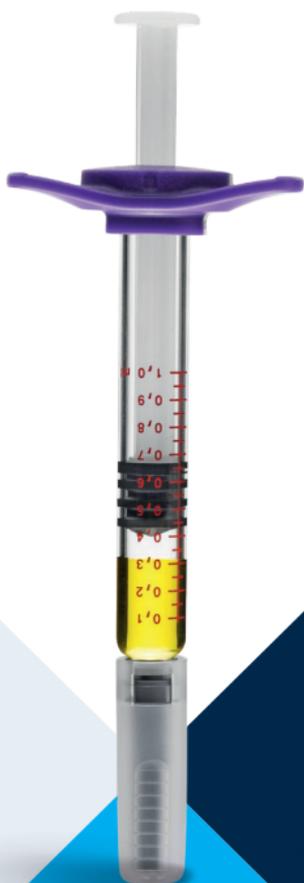


meto
/ect®

metex®

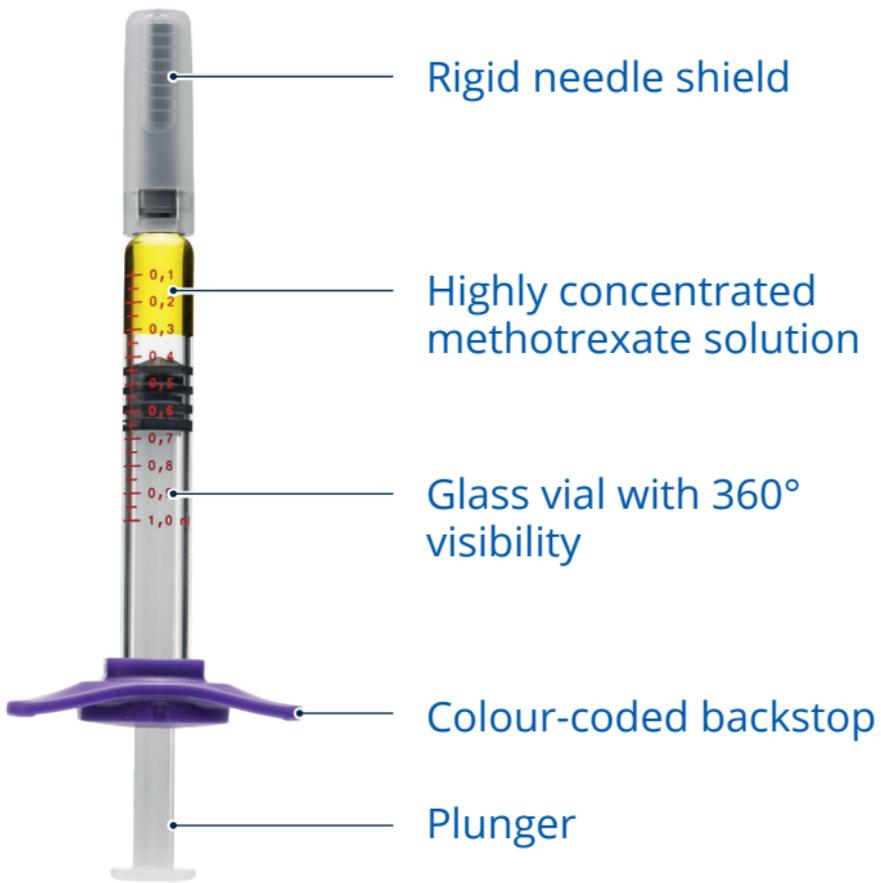
The world's market leader in parenteral methotrexate

metoject®/metex®
50 mg/ml pre-filled syringe



: medac

A detailed look



Available in up to 10 doses*

The different doses are colour-coded for an easy identification of the correct dosage

7.5 mg (0.15 ml)	10 mg (0.20 ml)	12.5 mg (0.25 ml)	15 mg (0.30 ml)	17.5 mg (0.35 ml)
20 mg (0.40 ml)	22.5 mg (0.45 ml)	25 mg (0.50 ml)	27.5 mg (0.55 ml)	30 mg (0.60 ml)

**depending on individual country*

metoject[®]/metex[®]

50 mg/ml pre-filled syringe

metoject[®] 50 mg/ml pre-filled syringe is used for self-injection of methotrexate in the treatment of autoimmune diseases.

The syringe has a pre-attached needle and is ready to use.

metoject 50 mg/ml offers the smallest available injection volume due to the high concentration of the solution.

