

metex[®] FS

Patient information

A user guide



: medac

Dear patient,

your doctor has prescribed the medication metex® pre-filled syringe and instructed you on how to inject yourself with the pre-filled syringe. The pre-filled syringe enables the active ingredient methotrexate to be injected subcutaneously (under the skin).

This information brochure shows you the key steps, in words and pictures, on how to give yourself the injection. However, it does not replace the metex® pre-filled syringe package leaflet. Please read through it carefully before you start using this medicine because it contains important information for you.

You can also find the key facts about metex® pre-filled syringe and frequently asked questions in the information brochure.

If you have any further questions, please feel free to contact medac GmbH (using the contact details on the back of this brochure) or speak to your doctor or pharmacist.

We wish you every success with your treatment!

Your medac Autoimmune Team

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Introduction

metex® pre-filled syringe is filled with a solution of methotrexate (MTX). It is applied subcutaneously (under the skin) **once a week**.

metex® pre-filled syringe is used for the treatment of

- Rheumatoid arthritis
- Juvenile idiopathic arthritis
- Plaque psoriasis
- Psoriatic arthritis
- Crohn's disease

The pre-filled syringe has the following features:

- ▶ Small injection volume
- ▶ Fixed integrated needle
- ▶ Ready for immediate use

Methotrexate

Methotrexate is a tried-and-tested medicine for the treatment of autoimmune diseases such as rheumatic diseases, plaque psoriasis, psoriatic arthritis and inflammatory bowel disease (Crohn's disease).

Autoimmune diseases occur when our body's immune system fails to function properly. The body's own cells are mistakenly recognised as being foreign and are attacked. This causes inflammation that damages the organs affected.

Methotrexate has a threefold mechanism of action: it has an anti-inflammatory effect, it modulates the immune system, i.e., it slows it down, and it reduces cell division.

In the field of rheumatology, methotrexate is currently the most commonly used disease-modifying anti-rheumatic drug (DMARD), which slows down or stops joint destruction. In psoriasis, methotrexate has an anti-inflammatory effect and suppresses the increased formation of skin cells.

In addition to autoimmune diseases, methotrexate is also used to treat cancer, but at doses up to 1,000 times higher. So, when treating autoimmune diseases, we also refer to 'low-dose methotrexate treatment'.

What you need to know before you use metex® pre-filled syringe

metex® pre-filled syringe must not be used if you

- are allergic to methotrexate or any of the other ingredients in this medicine listed in section 6 of the package leaflet.
- have liver disease, severe kidney disease, or a blood disorder.
- regularly drink a lot of alcohol.
- have a serious infection, e.g. tuberculosis, HIV or another immune deficiency syndrome.
- are pregnant or breastfeeding.
- are being given a live vaccine at the same time.
- have mouth ulcers or stomach ulcers.

Please talk to your doctor or pharmacist if

- you are dehydrated (have too little fluid in your body).
- your liver is not working properly.

Initial examination

Before starting treatment, your doctor will take a sample of your blood to check whether you are suitable for treatment with methotrexate. This will be used to test your blood count, your liver function and your kidney function. Your doctor may check whether you have a chronic infection and have your chest X-rayed.

During treatment

Like any effective treatment, side effects can occur. To be able to detect these in time, your doctor will have to carry out regular check-ups and laboratory tests.

These include:

- Examination of the mouth and throat for mucosal changes,
- Blood tests,
- Check of liver function,
- Check of kidney function,
- Check of respiratory system and, if necessary, lung function tests

