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7XXXXX

Nordimet 7.5 mg
Nordimet 10 mg
Nordimet 12.5 mg
Nordimet 15 mg
Nordimet 17.5 mg
Nordimet 20 mg
Nordimet 22.5 mg
Nordimet 25 mg

Nordimet®

solution for injection in pre-filled pen

methotrexate

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nordimet is and what it is used for

Nordimet contains the active substance methotrexate which works by:
- reducing inflammation or swelling, and
- reducing the activity of the immune system (the body's own defense mechanism). An overactive immune system has been linked to inflammatory diseases.

Nordimet is a medicine used to treat a range of inflammatory diseases:
- active rheumatoid arthritis in adults. Active rheumatoid arthritis is an inflammatory condition that affects the joints;
- severe, active juvenile idiopathic arthritis in five or more joints (the condition is therefore called polyarthritic), in patients who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs);
- a severe form of treatment resistant psoriasis (also called severe recalcitrant disabling psoriasis) that does not respond adequately to other treatments including phototherapy (light therapy), PUVA (ultraviolet light therapy), and retinoids (group of medicines derived from vitamin A) , as well as in severe psoriasis that also affects the joints (psoriatic arthritis) in adult patients;
- induction of remission in adults with moderate steroid-dependent Crohn's disease, in combination with corticosteroids;
- maintenance of remission of Crohn´s disease in adults who have responded to methotrexate, as monotherapy.

2. What you need to know before you use Nordimet

Do not use Nordimet if:
- you are allergic to methotrexate or any of the other ingredients of this medicine (listed in section 6)
- you have severe kidney disease (your doctor will be able to tell you if you have severe kidney disease)
- you have severe liver disease (your doctor will be able to tell you if you have severe liver disease)
- you have disorders of the blood-forming system
- your alcohol consumption is high
- you have an impaired immune system
- you have a severe or existing infection, e.g. tuberculosis or HIV
- you have gastrointestinal ulcers
- you are pregnant or breast-feeding (see section "Pregnancy, breast-feeding and fertility")
- you receive vaccinations with live vaccines at the same time.

Warnings and precautions
Acute bleeding from the lungs in patients with underlying rheumatologic disease has been reported with methotrexate. If you experience symptoms of spitting or coughing up blood you should contact your doctor immediately.

Enlarged lymph nodes (lymphoma) may occur and therapy does then have to be discontinued.

Diarrhoea can be a toxic effect of Nordimet and requires an interruption of therapy. If you suffer from diarrhoea please speak to your doctor.

Certain brain disorders (encephalopathy/leukoencephalopathy) have been reported in cancer patients receiving methotrexate. Such side effects cannot be excluded when methotrexate is used to treat other diseases.

If you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

Methotrexate may make your skin more sensitive to sunlight. Avoid intense sun and do not use sun-beds or a sun-lamp without medical advice. To protect your skin from intense sun, wear adequate clothing or use a sunscreen with a high protection factor.

Important warning about the dosing of Nordimet
Methotrexate for the therapy of rheumatic diseases, diseases of the skin and Crohn's disease must only be used **once weekly**. Incorrect dosing of methotrexate may lead to serious adverse effects which may be fatal. Please read section 3 of this package leaflet very carefully.

Talk to your doctor before using Nordimet if:
- you have diabetes mellitus and are being treated with insulin
- you have inactive, prolonged infections (e.g. tuberculosis, hepatitis B or C, shingles [herpes zoster])
- you have/had any liver or kidney disease
- you have problems with lung function
- you are severely overweight
- you have abnormal accumulation of liquid in the abdomen or in the cavity between the lungs and chest wall (ascites, pleural effusions)
- you are dehydrated or suffer from conditions leading to dehydration (e.g. dehydration as a result of vomiting, diarrhoea or inflammation of the mouth and lips)

If you have experienced problems with your skin after radiation therapy (radiation induced dermatitis) or sun-burn, these conditions can reappear when taking Nordimet.

Children, adolescents and elderly
Dose instructions depend on the patient's body weight.

Use in children under 3 years of age is not recommended due to insufficient experience of using this medicine in this age group.

Children, adolescents and the elderly being treated with Nordimet should be kept under close medical surveillance to identify possible side effects as early as possible.

The dose for elderly patients should be lowered due to age-related reduced liver and kidney function.

Special precautionary measures for treatment with Nordimet
Methotrexate temporarily affects sperm and egg production. Methotrexate can cause miscarriage and severe birth defects. You should avoid having a baby if you are being given methotrexate at the time and for at least 6 months after the end of your treatment with methotrexate if you are a woman. If you are a man you should avoid fathering a child if you are being given methotrexate at the time and for at least 3 months after the end of your treatment.. See also section "Pregnancy, breast-feeding and fertility".

