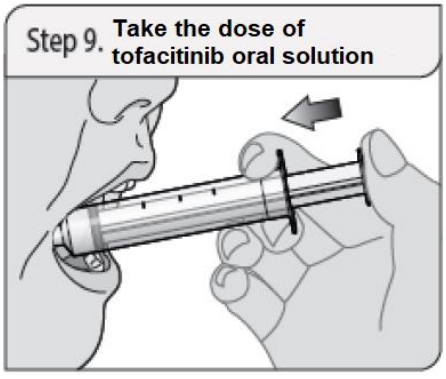
Step 8. Check the dose



Check that the correct dose was drawn up into the oral dosing syringe.

If the dose is not correct, insert the oral dosing syringe tip firmly into the press-in bottle adapter. Fully push in the plunger so that the oral solution flows back into the bottle. Repeat Step 6 and Step 7.

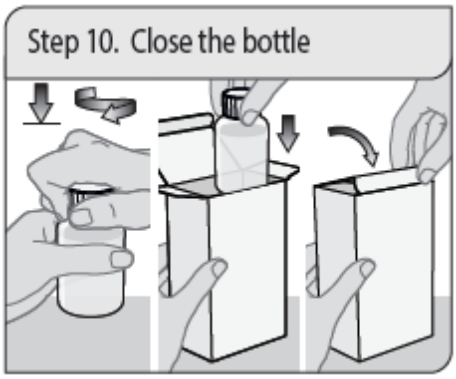
Step 9. Take the dose of tofacitinib oral solution



Place the tip of the oral dosing syringe into the inside of the cheek.

Slowly push the plunger all the way down to give all of the medicine in the oral dosing syringe. Make sure there is time to swallow the medicine.

Step 10. Close the bottle

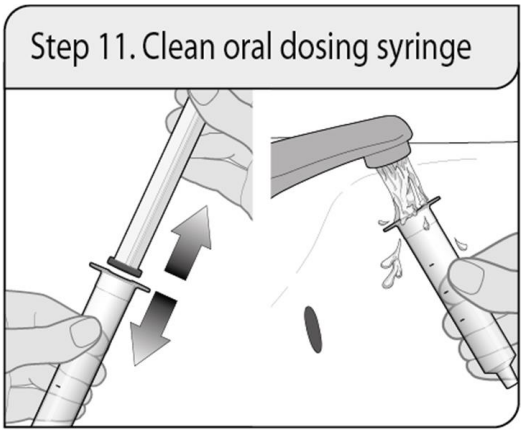


Close the bottle tightly by turning the child-resistant cap to the right (clockwise), leaving the press-in bottle adapter in place.

Place the bottle back into the carton.

Close the carton to protect tofacitinib oral solution from light.

Step 11. Clean oral dosing syringe



Remove the plunger from the barrel by pulling the plunger and the barrel away from each other.

Rinse both with water after each use.

Allow to air dry. When the barrel and plunger are dry, put the oral dosing syringe back together by inserting the plunger into the barrel.

Store the oral dosing syringe with the tofacitinib oral solution.

Do not throw away the oral dosing syringe.

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New Brunswick, NJ 08901

Distributed by:
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Cranbury, NJ 08512

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