



MANAGING YOUR CHILD'S METHOTREXATE:

FOR PARENTS AND CARERS OF YOUNG CHILDREN WITH JUVENILE IDIOPATHIC ARTHRITIS (JIA)

A GUIDE TO TAKING NORDIMET®

This booklet has been produced by Nordic Pharma to support patients prescribed Nordimet®

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ABOUT NORDIMET®



What is Nordimet®?

Nordimet[®] is a pre-filled auto-injector pen which contains the active drug methotrexate. Methotrexate is used to treat a number of inflammatory conditions including Juvenile Idiopathic Arthritis (JIA).

Nordimet[®] is sometimes used in combination with other treatments, therefore always follow the advice of a doctor or pharmacist in administering your medications as prescribed.

How does methotrexate work?

Methotrexate works by reducing inflammation or swelling, and reducing the activity of the immune system (the body's defence mechanism against diseases). An overactive immune system has been linked to inflammatory diseases, like JIA.



How often should your child be taking Nordimet[®]?

Nordimet[®] is administered once a week only and should be given on the same day each week. It is important to choose the most convenient

day of the week for you and your child to take their treatment on and keep to that day. You can use the enclosed planner to record the day you choose for your child's injection.

How long will your child be taking Nordimet[®]?

Nordimet[®] is a long-term treatment and your child's doctor will advise you on how long your child should continue taking it for. This will depend on how they respond to the treatment as well as the results of the regular blood and urine tests that will be carried out throughout their treatment.

It is important to know that a response to treatment is not immediate. It can take several weeks before you notice an improvement in your child's symptoms.

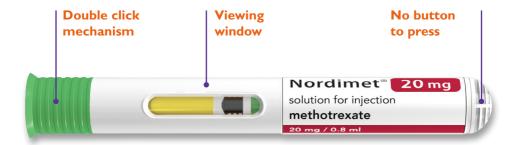
How much Nordimet[®] should your child be taking?

Nordimet[®] is available in different strengths and your child's doctor or nurse will decide on the dose after assessing their condition. They will be monitored carefully through tests and appointments and your child's doctor may recommend that you change their dose to find the exact dose that works best for your child. It is important not to alter the dosing routine yourself or stop giving your child Nordimet[®] without discussing it with your child's doctor.





KEY FEATURES OF A NORDIMET® PEN



The pen has been designed with no button to press; instead, you apply downward pressure on the pen on to the skin until you hear a "click" and feel a gentle vibration. You will then hear a second "click" and vibration once the injection is completed.

As you remove the Nordimet[®] pen from your child's skin, the safety shield locks to help prevent any needle stick injuries. There is a viewing window, where you can monitor the progress of the injection.

USING YOUR NORDIMET® AUTO-INJECTOR PEN

Your nurse or another member of your healthcare team will usually demonstrate how to use the Nordimet® pen on your child for the first time. If you have any difficulties in handling the pen, please ask for further assistance. Do not try to inject your child if you have not been trained on how to do so.

You can watch the self-injection demonstration video on the Nordimet® website –

www.nordimet.co.uk/patient or scan this QR code



SPEAKING WITH YOUR CHILD ABOUT TAKING NORDIMET®

- Try to use simple language to help explain why they need to take Nordimet[®]
- Explain what Nordimet[®] is and how it should help them feel better
- It can be useful to create a routine to help your child prepare for and get used to when they need to take Nordimet®
 - A useful planner can be found to help you and your child stick to this
 weekly routine. This can help your child know how and when to prepare to
 take their medicine
 - A reward system can be a useful way to encourage younger children

Resources included in this pack such as the injection cartoon sketch may be useful to help explain Nordimet® to young children.

Nordimet® is taken once a week only

Preparing for the injection

Wash your hands thoroughly with soap and water.



Ensure your child is sitting or lying in a relaxed and comfortable position.



Remove the pen from its box and check the tamper-evident seal between the white body of the pen and green cap is intact.

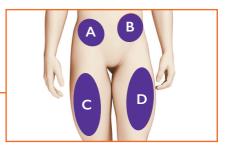


Check through the viewing window on the pen that the medicine inside is a clear, yellow solution, and if not use another pen.

You may see a small air bubble, this is normal.



Choose an injection site, rotating the site each time.



Wipe the area that you will inject with the alcohol swab provided.



