



MANAGING YOUR CHILD'S METHOTREXATE:

FOR PARENTS AND CARERS OF YOUNG CHILDREN WITH JUVENILE IDIOPATHIC ARTHRITIS (JIA) WHO HAVE BEEN PRESCRIBED NORDIMET®

A GUIDE TO TAKING NORDIMET®

This booklet has been produced by Nordic Pharma to support patients prescribed Nordimet $\ensuremath{^{\circledast}}$

It is important to read the product package leaflet provided with your medicine. This information is not a substitute for the product package leaflet. The package leaflet contains additional important information on the use of the medicine.



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 $\mathsf{Nordimet}^{\otimes}$ is colour-coded according to the dose that has been prescribed. Your treatment may look different to the picture.



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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 healthcare professional when administering your child's medications as prescribed.

Please take the time to read the Nordimet[®] Patient Information Leaflet that has been provided with your child's medication. Please read it before administering your child's Nordimet[®] for the first time, as it includes important information.

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 healthcare professional 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 healthcare professional will decide on the dose after assessing their condition. They will be monitored carefully through tests and appointments and your child's healthcare professional may recommend that you change their dose to find the exact dose that works best for them. It is important not to alter the dosing routine yourself or stop giving your child Nordimet[®] without discussing it with your child's healthcare professional. Nordimet[®] 20 mg solution for injection methotrexate



KEY FEATURES OF A NORDIMET[®] PEN

Double click mechanism	Viewing window	No button to press
		Nordimet [®] 20 mg
		solution for injection methotrexate
		20 mg / 0.8 ml

The pen has been designed with no button to press; instead, you apply downward pressure on the pen on your child's 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 $^{\scriptscriptstyle (\! 8\!)}$ website –

nordimet.co.uk/patient-support/support-for-children-with-jia or scan this QR code



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.

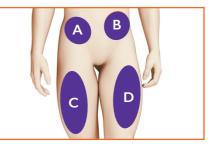


Check through the viewing window on the pen that the medicine inside is a clear, yellow solution, and if not use another pen.

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 directly away from the unit, do not twist or bend. 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.

This is a summary of the guidance. Please read the patient information leaflet contained in the medicine box carefully for further details.





Nordimet[®] is taken **once a week** only

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 $Nordimet^{(\!\!R\!)}$ to young children.



POSSIBLE SIDE EFFECTS AND IMPORTANT ADVICE

Tests and monitoring

Before starting treatment with Nordimet[®] your child's healthcare professional 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. During treatment with Nordimet, your child's healthcare professional may perform routine blood tests and other examinations to ensure your child is responding appropriately to Nordimet.

As with all medicines, Nordimet[®] can cause side effects which will affect some people and not others.

REPORTING SIDE EFFECTS: Make sure you closely monitor your child and if they experience any side effects, including any that are not listed in the patient information leaflet, you should report this to your child's healthcare professional. You can also report side effects directly via the Yellow Card Scheme at https:// yellowcard.mhra.gov.uk.

By reporting side effects you can help provide more information on the safety of Nordimet.

A full list of side effects can be found in the patient information leaflet in the box that contains your child's medicine. Please read this carefully.

Side effects

Possible side effects can include;

Very common	Common
may affect more than I in 10 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 abnormal digestion 	 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.

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.

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 interactions, 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 mouth or urinary problems) **a doctor should be seen immediately.**

Reporting side effects

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



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