Skin changes caused by psoriasis can worsen during treatment with Nordimet if exposed to ultraviolet irradiation.

Recommended follow-up examinations and precautions
Even if methotrexate is used in low doses, serious side effects can occur. In order to detect them in time, your doctor must perform monitoring examinations and laboratory tests.

Prior to the start of therapy:
Before you start treatment, your blood will be checked to see if you have enough blood cells. Your blood will also be tested to check your liver function and to find out if you have hepatitis. Furthermore, serum albumin (a protein in the blood), hepatitis (liver infection) status and kidney function will be checked. The doctor may also decide to run other liver tests, some of these may be images of your liver and others may need a small sample of tissue taken from the liver in order to examine it more closely. Your doctor may also check to see if you have tuberculosis and they may X-ray your chest or perform a lung function test.

During the treatment:
Your doctor may perform the following examinations:
- examination of the oral cavity and the pharynx for changes in the mucous membrane such as inflammation or ulceration
- blood tests/ blood count with number of blood cells and measurement of serum methotrexate levels
- blood test to monitor liver function
- Imaging tests to monitor liver condition
- small sample of tissue taken from the liver in order to examine it more closely
- blood test to monitor kidney function
- respiratory tract monitoring and, if necessary, lung function test

It is very important that you appear for these scheduled examinations.

If the results of any of these tests are conspicuous, your doctor will adjust your treatment accordingly.

Other medicines and Nordimet
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking:

- other treatments for rheumatoid arthritis or psoriasis such as leflunomide, sulphasalazine (a medicine that besides arthritis and psoriasis is also used to treat ulcerative colitis), aspirin, phenylbutazone, or amidopyrine
- cyclosporine (for suppressing the immune system)
- azathioprine (used to prevent rejection after an organ transplant)
- retinoids (used to treat psoriasis and other skin disorders)
- anticonvulsant medicines (used to prevent fits), such as phenytoin, valproate or carbamazepine
- cancer treatments
- barbiturates (sleeping injection)
- tranquillisers
- oral contraceptives
- probenecid (used to treat gout)
- antibiotics (e.g. penicillin, glycopeptides, trimethoprim-sulphamethoxazole, sulfonamides, ciprofloxacin, cefalotin, tetracyclines, chloramphenicol)
- pyrimethamine (used to prevent and treat malaria)
- vitamin preparations containing folic acid
- proton-pump inhibitors (medicines that reduce the production of gastric acid and that are used to treat severe heartburn or ulcers), such as omeprazole or pantoprazole
- theophylline (used to treat asthma)
- colestyramine (used to treat high cholesterol, pruritus or diarrhoea)
- NSAID's, non-steroidal anti-inflammatory drugs (used to treat pain or inflammation)
- p-aminobenzoic acid (used to treat skin disorders)
- any vaccination with a live vaccine (must be avoided), such as measles, mumps or yellow fever vaccines
- metamizole (synonyms novaminsulfon and dipyrone) (medicine against severe pain and/or fever)
- nitrous oxide (a gas used in general anaesthesia

Nordimet with food, drink and alcohol
During treatment with Nordimet, you must not drink any alcohol and should avoid excessive consumption of coffee, soft drinks containing caffeine and black tea as this may enhance side effects or interfere with the efficacy of Nordimet. Also, make sure you drink plenty of liquids during treatment with Nordimet because dehydration (reduction in body water) can increase the toxicity of Nordimet.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
Do not use Nordimet during pregnancy or if you are trying to become pregnant. Methotrexate can cause birth defects, harm unborn babies or cause miscarriages. It is associated with malformations of the skull, face, heart and blood vessels, brain and limbs. Therefore, it is very important that methotrexate is not given to pregnant patients or patients planning to become pregnant. In women of child-bearing age any possibility of pregnancy must be excluded with appropriate measures, e.g. a pregnancy test before starting treatment. You must avoid becoming pregnant whilst taking methotrexate and for at least 6 months after treatment is stopped by using reliable contraception throughout this time (see also section "Warnings and precautions").

If you do become pregnant during treatment or suspect you might be pregnant, speak to your doctor as soon as possible. You should be offered advice regarding the risk of harmful effects on the child through treatment.

If you wish to become pregnant you should consult your doctor, who may refer you for specialist advice before the planned start of treatment.

Breast-feeding
Do not breast-feed during treatment because methotrexate passes into breast milk. If your doctor considers treatment with methotrexate absolutely necessary during the lactation period, you must stop breast-feeding.

