

metoject®/metex®

PATIENT INFORMATION



: medac

Dear patient,

You have been subscribed metoject® PEN/ metex® PEN. The pre-filled pen facilitates the subcutaneous (“under the skin”) injection of the active ingredient methotrexate. Your physician has trained you how to self-inject with the pen yourself. This administration guide illustrates all the different steps to a successful self-injection.

Furthermore, this information leaflet summarizes the most important facts about metoject® PEN and answers the most frequently asked questions.

In case you have any further questions please do not hesitate to contact medac or your health care professional.

We wish you all the best for a successful therapy!

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Introduction

metoject® PEN/ metex® PEN is a pre-filled pen containing a 50 mg/mL methotrexate (MTX) solution. It is administered subcutaneously (under the skin) once weekly at the same weekday.

metoject® PEN/ metex® PEN is indicated for the treatment of

- Active rheumatoid arthritis
- Polyarthritic form of severe, active juvenile idiopathic arthritis
- Moderate-to-severe psoriasis
- Severe psoriatic arthritis
- Mild-to-moderate Crohn's disease

The pen has patient-friendly characteristics:

- ▶ Combines new and established features in one PEN
- ▶ 2-step injector
- ▶ Up to 10 available doses for a patient-individual and flexible therapy*
- ▶ Fast injection in max. 5 seconds

**depending on individual country*

Methotrexate

The active ingredient of metoject® PEN/ metex® PEN is methotrexate (MTX). Methotrexate is a very well-known so-called disease modifying antirheumatic drug (DMARD) meaning that it does not just relieve the pain of patients with joint inflammation and/or psoriasis, but actually may help to stop and prevent this inflammation and the resulting damage. In these autoimmune diseases, the immune system is too active and mistakenly attacks the own body. Methotrexate can help to slow down the effects of an over-stimulated immune system and thus to control disease activity.

Like any other medication, methotrexate can possibly be accompanied by side effects. Due to the relatively low doses of methotrexate used for the treatment of autoimmune diseases for which metoject® PEN/ metex® PEN is indicated, these effects occur less often and are less severe than in the treatment with higher doses. Furthermore, there are several possibilities to reduce these discomforts. Therefore, should you have any side effect while taking the drug, please inform your doctor.

When you should not use metoject® PEN

- if you are allergic to methotrexate or any of the other ingredients of this medicine (as listed in section 6 in the package leaflet).
- if you suffer from liver or severe kidney diseases or blood diseases.
- if you regularly drink large amounts of alcohol.
- if you suffer from a severe infection, such as tuberculosis, HIV or other immunodeficiency syndromes.
- if you suffer from stomach ulcer or intestinal ulcer.
- if you are pregnant or breast-feeding.
- if you receive vaccinations with live vaccines at the same time.
- if you have diabetes mellitus and are being treated with insulin