How to inject yourself – step-by-step instructions

General Information

- Only use metex® pre-filled syringe once a week.
 - Decide on a suitable day of the week for injecting yourself together with your doctor.
 - Always inject yourself on the same day of the week.
 - If you have missed an injection, you should make up for it as soon as possible. The day of your next injection will move accordingly. If you are unsure about how to proceed with your treatment, ask your doctor for advice.
 - Store the pre-filled syringes at room temperature (up to 25°C). Storage in the refrigerator is possible, but the temperature must not fall below 2°C.
 - Keep the pre-filled syringes in their outer packaging to protect them from light.
 - In principle, you should avoid having any live vaccines (see also page 15). If you have any questions, contact your doctor.
 - Do not use metex® pre-filled syringe if you are pregnant or breastfeeding.
 - Women need to stop injecting themselves with metex® pre-filled syringe at least 6 months before a planned pregnancy; for men, this is at least 3 months beforehand.
 - If you have accidentally used metex® pre-filled syringe more than once a week, please speak to your doctor immediately.
 - To be on the safe side, your pharmacist will write the agreed day of the week for injecting yourself (as noted on your prescription) on the outer packaging of your medication.
- Note on packaging indicating weekly use, with a space for writing down the agreed day of the week for the injection.**

Nur einmal wöchentlich anwenden

am

(Wochentag der Anwendung ungekürzt eintragen)

What you need to know before the injection

- Use the medicine exactly as prescribed by your doctor. If you have any questions, ask your doctor or pharmacist.
- The package contains:



- ▶ the pre-filled syringe
 - ▶ the package leaflet, including detailed instructions on how to inject yourself
- Please read the package leaflet carefully before you start the injection.
 - Before the injection, wash your hands.
 - Find a quiet, clean place.
 - Only use the pre-filled syringe on skin that has been cleaned with soap and water or disinfectant.

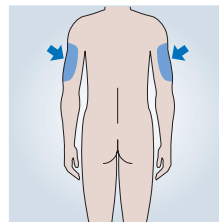
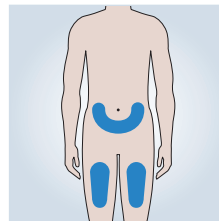
Recommended injection sites

The following sites are best suited for injection:

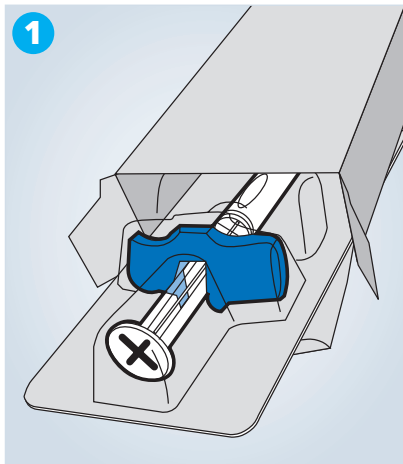
- the abdomen, except for the area 5 cm around the navel
- the upper thigh

If someone else is giving you the injection, it can also be administered in the back of your upper arm, just below the shoulder. Change the injection site each time you use the prefilled syringe. This helps to prevent skin reactions.

Never use the injection on areas of skin that are tender, broken, red, hard, scarred, or with stretch marks. If you have been diagnosed with psoriasis, you should not inject directly into affected areas of skin (plaques). Never inject yourself while standing up. Do it while you are sitting or lying down.

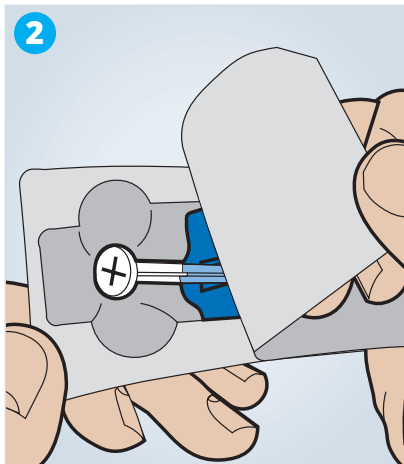


Carrying out the injection



Open the syringe and you are ready to go!

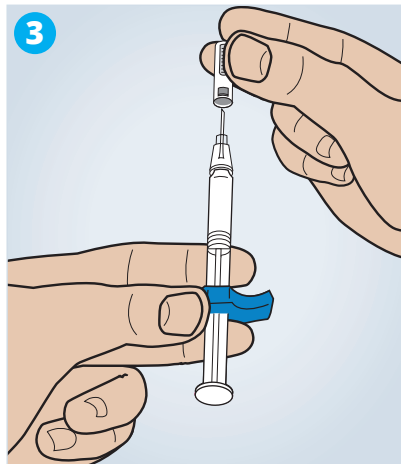
Open the carton of the pre-filled syringe and read through the package leaflet carefully.



