

LIVING WITH JUVENILE ARTHRITIS

A parent's guide to the metoject® PEN/metex® PEN



:medac

Dear Parents,

Your child has been diagnosed with juvenile idiopathic arthritis (JIA). JIA is a chronic condition but the symptoms of the condition can be managed to help the child live a normal life. Once your child has been evaluated by a pediatric rheumatologist and the diagnosis has been confirmed, the physician will develop a treatment plan. This brochure will give you a brief overview about the diagnosis, the respective therapeutic options and some recommendations regarding your child's general lifestyle.

Your physician prescribed metoject® PEN/metex® PEN. This is a pre-filled pen to facilitate the subcutaneous ("under the skin") injection of the active ingredient methotrexate.

The included administration guide illustrates all the different steps for a successful injection. In addition, at the end of this information leaflet you'll find the most important facts about metoject® PEN/metex® PEN and answers to the most frequently asked questions.

We wish your child all the best for a successful therapy!

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General information about JIA

What is juvenile idiopathic arthritis?

Juvenile idiopathic arthritis (JIA) is a collective term for chronic inflammatory joint diseases in children and young people. There are various forms of the disease, differing in terms of the number and pattern of joints affected. Only a few joints are inflamed initially in some patients. It often affects the large joints, such as the knees and ankles (oligoarthritic form of JIA, from the Greek “oligos” meaning few). When the disease is active, the joints are painful, swollen and overheated and their movement is clearly impaired.

What are the causes and risks for the development of juvenile idiopathic arthritis?

Not very much is known as yet about the cause of juvenile arthritis. However, it may be assumed that the decisive process is a malfunctioning immune

system response. The task of this defence system is to detect dangerous pathogens (germs), foreign bodies and pollutants and to destroy them in a targeted fashion. The body's own substances and surrounding tissue are normally recognised by the immune system cells and tolerated. Yet if the communication between cells is impaired, the immune system will also direct its destructive activity against the body's own tissue, resulting in an inflammatory reaction.

What role does lifestyle play in juvenile idiopathic arthritis?

Eating healthy is important in the management of JIA. Physicians often recommend a balanced diet with an adequate supply of energy sources, vitamins, fibre and trace elements. An imbalanced diet should be avoided in any case. The majority of children eat more meat and sausage and less fruits and vegetables than recommended. A calcium supply appropriate for the patient's age should always be

ensured. A poor diet may lead to health problems such as anaemia (decreased oxygen going to body tissues), eating disorders, or being overweight.

Sleep is an important part of a child's well-being. It can help him or her to concentrate and manage stress better. Not getting enough sleep can make some JIA symptoms even worse. If a child doesn't sleep, she or he will be tired and will not feel like exercising. Without exercise, his or her joints can become more stiff and painful. Not sleeping enough can also increase feelings of fatigue which may already be present due to JIA. Lack of sleep over a long period of time can also lead to changes in body metabolism and weight gain.

How is juvenile idiopathic arthritis diagnosed?

In order to make a diagnosis, the doctor asks about the type, onset and progression of the current symptoms. Information about triggering events and other cases of inflammatory rheumatic disease in

the family history is important. Each of the painful joints is included in a thorough physical examination. The doctor will also take note of any changes in the skin and involvement of the eyes.

The following procedures are available for diagnosis:

- Physical examination
- Blood test
- X-ray examination
- Ultrasound examination

The blood test provides information about the current inflammatory process. The blood values show the functional state of the internal organs and allow more precise statements to be made as to how the disease will progress.

If the patients are still in early childhood, it is sometimes not easy to diagnose juvenile idiopathic arthritis. Only after a certain age are children able to report their symptoms themselves and describe them exactly.

In the early stages, the symptoms of juvenile



idiopathic arthritis resemble those of other rheumatic diseases. A paediatric rheumatologist specialises in the particular characteristics of diagnosis will be able to initiate and monitor effective and tolerable treatment.

How is juvenile idiopathic arthritis treated?

The principal medicines available for treating juvenile idiopathic arthritis are nonsteroidal antirheumatic agents (NSARs) (e.g. the active substance diclofenac), what are known as “disease-modifying drugs” and corticosteroids (e.g. the active substance prednisolone). The NSARs help to combat joint pain, swelling and fever. They act quickly with an improvement usually occurring within hours or days. For mild cases, this treatment is often sufficient, but if the disease advances to a chronic form, disease-modifying drugs will also be necessary. They intervene in the malfunctioning immune system and are able to attenuate and prevent the disease from progressing further.

