ACR/ARP Medication Guide



ASSOCIATION of RHEUMATOLOGY PROFESSIONALS The Interprofessional Division of the American College of Rheumatology

Methotrexate Brand Names (Otrexup, Rasuvo)

Methotrexate is a folate antimetabolite that inhibits DNA synthesis, repair and cellular replication by inhibiting dihydrofolate reductase therefore inhibiting the formation of reduced folates. The mechanism for treatment in rheumatologic conditions is not completely understood but may affect immune function and anti-inflammatory properties. It is known as a disease-modifying anti-rheumatic drug (DMARD) because it not only decreases the pain and swelling of arthritis, but it also can decrease damage to joints and long-term disability.

Resources from Manufacturer

<u>Full Prescribing Information (tablets)</u> <u>Otrexup Co-pay Card (autoinjector)</u> <u>Rasuvo Co-pay Card (autoinjector)</u>]

Indications and Dosing in Rheumatology

*FDA Approved Indications

Adult

- Crohn's Disease: PO/SUBQ/IM: 15 to 25 mg once weekly, in combination with folic acid
- Dermatomyositis, cutaneous: PO/SUBQ/IM: 5 to 15 mg once weekly, in combination with folic acid
- Discoid lupus erythematosus, cutaneous lupus erythematosus: PO/SUBQ/IM: 10 to 25 mg once weekly, in combination with folic acid
- Eosiniphilic granulomatosis with polyangiitis: PO/SUBQ: 15 mg once weekly, in combination with folic acid
- Giant cell arteritis: PO/SUBQ: 10 to 15 mg once weekly, in combination with folic acid
- Granulomatosis with polyangiitis and microscopic polyangiitis: PO/SUBQ/IM: 15 to 20mg once weekly, in combination with folic acid
- *Psoriasis: PO/SUBQ/IM: 10 to 25 mg once weekly, in combination with folic acid
- *Rheumatoid Arthritis: PO/SUBQ/IM: 7.5mg once weekly, in combination with folic acid, adjust response to achieve optimal response
- Still's Disease: PO/SUBQ/IM: 10 to 15 mg once weekly, in combination with folic acid
- Systemic lupus erythematosus: PO/SUBQ: 5 to 15mg once weekly, in combination with folic acid
- Systemic sclerosis or scleroderma: PO/SUBQ: 10mg once weekly, in combination with folic acid

continued

ACR/ARP Medication Guide



association∉ Rheumatology Professionals

The Interprofessional Division of the American College of Rheumatology

Indications and Dosing in Rheumatology continued

*FDA Approved Indications

Pediatric

- Crohn's Disease: Use in combination with folic acid
 - BSA directed: 15 mg/m2 once weekly; maximum dose 25mg/dose
 - Fixed Dosing:
 - 20-29kg: 10mg once weekly
 - 30-39kg: 15mg once weekly
 - 40-49kg: 20mg once weekly
 - ≥50kg: 25mg once weekly
- Dermatomyositis: IM/SUBQ preferred: 15 to 20 mg/m2 or 1mg/kg once weekly, whichever is less; maximum 40mg/dose

JIA:

BSA directed: PO/SUBQ/IM: 10 to 15 mg/m2 once weekly, in combination with folic acid
Weight based: PO/SUBQ: 0.5mg/kg once weekly, used in combination with folic acid

- Psoriasis: PO/SUBQ: 0.2mg to 0.4mg/kg once weekly, used in combination with folic acid
- Scleroderma: 1mg/kg once weekly, use in combination with folic acid, may be use with corticosteroids
- Uveitis

BSA directed: PO/SUBQ: 15 mg/m2 once weekly, used in combination with folic acid

Used in combination with folic acid Weight based: 0.5mg to 1mg/kg once weekly, used in combination with folic acid

Contraindications

Severe hypersensitivity to methotrexate, pregnancy (for certain indications)

Warnings and Precautions

- Serious Infections-use in caution with patients who have active infection
- Renal impairment, dose adjustment may be required
- Avoidance of live vaccines while on treatment
- Non-neoplastic dosing is weekly, use extreme caution to ensure correct dosing

Adverse Reactions

Common: ulcerative stomatitis, leukopenia, nausea and abdominal distress

continued

ACR/ARP Medication Guide



association# Rheumatology Professionals

The Interprofessional Division of the American College of Rheumatology

Medication Strength and Preparations

Oral formulations: 2.5mg tablets, 2.5mg/mL oral solution

Injections:

- 50mg/2mL vials
- Otrexup Autoinjectors: 10mg/0.4mL, 12.5mg/0.4mL, 15mg/0.4mL, 17.5mg/0.4mL, 20mg/0.4mL 22.5mg/0.4mL and 25 mg/0.4mL autoinjector
- Rasuvo Autoinjectors:7.5mg/0.15mL, 10mg/0.2mL, 12.5mg/0.25mL, 15mg/0.3mL, 17.5mg/0.35mL, 20mg/0.8mL, 22.5mg/0.45mL, 25mg/0.5mL, 30mg/0.6mL
- Vials, tablets and autoinjectors should be stored at room temperature
- Oral solution should be stored under refrigeration or up to 60 days at room temperature

Medication Administration

Oral

Tablets should be taken on same day, once weekly. If intolerable side effects can split dose into two days a week. Should be taking folic acid as well

Subcutaneous

- Autoinjectors, prefilled syringes, vial/syringe should be administered subcutaneously into the middle thigh, upper outer arm or abdomen at least 2 inches away from belly button
- Do not inject into skin that it irritated, tender, bruised or scarred
- Do not reuse needles or autoinjectors, discard used needles/syringes/pens into sharps container

Additional Considerations

Monitoring: Pregnancy test in females of reproductive age, CBC with differential, renal function and liver function tests at baseline and every 3 months

Updated June 2023–ARP Practice Committee

DISCLAIMER: The information contained in this biologic reference guide is published by the American College of Rheumatology ["ACR"] for informational purposes only, in furtherance of its educational mission. It is not a substitute for user's independent medical discretion or decision making, nor a replacement for the manufacturer's complete prescribing and labeling information, as in effect at the time of use. The information contained herein reflects the conclusions of the individual companies who manufacture the products and not those of the ACR. ACR does not endorse or make any statement regarding the efficacy or safety of any of the listed companies or any of their drugs or other products. ACR specifically disclaims any and all responsibility or liability for the accuracy or completeness of the contents of this reference guide, the use of such information by anyone and/or for the performance of any of the drugs listed in this biologic reference guide (including without limitation, any adverse effects).