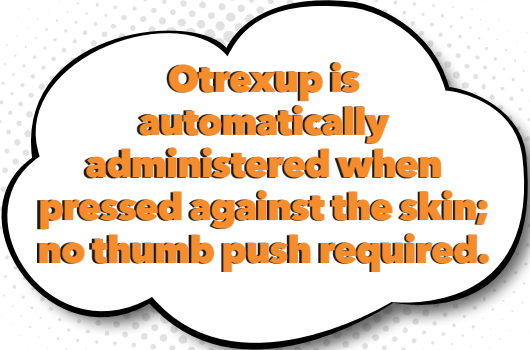




What is Otrexup?

Otrexup is a single-dose auto-injector containing a prescription medicine, methotrexate. Methotrexate is used to:

- Treat certain adults with severe, active rheumatoid arthritis (RA), and children with active polyarticular juvenile idiopathic arthritis (pJIA), after treatment with other medicines including non-steroidal anti-inflammatory drugs (NSAIDs) have been used and did not work well.
- Control the symptoms of severe, resistant, disabling psoriasis in adults when other types of treatment have been used and did not work well.

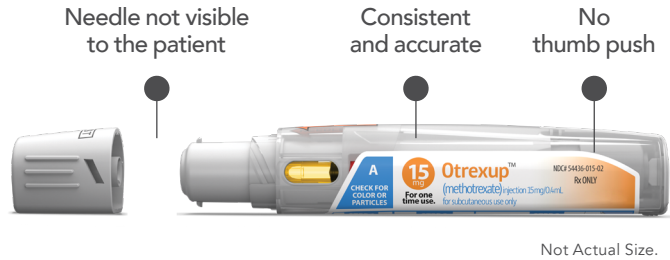


IMPORTANT SAFETY INFORMATION (continued)

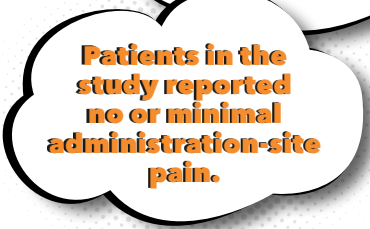
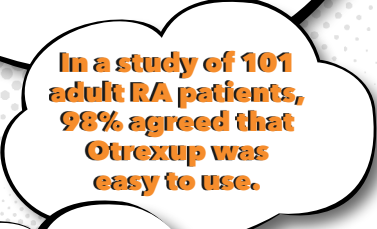
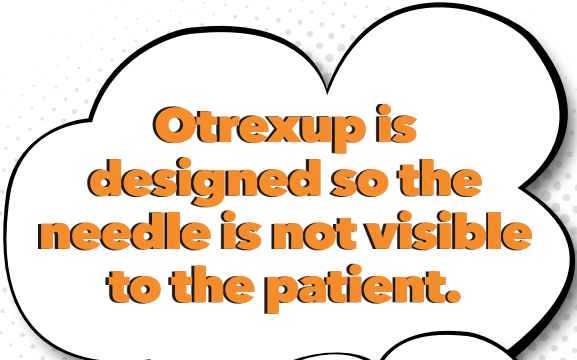
- o liver
- o immune system
- o kidneys
- o skin

Your doctor will do blood tests and other types of tests before you take and while you are taking OTREXUP to check for signs and symptoms of organ toxicity. Call your doctor right away if

Please see additional Important Safety Information on the next pages.



Dose Strengths



IMPORTANT SAFETY INFORMATION (continued)

- o fever
- o confusion
- o weakness
- o temporary blindness
- o seizures
- o headache
- o sleepiness
- o problems with coordination
- o dry cough
- o trouble breathing
- o severe skin rash
- o back pain



IMPORTANT SAFETY INFORMATION (continued)

WHO SHOULD NOT TAKE OTREXUP?

Do not use OTREXUP if you:

- Are pregnant or planning to become pregnant. See **“What is the most important information I should know about OTREXUP?”**
- Are breastfeeding; OTREXUP can pass into your breast milk and may harm your baby.
- Have alcohol problems (alcoholism)
- Have liver problems
- Have problems fighting infection (immunodeficiency syndrome)
- Have been told you have (or think you have) a blood disorder such as low levels of white blood cells, red blood cells (anemia), or platelets
- Have had an allergy to methotrexate or any of the ingredients in OTREXUP. See the Prescribing Information for a list of ingredients in OTREXUP.