Indicated for*

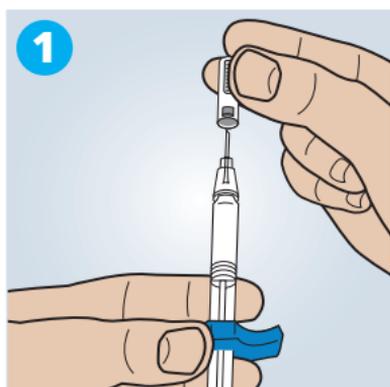
- Active rheumatoid arthritis
- Severe, active juvenile idiopathic arthritis
- Severe psoriasis
- Severe psoriatic arthritis
- Mild to moderate Crohn's disease



Storage

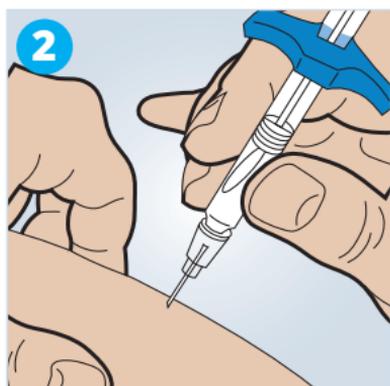
- Room temperature storage
- 30 months shelf life at 15 to 25°C
- Keep in the outer carton to protect from light

Self-injection steps



Remove cap

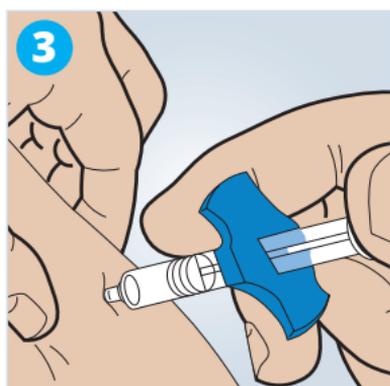
Carefully remove the grey protective plastic cap by pulling it straight off the syringe



Build skin fold

Using two fingers, pinch up a fold of skin and quickly insert the needle vertically into the skin.

Insert the needle fully into the fold of skin



Inject

Push the plunger down slowly and inject the liquid

Hold the skin securely until the injection is completed

Carefully pull the needle straight out

Benefits of using metoject® 50 mg/ml pre-filled syringe

- ▶ Higher efficacy and increased bioavailability compared to oral MTX¹
- ▶ Smallest available injection volume
- ▶ Pre-attached needle
- ▶ Clear colour code for each dose

Further Questions?