Disease-modifying drugs include, for example, the active substances methotrexate, leflunomide,

sulfasalazine, azathioprine and antimalarial drugs. Methotrexate is currently regarded as the gold standard for JIA.

Corticosteroids have proved their worth as a third pillar of drug treatment. They have a strong anti-inflammatory action and are taken either in tablet form or injected in solution directly into the inflamed joint. These substances act very quickly to alleviate pain and as short-term anti-inflammatories, but they do not affect the actual course of the disease. In the majority of patients, corticosteroids are used until the inflammation and pain have subsided to a significant extent. Their dose is then often reduced or the product is tapered off entirely.

Non-drug treatments are also available in addition to the medicinal treatment. The most important of these are physiotherapy, patient training sessions and aids, such as insoles.

Physiotherapy is used to prevent impaired mobility, stiffening of the joints and incorrect posture, and to avoid compensatory movements and awkward patterns of movement. If changes of this type have already developed, physiotherapy attempts to correct them with the aim of restoring normal conditions.

General information about Methotrexate

General information about 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 helps to stop and prevent this inflammation and the resulting damage. In these autoimmune diseases the immune system is too active and mistakenly attacks the body itself. Methotrexate can help to slow down the effects of an over-stimulated immune system and thus to control disease activity.

How often is methotrexate given?

Methotrexate is given **once a week at the same weekday**.

How long does it take for methotrexate to work?

Don't expect to see relief with the first dose. It generally takes between 8 to 12 weeks for the positive effects of methotrexate to be felt by your child. In the meantime, your child's doctor will likely prescribe other medications (including NSAIDs) to ease inflammation while the drug is taking effect.

How is methotrexate given?

Methotrexate can be given either as a tablet or by injection. While tablets may not be completely absorbed, the injection results in complete absorption. Subcutaneous self-injections at home are both convenient and relatively painless.

Which side effects can we expect?

The most frequently (very common) observed adverse reactions include gastrointestinal disorders, e.g. mild nausea (feeling sick) for one or two days after the weekly dose.

In some cases gastrointestinal problems such as vomiting and/or diarrhoea may occur. To reduce the occurrence of side effects, your doctor will most probably recommend your child take a supplement called Folate (folic acid). Also it might be helpful to take methotrexate on a weekend night rather than during the week and if the nausea persists your doctor might also prescribe an additional pill.

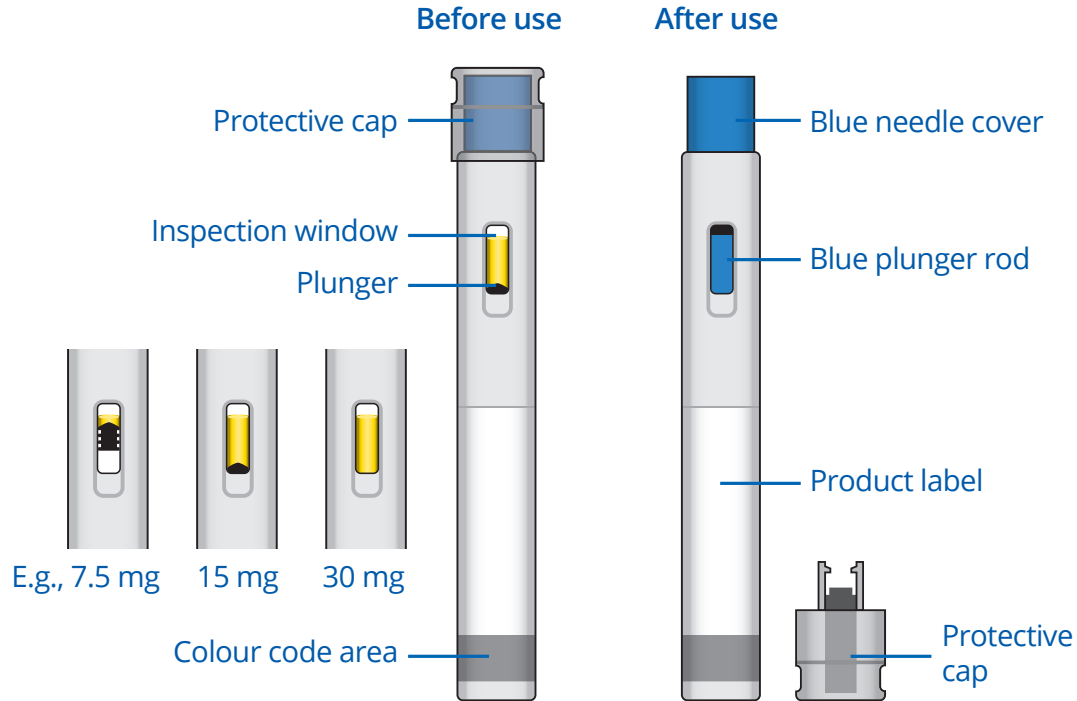
Guidelines to administering metoject® PEN/metex® PEN

If your child is prescribed metoject® PEN/metex® PEN you will receive appropriate training by a healthcare professional first. Before administering metoject® PEN/metex® PEN to your child please remember to:

- Choose a quiet, clean area which has a flat surface
- Wash your hands
- Choose a different injection site each week to minimise possible skin irritation

Please read the following guidelines carefully.