Talk to your doctor before taking this medicine if you have any of these conditions.



How to use video instruction

Watch our free self-administration video at www.otrexup.com/PI.

IMPORTANT SAFETY INFORMATION (continued)

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

HOW SHOULD I USE OTREXUP?

- **Read the Instructions for Use that come with OTREXUP.**

- Take OTREXUP exactly as your doctor tells you to take it.

- Inject OTREXUP **only 1 time each week. Do not** take OTREXUP every day. Taking OTREXUP every day may cause death from toxicity.

- Your doctor will show you or your caregiver how to inject OTREXUP. You should not inject OTREXUP until you have been trained on the right way to use it.

- Check OTREXUP before you inject it. OTREXUP should be yellow in color and should not have any lumps or particles in it.

- OTREXUP should be injected in the stomach (abdomen) or thigh.

- **Do not** inject OTREXUP within 2 inches of the belly button (navel).

- **Do not** inject OTREXUP in the arms or any other areas of the body.

- **Do not** inject OTREXUP in areas where the skin is tender, bruised, red, scaly, hard, or has scars or stretch marks.

- If you are not sure if OTREXUP was injected, or if you have a hard time giving the injection, **do not** inject another dose. Call your pharmacist or doctor right away.

- If you inject too much OTREXUP, call your doctor or go to the nearest hospital emergency room right away.

WHAT SHOULD I AVOID WHILE USING OTREXUP?

- Do not drink alcohol while taking OTREXUP. Drinking alcohol can increase your chances of getting serious side effects.

- OTREXUP can cause dizziness and tiredness. Do not drive a car, operate machinery, or do anything that needs you to be alert until you know how OTREXUP affects you.

- Certain vaccinations should be avoided while taking OTREXUP. Talk to your doctor before you or members of your household receive any vaccines.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF OTREXUP?

OTREXUP may cause serious side effects, including:

- **Fertility problems.** Methotrexate, the active ingredient in OTREXUP, may affect your ability to have a baby. Males may have a decreased sperm count, and females may have

IMPORTANT SAFETY INFORMATION (continued)

changes to their menstrual cycle. This can happen while taking OTREXUP and for a short period of time after you stop.

- **Certain cancers.** Some people who have taken methotrexate have had a certain type of cancer called Non-Hodgkin’s lymphoma and other tumors. Your doctor may tell you to stop taking OTREXUP if this happens.

- **Tissue and bone problems.** Taking methotrexate while having radiation therapy may increase the risk of your tissue or bone not receiving enough blood. This may lead to death of the tissue or bone.

Common side effects of OTREXUP include:

- | | |
|--|---|
| o nausea | o vomiting |
| o stomach pain | o headache |
| o indigestion (dyspepsia) | o bronchitis |
| o mouth sores | o low red, white, and platelet cell count |
| o rash | o hair loss |
| o stuffy or runny nose and sore throat | o dizziness |
| o diarrhea | o sensitivity to light |
| o abnormal liver function tests | o burning skin lesions |
| | o lung problems |

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

Call your doctor for medical advice about side effects. You may report side effects to **FDA** at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please see full Prescribing Information, including **Boxed Warning** and **Patient Information**, at www.otrexup.com/PI.



With Otrexup, less of the bright yellow color of methotrexate is visible

- Prior to injection, less of the bright yellow color of methotrexate is visible with Otrexup compared to other injectable methotrexate products.

Otrexup is designed so the parent and child do not see the needle before, during, or after the injection



Not Actual Size.

IMPORTANT SAFETY INFORMATION (continued)

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE USING OTREXUP?

Before you take OTREXUP, tell your doctor if you have any other medical conditions.

Tell your doctor about all of the medicines you take, including prescription, over-the-counter medicines, vitamins, and herbal supplements. OTREXUP may affect how other medicines work, and other medicines may affect how OTREXUP works causing side effects. Ask your doctor or pharmacist for a list of medicines if you are not sure.

Please see additional Important Safety Information on the next pages.

When thinking of injectable methotrexate,

consider **Otrexup!**



Not Actual Size.

IMPORTANT SAFETY INFORMATION (continued)

- 2. Women who are pregnant are at increased risk for death of the baby and birth defects.** Women who are pregnant or who plan to become pregnant **must not take OTREXUP.** A pregnancy test should be performed before starting OTREXUP. Contraception should be used by both females and males while taking OTREXUP. Pregnancy should be avoided if either partner is receiving OTREXUP:
- o for a minimum of 3 months after treatment with OTREXUP for males.
 - o during and for 6 months after treatment with OTREXUP for females.