Please do not hesitate to contact medac or your local representative

You can also get more information on our website: www.metoject.com

¹ Braun J. et al, Arthritis Rheum. 2008; 58(1): 73-81

metoject® / metex® 50 mg/ml solution for injection, pre-filled syringe

Qualitative and quantitative composition: 1 ml of solution contains 50 mg methotrexate (as methotrexate disodium), 1 pre-filled syringe of 0.15 ml (0.20 ml; 0.25 ml; 0.30 ml; 0.35 ml; 0.40 ml; 0.45 ml; 0.50 ml; 0.55 ml; 0.60 ml) contains 7.5 mg (10 mg; 12.5 mg; 15 mg; 17.5 mg; 20 mg; 22.5 mg; 25 mg; 27.5 mg; 30 mg) methotrexate. **Excipients:** NaCl, NaOH, water for injections. **Therapeutic indications:** Active rheumatoid arthritis in adult patients; polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate; severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA and retinoids; severe psoriatic arthritis in adult patients; mild to moderate Crohn's disease either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines. **Posology and method of administration:** Should only be prescribed by physicians who are familiar with the various characteristics of the medicinal product and its mode of action. Patients must be educated and trained in the proper injection technique when self-administering methotrexate. The first injection of Metoject should be performed under direct medical supervision. **Adults, rheumatoid arthritis:** The recommended initial dose is 7.5 mg of Metoject once weekly, administered subcutaneously. Depending on the individual activity of the disease and tolerability, the dose may be increased gradually by 2.5 mg per week. A weekly dose of 25 mg should in general not be exceeded. **Polyarthritic forms of juvenile idiopathic arthritis:** The recommended dose is 10-15 mg/m² body surface area (BSA) once weekly, administered by subcutaneous injection. In therapy-refractory cases the weekly dosage may be increased up to 20 mg/m² BSA once weekly. Use in children < 3 years of age is not recommended as insufficient data on efficacy and safety is available for this population. **Psoriasis vulgaris, psoriatic arthritis:** Test dose of 5-10 mg should be administered parenterally, one week prior to therapy to detect idiosyncratic adverse reactions. The recommended initial dose is 7.5 mg of methotrexate once weekly, administered subcutaneously. The dose is to be increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate. **Crohn's disease:** Induction treatment: 25 mg/week administered subcutaneously. Response to treatment can be expected after approximately 8-12 weeks. Maintenance treatment: 15 mg/week. **Elderly:** Dose reduction should be considered due to reduced liver and kidney function as well as lower folate reserves. If changing from oral methotrexate a reduction in dose may be required due to the variable bioavailability. **Contraindications:** Hypersensitivity to methotrexate or any of the excipients; severe liver impairment; alcohol abuse; severe renal impairment (creatinine clearance <30 ml/min); pre-existing blood dyscrasias (bone marrow hypoplasia, leukopenia, thrombocytopenia, significant anaemia); serious, acute or chronic infections such as tuberculosis, HIV, other immunodeficiency syndromes; ulcers of the oral cavity and known active gastrointestinal ulcer disease; pregnancy, breastfeeding; concurrent vaccination with live vaccines. **Special warnings and precautions for use:** In the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis and psoriatic arthritis, and Crohn's disease, Metoject (methotrexate) must only be used once a week. Dosage errors in the use of Metoject can result in serious adverse reactions, including death. **Undesirable effects:** Most serious adverse reactions of methotrexate include bone marrow suppression, pulmonary toxicity, hepatotoxicity, renal toxicity, neurotoxicity, thromboembolic events, anaphylactic shock and Stevens-Johnson syndrome. Most frequently (very common) observed adverse reactions of methotrexate include gastrointestinal disorders e.g. stomatitis, dyspepsia, abdominal pain, nausea, loss of appetite and abnormal liver function tests e.g. increased ALAT, ASAT, bilirubin, alkaline phosphatase. Other frequently (common) occurring adverse reactions are leukopenia, anaemia, thrombopenia, headache, tiredness, drowsiness, pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia, oral ulcers, diarrhoea, exanthema, erythema and pruritus. **Effects:** Pharyngitis, infection (incl. reactivation of inactive chronic infection), sepsis, conjunctivitis. Lymphoma. Leukopenia, anaemia, thrombopenia, pancytopenia, agranulocytosis, severe courses of bone marrow depression, lymphoproliferative disorders, eosinophilia. Allergic reactions, anaphylactic shock, hypogammaglobulinaemia. Precipitation of diabetes mellitus. Depression, confusion, mood alterations. Headache, tiredness, drowsiness, dizziness, pain, muscular asthenia or paraesthesia/hypoesthesia, changes in sense of taste (metallic taste), convulsions, meningism, acute aseptic meningitis, paralysis, encephalopathy/leukoencephalopathy. Visual disturbances, impaired vision, retinopathy. Pericarditis, pericardial effusion, pericardial tamponade. Hypotension, thromboembolic events. Pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia. Symptoms indicating potentially severe lung injury (interstitial pneumonitis) are: dry, not productive cough, short of breath and fever, pulmonary fibrosis, Pneumocystis jirovecii pneumonia, shortness of breath and bronchial asthma, pleural effusion, epistaxis, pulmonary alveolar haemorrhage. Stomatitis, dyspepsia, nausea, loss of appetite, abdominal pain, oral ulcers, diarrhoea, gastrointestinal ulcers and bleeding, enteritis, vomiting, pancreatitis, gingivitis, haematemesis, haemorrhage, toxic megacolon. Abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin), cirrhosis, fibrosis and fatty degeneration of the liver, decrease in serum albumin, acute hepatitis, hepatic failure. Exanthema, erythema, pruritus, photosensitivity reactions, loss of hair, increase in rheumatic nodules, skin ulcer, herpes zoster, vasculitis, herpetic eruptions of the skin, urticarial, increased pigmentation, acne, petechiae, ecchymosis, allergic vasculitis, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), increased pigmentary changes of the nails, acute paronychia, furunculosis, telangiectasia, skin exfoliation / dermatitis exfoliative. Arthralgia, myalgia, osteoporosis, stress fracture, osteonecrosis of jaw (secondary to lymphoproliferative disorders). Inflammation and ulceration of the urinary bladder, renal impairment, disturbed micturition, renal failure, oliguria, anuria, electrolyte disturbances, proteinuria. Inflammation and ulceration of the vagina, loss of libido, impotence, gynaecomastia, oligospermia, impaired menstruation, vaginal discharge. Fever, wound-healing impairment, local damage (formation of sterile abscess, lipodystrophy) of injection site following intramuscular or subcutaneous administration, asthenia, injection site necrosis, oedema. Subcutaneous application of methotrexate is locally well tolerated. Only mild local skin reactions (such as burning sensations, erythema, swelling, discolouration, pruritus, severe itching, pain) were observed, decreasing during therapy. **Overdose:** Calcium folinate is the specific antidote for neutralising the toxic undesirable effects of methotrexate. **Legal classification:** Prescription only. **Marketing authorisation holder:** medac GmbH, Theaterstr. 6, 22880 Wedel, Germany. **Date of revision of text:** 19.09.2024

Registered in the following countries: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden

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