3. PEN Details/Instruction Guide



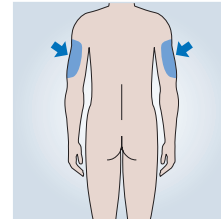
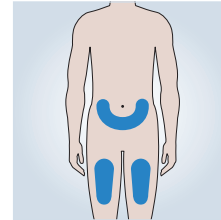
Recommended injection sites

The recommended injection sites are:

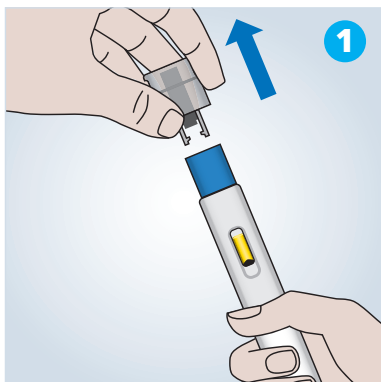
- ▶ The upper thigh
- ▶ The lower part of the abdomen except the 5 cm diameter around your navel
- Choose a different injection site each week.
- If someone other than you administers the injection for you, the person may also use the top of the zone at the back of the arm, below the shoulder.
- Never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

For psoriasis patients:

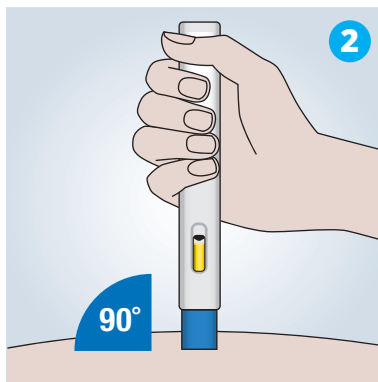
You should not try to inject directly into any raised, thick, red or scaly skin patches or lesions.



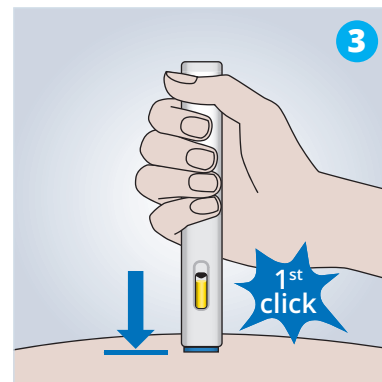
Inject your dose



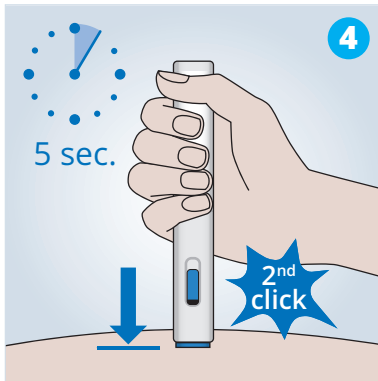
Remove the cap



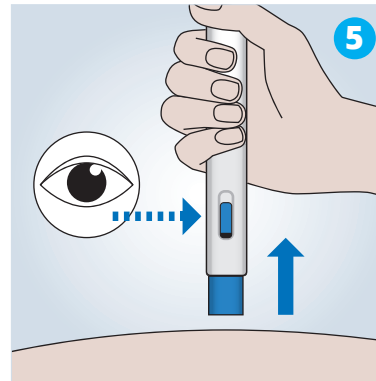
Position your pen



Start your injection



Hold the pen in place to complete your injection



Finishing your injection



Travelling with metoject® PEN/metex® PEN

Please carry metoject® PEN/metex® PEN in the closed **original packaging in your hand luggage**. In this way, you can control the **storage temperature of > 0°C to < 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 hotel.

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 your child's 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.

Frequently asked questions

Storage

metoject® PEN is stored at room temperature (< 25°C). On hot days above 25°C, please store the pen in the fridge (> 2°C), but let it warm up to room temperature before administration.

Disposal

For information on the disposal of metoject® PEN, please ask your health care professional or pharmacist.

Air bubble

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

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