WHAT IS OTREXUP?

OTREXUP is a single-dose auto-injector containing a prescription medicine, methotrexate. Methotrexate is used to:

- Treat certain adults with severe, active rheumatoid arthritis (RA), and children with active polyarticular juvenile idiopathic arthritis (pJIA), after treatment with other medicines including non-steroidal anti-inflammatory drugs (NSAIDs) have been used and did not work well.
- Control the symptoms of severe, resistant, disabling psoriasis in adults when other types of treatment have been used and did not work well.

OTREXUP should not be used for the treatment of cancer.

OTREXUP should not be used for the treatment of children with psoriasis.

Otrexup General Steps for Administration

Please read the accompanying full Instructions for Use before using Otrexup, including the preparation steps before injection.

Step 1



Remove cap

- Twist cap marked 1 to remove. This will break the seal.
- Do not replace the cap after it has been removed.
- After the cap is removed, Otrexup must be used or disposed of safely.

Step 2



Remove the safety clip

- Flip the safety clip marked 2.

Step 3



Administer Otrexup in the thigh or abdomen

- Place the needle at the end of Otrexup flat against thigh or stomach at a 90° and firmly push device against the injection site until fully depressed. Do not inject Otrexup within 2 inches of the belly button (navel). You will hear a click, then hold for 3 seconds.



- You may notice a small amount of blood or liquid at the administration site, which is normal.
- Remove Otrexup from the site and press a cotton ball on the area for 10 seconds. Do not rub the area.

IMPORTANT SAFETY INFORMATION (continued)

you have any of the following symptoms of organ toxicity:

- o vomiting
- o diarrhea
- o mouth sores
- o neck stiffness
- o paralysis
- o irritability

Eligible patients with commercial insurance may pay as low as \$0* co-pay per prescription

The Otrexup Co-Pay Assistance Program provides financial support to most commercially insured patients to assist with out-of-pocket costs of Otrexup. This card is valid for up to 13 fills per calendar year.

Once you've enrolled, simply present your card along with your Otrexup prescription to the pharmacist, and the savings will be applied.



For more information, visit www.otrexup.com/PI.

*Eligibility Restrictions: Offer only valid for patients with commercial prescription insurance. Maximum benefit of up to \$250 for each prescription filled. Offer not valid for prescriptions reimbursed under any federal or state healthcare program, including Medicare, Medicaid, or any state medical assistance programs. Offer void where prohibited by law, taxed, or restricted. Offer only valid in the USA. Otter Pharmaceuticals reserves the right to rescind, revoke, or amend this offer at any time without notice. By using this card, you understand and agree to comply with the terms and conditions of this offer.

Please read Patient Instructions for Use† in attached pocket before using Otrexup for complete administration steps.

†See the complete injection process in the Instruction for Use.



© 2023 Otter Pharmaceuticals
A subsidiary of Assertio Holdings, Inc. All rights reserved.
100 South Saunders Road, Suite 300, Lake Forest, IL 60045
Otrexup is a registered trademark of Otter Pharmaceuticals, LLC.
APL-OTX-XXXX Mar 2023

Otrexup[®]
(methotrexate) injection
for subcutaneous use

Taking methotrexate?

Learn about **Otrexup!**

What is Otrexup?

Otrexup is a single-dose auto-injector containing a prescription medicine, methotrexate. Methotrexate is used to:

- Treat certain adults with severe, active rheumatoid arthritis (RA), and children with active polyarticular juvenile idiopathic arthritis (pJIA), after treatment with other medicines including non-steroidal anti-inflammatory drugs (NSAIDs) have been used and did not work well.
- Control the symptoms of severe, resistant, disabling psoriasis in adults when other types of treatment have been used and did not work well.

IMPORTANT SAFETY INFORMATION FOR OTREXUP[®]

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT OTREXUP[®]?

OTREXUP can cause serious side effects that can lead to death, including:

- 1. Organ system toxicity.** People who use methotrexate for the treatment of cancer, psoriasis, or rheumatoid arthritis, have an increased risk of death from organ toxicity. Types of organ toxicity can include:

- o gastrointestinal
- o bone marrow
- o nerve
- o lung

Please see additional Important Safety Information inside and accompanying full Prescribing Information and Patient Information including Boxed Warning.