Unpack the pre-filled syringe

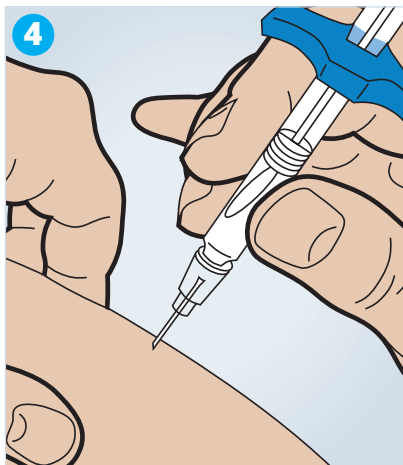
Loosen the foil at one corner of the packaging and slowly pull the foil off the packaging.

Hold the packaging straight so that the pre-filled syringe does not fall out, and remove the pre-filled syringe from the packaging.



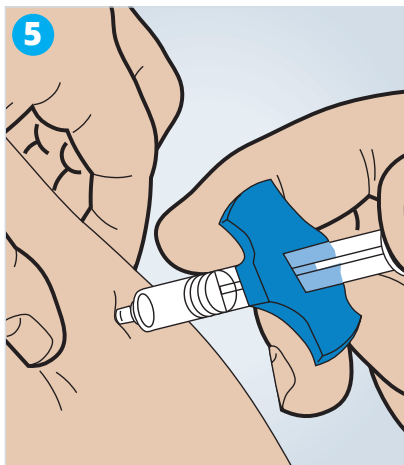
Remove the protective plastic cap

Carefully remove the protective plastic cap from the syringe in a straight motion. Important: Make sure not to touch the needle of the pre-filled syringe in the process!



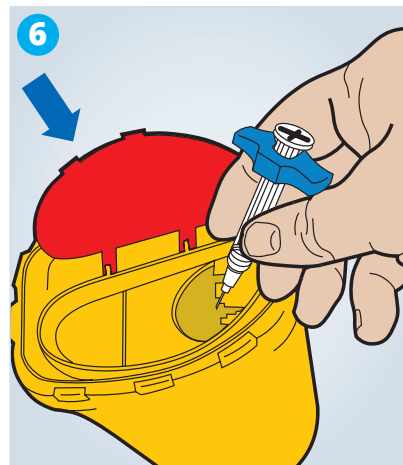
Inserting the cannula

Using two fingers, form a skin fold and insert the needle vertically to the skin surface with a quick and short movement.



Injection

Insert the needle fully into the skin fold. Now press the plunger down slowly and inject the fluid under your skin. Do not let go of the skin fold until the injection is completed. Then, carefully pull the needle straight out.



Disposal

Once the injection is complete, the pre-filled syringe can be collected in a special disposal box and disposed of with household waste as described on page 19.

Useful information

Vaccinations during methotrexate treatment

If you are planning to travel abroad, in many cases you will need vaccinations beforehand. If you require a vaccination and are being treated with methotrexate, consult your doctor for information on any potential risks. Immunisation with so-called 'inactivated' vaccines is generally possible

during treatment with methotrexate. However, you should not have any 'live' vaccines while taking methotrexate. If you need a live vaccine, you first need to stop taking methotrexate for a sufficient period of time.