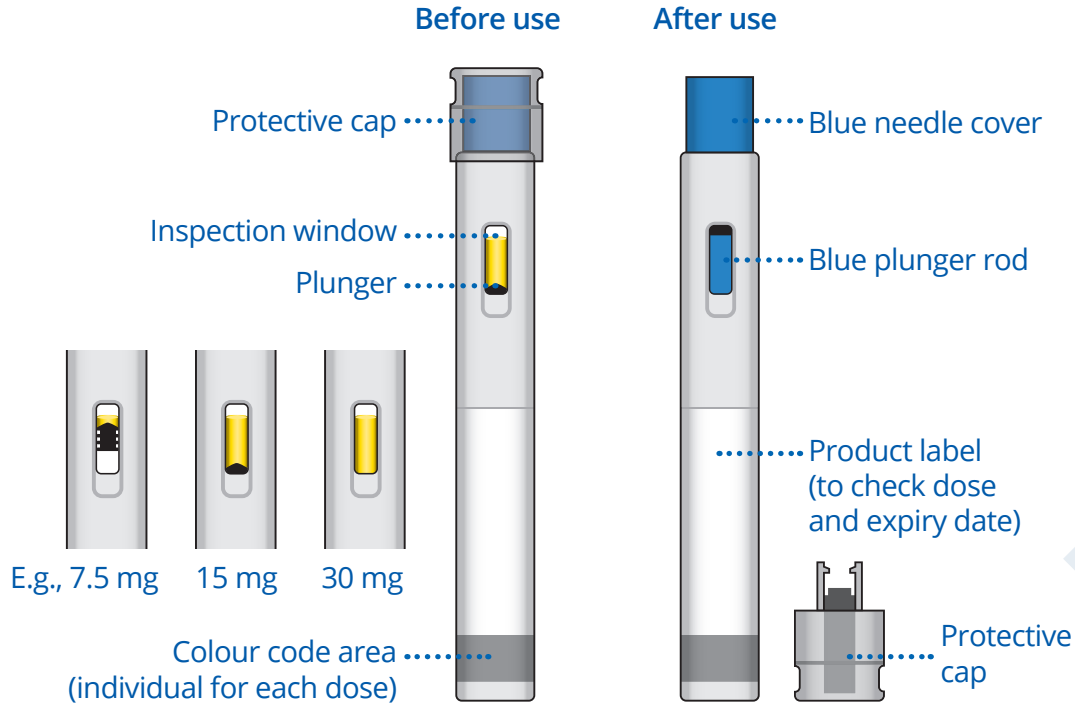
Warnings and precautions

Talk to your doctor or pharmacist before taking metoject® Pen if you:

- are elderly or if you feel generally unwell and weak.
- have problems with the way your liver works.
- suffer from dehydration (water loss).

Step by step guide to injection

Details about metoject® PEN



Important facts

- Administer only ONCE weekly
- Find a suitable injection day
- Inject each week on the same day
- If you have forgotten your injection or injected too early, please contact your health care professional for further advice.
- Store at temperature below 25°C
- Keep the pens in the outer carton to protect the drug from light
- Regular monitoring with a health care professional is essential
- Consult with your health care professional prior to vaccination as live vaccines must be avoided
- Do not take methotrexate during pregnancy. Both women and men must use a reliable method of contraception during treatment with methotrexate. If you are planning a pregnancy, women must discontinue MTX at least 6 months beforehand, men 3 months beforehand.

Before injection

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Under no circumstances should you or your caregiver try to inject metoject® PEN yourself before you have received an appropriate training by medical staff.

The convenient packaging contains:



- The pen
- The patient information leaflet including an administration guide

Before administering, carefully read the patient information leaflet.



- metoject® PEN is administered only ONCE a week on the same weekday
- Wash your hands very carefully before injection
- Choose a quiet area with a clean, flat surface like a table

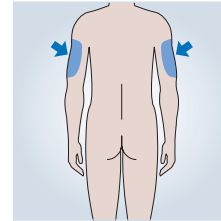
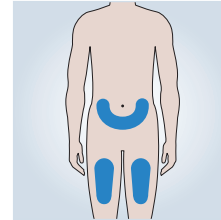
Recommended injection sites

The recommended injection sites are:

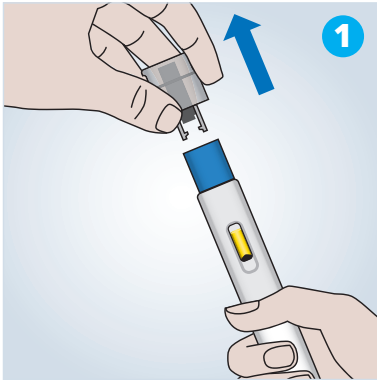
- ▶ The upper thigh
- ▶ The lower part of the abdomen except the 5 cm diameter around your navel
- Choose a different injection site each week.
- If someone other than you administers the injection for you, the person may also use the top of the zone at the back of the arm, below the shoulder.
- Never inject into areas where the skin is tender, bruised, red or hard or where you have scars or stretch marks.

For psoriasis patients:

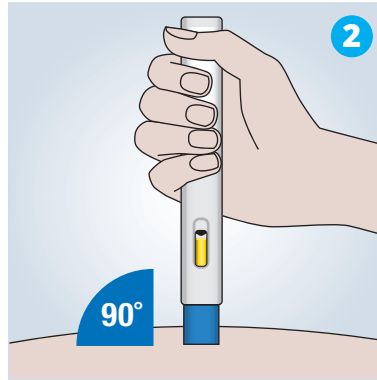
You should not try to inject directly into any raised, thick, red or scaly skin patches or lesions.



