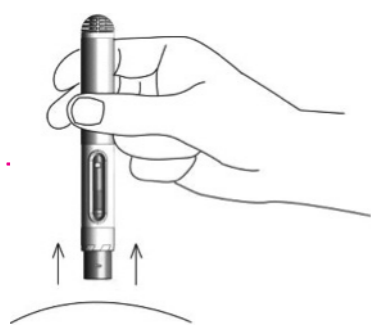


9) The injection lasts for a maximum of 10 seconds. You will feel and hear a second "click" once the injection is completed.



10) Wait another 2-3 seconds before removing the pen from your skin. The safety shield on the pen is now locked to prevent any needlestick injuries. You can now let go of the skin fold.



11) Visually inspect the pen through the viewing window. You should see green plastic. This means that all the fluid has been injected. Discard the used pen into the sharps bin provided. Close the container lid tightly and place the container out of reach of children. If you accidentally get methotrexate on the surface of the skin or soft tissues you must rinse with plenty of water.

If you use more Nordimet than you should

Follow the dose recommendations of your treating doctor. Do not change the dose without your doctor's recommendation.

If you suspect that you have used too much Nordimet, tell your doctor or contact the nearest hospital immediately. Take your medicine package and this leaflet with you if you go to a doctor or hospital.

An overdose of methotrexate can lead to severe toxic reactions. Overdose symptoms may include easy bruising or bleeding, unusual weakness, mouth sores, nausea, vomiting, black or bloody stools, coughing up blood or vomit that looks like coffee grounds, and decreased urinating. See also section 4.

If you forget to use Nordimet

Do not take a double dose to make up for a forgotten dose, but continue taking the prescribed dose as normal. Ask your doctor for advice.

If you stop taking Nordimet

You should not interrupt or discontinue Nordimet treatment before discussing with your doctor. If you suspect that you are experiencing side effects, contact your doctor immediately for advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects

If you develop 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)
- spitting or coughing blood
- severe peeling or blistering of the skin
- unusual bleeding (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

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people)
loss of appetite, nausea (feeling sick), tummy pain, inflammation of the mouth lining, abnormal digestion, and increase in liver enzymes.

Common (may affect up to 1 in 10 people)
Reduced blood cell formation with decrease in white and/or red blood cells and/or platelets (leukopenia, anaemia, thrombocytopenia), headache, tiredness, drowsiness, inflammation of the lungs (pneumonia) with dry, non-productive cough, shortness of breath and fever, mouth ulcers, diarrhoea, rash, reddening of the skin, itching.

Uncommon (may affect up to 1 in 100 people)
Decrease in the number of blood cells and platelets, throat inflammation, dizziness, confusion, depression, inflammation of blood vessels, ulcers and bleeding in the digestive tract, inflammation of the bowels, vomiting, inflammation of pancreas, liver disorders, diabetes, decreased blood protein, herpes-like skin rash, nettle rash, sunburn-like reactions due to increased sensitivity of the skin to sunlight, hair loss, increase of rheumatic nodules, skin ulcer, shingles, joint or muscle pain, osteoporosis (reduction of bone mass), inflammation and ulcers of the bladder (possibly with blood in the urine), reduced kidney function, painful urination, inflammation and ulcers of the vagina.

Rare (may affect up to 1 in 1,000 people)

Infection (incl. reactivation of inactive chronic infection), sepsis, red eyes, allergic reactions, anaphylactic shock, decreased numbers of antibodies in the blood, inflammation of the sac around the heart, accumulation of fluid in the sac around the heart, obstruction of cardiac filling due to fluid in the sac around the heart, visual disturbance, mood fluctuations, low blood pressure, blood clots, formation of scar tissue in the lung (pulmonary fibrosis), *Pneumocystis jirovecii* pneumonia, interruption of breathing, asthma, accumulation of fluid in the sac around the lungs, inflammation of the liver, brown skin, acne, red or purple spots due to vessel bleeding, allergic inflammation of blood vessels, bone fracture, kidney failure, decrease or absence of urine, electrolyte disturbances, fever, slow wound healing.

Very rare (may affect up to 1 in 10,000 people)

Reduction in certain white blood cells (agranulocytosis), severe failure of the bone marrow, liver failure, swollen glands, sleeplessness, pain, muscle weakness, sensation of numbness or tingling / having less sensitivity to stimulation than normal, changes in sense of taste (metallic taste), fits, inflammation of the lining of the brain causing paralysis or vomiting, impaired vision, damage to the retina of the eye, vomiting blood, toxic megacolon (enlargement of the large intestine associated with severe pain), defective sperm formation (oligospermia), Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), increased pigmentation of the nails, loss of sex drive, problems having an erection, infection around a fingernail, severe complications of the gastrointestinal tract, boils, visible enlargement of small blood vessels in the skin, menstrual disorders, vaginal discharge, infertility, male breast enlargement (gynaecomastia), lymphoproliferative disorders (excessive growth of white blood cells).

Frequency not known (cannot be estimated from the available data)

Increased number of certain white blood cells (eosinophilia), certain brain disorders (encephalopathy/leucoencephalopathy), nose bleeds, bleeding from the lungs, bone damage in the jaw (secondary to excessive growth of white blood cells), protein in the urine, feeling of weakness, tissue destruction at injection site, redness and shedding of skin, swelling.

Only mild local skin reactions (such as burning sensations, erythema, swelling, discolouration, severe itching, pain) were observed with Nordimet and these decreased during therapy.

Nordimet may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/sore pharynx/sore mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check for possible reduction of white blood cells (agranulocytosis). It is important to tell your doctor that you are taking Nordimet.

Methotrexate is known to cause bone disorders such as joint and muscle pain and osteoporosis. The frequency of these risks in children is not known.

Nordimet may cause serious (sometimes life-threatening) side effects. Your doctor will do tests to check for abnormalities developing in the blood (e.g. low white blood cells, low platelets, lymphoma) and changes in

the kidney and the liver.

Skin that is more sensitive to sunlight than normal. You may get a skin rash, redness, swelling or severe sunburn.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple store.

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

5. How to store Nordimet

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label of the pre-filled pen and the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Keep the pen in the outer carton in order to protect from light.

Do not freeze.

Do not use this medicine if you notice that the solution is not clear and contains particles.

Nordimet is for single use only. Any used pen should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nordimet contains

The active substance is methotrexate. 1 ml of solution contains 25 mg methotrexate.

The other ingredients are sodium chloride, sodium hydroxide and water for injections.

The following pens are available:

Pre-filled pens of 0.3 ml containing 7.5 mg methotrexate.

Pre-filled pens of 0.4 ml containing 10 mg methotrexate.

Pre-filled pens of 0.5 ml containing 12.5 mg methotrexate.

Pre-filled pens of 0.6 ml containing 15 mg methotrexate.

Pre-filled pens of 0.7 ml containing 17.5 mg methotrexate.

Pre-filled pens of 0.8 ml containing 20 mg methotrexate.

Pre-filled pens of 0.9 ml containing 22.5 mg methotrexate.

Pre-filled pens of 1.0 ml containing 25 mg methotrexate.

What Nordimet looks like and contents of the pack

Nordimet pre-filled pens contain a clear, yellow solution for injection.

Nordimet is available in packs containing 1 or 4 pre-filled pens and 1 or 4 alcohol swabs and in multipacks comprising 4 cartons, each containing 1 pre-filled pen and one alcohol swab.

Nordimet is also available in multipacks comprising 3 cartons, each containing 4 pre-filled pens and alcohol swabs.

Not all pack sizes may be marketed.

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Manufacturer

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Front

Back