Vaccine classes ¹	Disease/Pathogen
Live attenuated vaccines (LAVs)	
viral	yellow fever, measles, mumps, rubella, chickenpox, rotavirus, flu (nasal) ² , shingles live vaccine ³
bacterial	typhoid (oral)

Vaccine classes ¹	Disease/Pathogen
Inactivated vaccines Inactivated pathogens viral bacterial	polio, rabies, tick-borne encephalitis (TBE), hepatitis A, Japanese encephalitis, COVID-19* cholera
Subunit vaccines viral bacterial	flu, hepatitis B, human papillomavirus (HPV), shingles subunit (HZ/su-)vaccine ³ , COVID-19** pneumonia, whooping cough, meningococcal disease, haemophilus influenzae type b, typhoid (intramuscular)
Toxoid vaccines	tetanus, diphtheria
mRNA vaccines (not LAV ⁴)	COVID-19***
Vector vaccines (not LAV ⁴)	COVID-19****

nasal = administered using a nasal spray

*Valneva® vaccine

**Vaccines Nuvaxovid® and VidPrevtyl® Beta

***Vaccines Comirnaty® and Spikevax®

****Vaccines Vaxzevria TM and Jcovden®

More information is available on the Robert Koch Institute website: www.rki.de/EN

Travel tips

- As you urgently need the metex® prefilled syringe for your health, it should be kept in your carry-on luggage. Leave the metex® pre-filled syringe in its original packaging.
- Take enough extra pre-filled syringes with you to cover an unexpected delay in returning home.
- Medicines can often make your skin more sensitive to sunlight. Methotrexate can occasionally cause higher sensitivity to the sun. Avoid too much sun exposure and do not use tanning beds.

If possible, avoid exposing bare skin to the mid-day sun, and remember to use sun cream with a sufficiently high sun protection factor.

- Should you require a document certifying that you need metex® pre-filled syringe for your treatment when travelling abroad, you will find a certificate in multiple languages to download in the metex® travel brochure or at www.metex-fs.de. If necessary, you can then present this at the security check.

Frequently Asked Questions (FAQs)

Storage

Keep the pre-filled syringes in their outer packaging to protect them from light. The metex® pre-filled syringe can be easily stored at room temperature (up to 25 °C).

During longer periods of heat, the prefilled syringe can also be stored in the fridge at 2 to 8 °C. The temperature must not fall below 2 °C, as this could render the medicine ineffective. Remove the pre-filled syringe from the fridge approx. 15 minutes before the planned injection so that the solution can reach room temperature. This makes the injection more comfortable.

The pre-filled syringe must never be exposed to extreme heat. Do not leave the pre-filled syringe in the car, as very high temperatures can occur there, especially in summer.

Air bubbles

If there is an air bubble in the fluid, don't worry. It is safe to inject an air bubble under your skin. Please do not try to remove the air bubble.

Injection sites

To prevent skin reactions, choose a different injection site each week. When you choose an injection site, for example your abdomen, feel it with your fingertips before the injection. If it feels lumpy or sore, choose a different site as far away from it as possible. Never inject yourself while standing up. Do it while you are sitting or lying down.

Droplets on injection needle

When removing the plastic protective cap, a small amount of fluid may leak out of the tip of the needle. You do not need to worry about this. After the injection, remove any small liquid residues on the skin by carefully dabbing them off with a cotton pad.

Methotrexate on the skin

The methotrexate solution for injection should not come into contact with the skin. If this does happen, wash the affected area immediately with plenty of water.

Disposal

After you have injected yourself, you can first put the metex® pre-filled syringe in a disposal box. Close the disposal box tightly as soon as it is completely full. The container can now be disposed of with your household waste. We are happy to send you a disposal box. You can reach the Autoimmune Service as follows:

Tel.: +49(0) 41 03/80 06-311

Mailto:contact@medac.de

References:

¹ DocCheck Flexikon – Impfung. <https://flexikon.doccheck.com/de/Impfung> (retrieved on 3/7/2023)

² Minden K et al. Z Rheumatol 2014; 73:878–9

³ Wagner N et al. Bundesgesundheitsbl 2019; 62:494–515

⁴ SARS-CoV-2 vaccines for people with rheumatic diseases: recommendations from the German Society for Rheumatology (Update 06/04/2021). <https://dgrh.de/Start/Wissenschaft/Forschung/COVID-19/Impfung-gegen-SARS-CoV-2-für-Menschen-mit-rheumatischen-Erkrankungen.html>

You can find further information
all about your treatment at
metex-fs.de



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