The two-step injection technique

The pen has been designed to be as easy as possible to operate by following 2 steps.

Step I - Uncap

Pull the cap off, ensure the pen remains sterile and does not touch anything else.



Step 2 - Inject

Gently pinch your child's skin at the chosen injection site and hold this skin fold throughout the injection.

Place the yellow needle shield against the injection site, ensuring the entire rim of the needle shield is touching the skin.

Apply downward pressure on the pen until you hear and feel a "click". This activates the pen and the solution will inject automatically into the skin.

When the injection is complete you will hear a second "click". Wait for another 2-3 seconds before the pen is removed.

If any of the solution comes into contact with your child's skin you must rinse with plenty of water.







After your injection

Check the viewing window. If you can see green plastic, this indicates that the fluid has been injected.

Each pen is for single use only. After injecting, place your pen into the sharps bin provided. Keep the sharps bin out of reach from children.

The packaging can be placed in normal household waste.





Nordimet® is taken once a week only



POSSIBLE SIDE EFFECTS AND IMPORTANT ADVICE

Tests and monitoring

Before starting treatment with Nordimet® your child's doctor will have organised for them to have blood tests and urine tests to check how well their liver and kidneys are working. They may also need to have a chest X-ray. Further tests may be done during treatment.

As with all medicines, Nordimet® can cause side effects which will affect some people and not others. Make sure you closely monitor your child and if they experience any side effects, you must tell your doctor, nurse or pharmacist.

Side effects

Possible side effects can include:

| Very common | Common |
|---|---|
| may affect more than I in I0 patients | may affect up to 1 in 10 patients |
| loss of appetite nausea (feeling sick) vomiting tummy pain or discomfort inflammation and ulcers in the mouth and throat increase in liver enzymes | reduced blood cell formation headache tiredness or drowsiness inflammation of the lungs (pneumonia) with dry, non-productive cough, shortness of breath and fever diarrhoea rash reddening of the skin itching |

IMPORTANT – contact your doctor straightaway if your child experiences any sudden wheeziness, difficulty breathing, swelling of the eyelids, face or lips, rash or itching – especially affecting the whole body.

There are other adverse events which are listed in the patient information leaflet inside the box with your pen – please read these carefully.

If your child develops any of the following side effects, contact your doctor immediately:

- inflammation of the lungs (symptoms may be general illness, dry, irritating cough, shortness of breath, breathlessness at rest, chest pain, or fever)
- · severe peeling or blistering of the skin
- · unusual bleeding, spitting or coughing blood (including vomiting blood) or bruising
- severe diarrhoea
- · ulcers in mouth
- black or tarry stools
- blood in the urine or stools
- tiny red spots on the skin
- fever
- yellowing of the skin (jaundice)
- · pain or difficulty in passing urine
- thirst and/or frequent urination
- fits (convulsions)
- loss of consciousness
- blurred or decreased vision

IMPORTANT ADVICE

Taking Nordimet® with food and drink



Ensure your child is not consuming excessive amounts of drinks containing caffeine, such as fizzy drinks. Caffeine can affect how well methotrexate works or may enhance side effects. Your child must not drink any alcohol.

Try to ensure lots of other water and liquids are consumed because dehydration whilst taking this treatment can also lead to side effects.

Storage

Nordimet® pens should be kept out of reach of children. They should be stored within their box to protect the medicine from light and kept at room temperature, below 25°C. The expiry date of each pen should be checked before use and discarded if out of date. If the solution inside is not clear and contains particles, also discard and use another pen.





Vaccinations

Live vaccines must be avoided when using Nordimet[®]. Please speak with your healthcare professional before your child receives a vaccination.



Nordimet® and other medicines

Tell your nurse or doctor if your child is taking any other medicines. This includes any herbal or natural remedies as there may be some contraindications, which means certain medicines should not be taken together due to a risk of side effects or adverse reactions.

Fighting infections

Methotrexate works to reduce the activity of the immune system. Therefore your child's resistance to infection may be reduced. If they experience an infection with fever like symptoms and serious deterioration of their general condition, or a fever with local infection symptoms (such as sore throat/sore pharynx/sore mouth or urinary problems) a doctor should be seen immediately.

Reporting side effects

If your child experiences any side effects, speak to their doctor or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can also be reported directly at **www.yellowcard.mhra.gov.uk** By reporting side effects, you can help provide more information on the safety of this medicine.



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