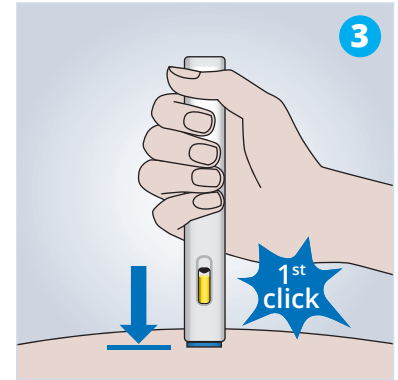
Inject your dose



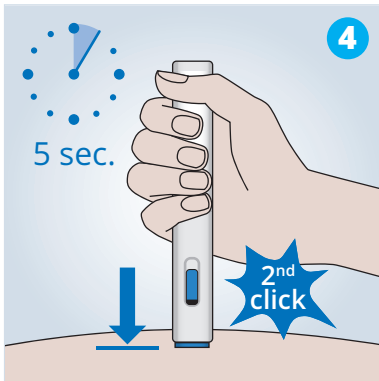
Remove the cap



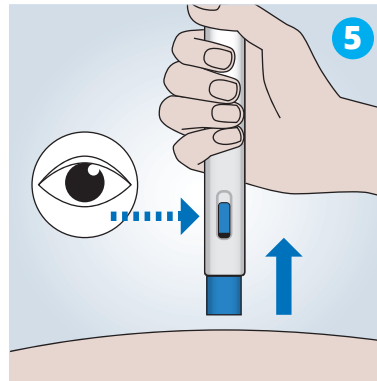
Position your pen



Start your injection



Hold the pen in place to complete your injection



Finishing your injection

Summary of the most important points



Convenient packaging containing the pen and the patient information leaflet



Complete injection in only 5 seconds



Once weekly injection



Safe handling through automatic needle shield protection

Useful Information

Travelling with metoject® PEN / metex® PEN

- Please carry metoject® PEN / metex® PEN in the closed original packaging in your hand luggage. Hereby, you can control the storage temperature below 25°C. Should the temperature rise above 25°C in the aircraft cabin, please ask a stewardess to put the pens in a fridge on board.
- If you plan to travel to warmer areas, please consider carrying a small cooling box for the transport from the airport to your accommodation.
- In case of unexpected extension of your trip, please consider taking additional metoject® PENS / metex® PENS with you.
- Should you require any document to attest that you need metoject® PEN / metex® PEN for your therapy when entering a foreign country, please find a certificate in English, Spanish, French, German and Turkish available for download on www.metoject.com. A completely filled out form should be accepted in most countries.

Your diary of injections with metoject® PEN / metex® PEN

Day of injection	Site of injection	Weekly dose	Observation

Day of injection	Site of injection	Weekly dose	Observation

Frequently asked questions

Storage

metoject® PEN is stored at a temperature below 25°C. On hot days above 25°C, please store the pen in the fridge (> 0°C). Freezing should be avoided. Let it warm up to room temperature before administration.

Disposal

The metoject®/metex® PEN is an autoinjector for single use and cannot be refilled. After use, the metoject®/metex® PEN should be disposed of in accordance with the local requirements. All other waste can be disposed of in the normal household waste.

Air bubble

Please note that there might be an air bubble visible through the transparent control zone. This is completely harmless.

Start of injection

To start your injection, push the pen down all the way. This will slide the blue needle cover up into the pen and the injection will start automatically. A first “click” hereby indicates the start of the injection. The blue plunger rod will move down. Keep holding the pen against the skin until all of the medicine is injected. A second „click“ is audible at the end of the injection.

Methotrexate on skin

Methotrexate should not come into contact with the surface of the skin or mucosa. In the event of contamination, the affected area must be rinsed immediately with plenty of water.

Further Questions?

Do not hesitate to contact medac GmbH or your healthcare professional

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