Male fertility
The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes methotrexate less than 30 mg/week. However, a risk cannot be completely excluded. Methotrexate may be genotoxic. This means that the medicine may cause genetic mutation. Methotrexate can affect sperm production with the potential to cause birth defects. Therefore, you should avoid fathering a child or to donate semen whilst taking methotrexate and for at least 3 months after treatment is stopped.

Driving and using machines
Side effects affecting the central nervous system, such as tiredness and dizziness, may occur during treatment with Nordimet. In some cases, the ability to drive vehicles and/or use machines may be impaired. If you feel tired or dizzy, you should not drive or use machines.

Nordimet contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to use Nordimet

Important warning about the dose of Nordimet

Use Nordimet **only once a week** for the treatment of rheumatoid arthritis, active juvenile idiopathic arthritis, psoriasis, psoriatic arthritis and Crohn's disease requiring dosing once a week. Using too much of Nordimet may be fatal. Please read section 3 of this leaflet very carefully. If you have any questions, please talk to your doctor or pharmacist before you take this medicine.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Nordimet is administered **once a week only**. You and your doctor can decide on a suitable day each week to receive your injection.

Incorrect administration of Nordimet can lead to severe side effects that may be fatal.

The recommended dose is:

Dose in patients with rheumatoid arthritis
The recommended starting dose is 7.5 mg methotrexate **once a week**.

The doctor may increase the dose if the used dose is not effective but tolerated well. The average weekly dose is 15-20 mg. Generally, a weekly dose of 25 mg should not be exceeded. Once Nordimet starts working, the doctor may reduce the dose gradually to the lowest possible effective maintenance dose.

Generally, improvement of symptoms can be expected after 4-8 weeks of treatment. Symptoms may return if treatment with Nordimet is stopped.

Use in adults with severe forms of psoriasis vulgaris or psoriatic arthritis
Your doctor will give you a single test dose of 5-10 mg, in order to assess possible side effects.
If the test dose is well tolerated, treatment will be continued after a week with a dose of approximately 7.5 mg.

Response to treatment can generally be expected after 2-6 weeks. Depending on the effects of treatment and results of blood and urine tests, the therapy is then continued or stopped.

Dose in adult patients with Crohn's disease:
Your doctor will start with a weekly dose of 25 mg. Response to treatment can generally be expected after 8-12 weeks. Depending on the effects of treatment in time, your doctor may decide to reduce the dose to 15 mg weekly.

Use in children and adolescents below 16 years with polyarthritic forms of juvenile idiopathic arthritis
The doctor will calculate the dose required from the child's body surface area (m^2), and the dose is expressed as mg/m^2.

Use in children under 3 years of age is not recommended due to insufficient experience in this age group.

Method and duration of administration
Nordimet is given as injection under the skin (subcutaneously). It must be injected once weekly and it is recommended to always inject Nordimet on the same day of the week.

At the start of your treatment, Nordimet may be injected by medical staff. However, your doctor may decide that you can learn how to inject Nordimet yourself. You will receive appropriate training for you to do this. Under no circumstances should you attempt to inject yourself, unless you have been trained to do so.

The duration of treatment is determined by the treating physician.

Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis vulgaris, psoriatic arthritis and Crohn's disease with Nordimet is a long-term treatment.

How to give yourself an injection of Nordimet
If you have difficulty handling the pen, ask your doctor or pharmacist. Do not try to inject yourself if you have not been trained on how to do so. If you are not sure what to do, talk to your doctor or nurse immediately.

Before injecting yourself with Nordimet
- Check the expiry date on the medicine. Do not use if the date has passed.
- Check the pen is not damaged and the medicine in it is a clear, yellow solution. If not, use another pen.
- Check your last injection site to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful, if so talk to your doctor or nurse.
- Decide where you are going to inject the medicine. Change the place where you inject each time.

Instructions on injecting yourself with Nordimet
1) Wash your hands thoroughly with soap and water.

2) Sit or lie in a relaxed, comfortable position. Make sure you can see the skin area you are going to inject.

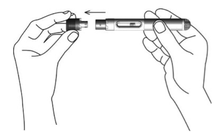
3) The pen is pre-filled and ready to use. Visually inspect the pen. You should see a yellow fluid through the viewing window. You may see a small air bubble, this does not affect the injection and will not harm you.

A droplet may appear at the tip of the needle. This is normal.

4) Choose an injection site and clean it with the enclosed alcohol swab. It requires 30-60 seconds to be effective. The skin on the front side abdominal wall and the skin at the front of the thigh are suitable as injection sites.

5) While holding the body of the pen, remove the green protective cap by pulling it smoothly and directly away from the unit. Do not twist or bend.

Once you have taken the cap off, keep the pen in your hand. Do not allow the pen to touch anything else. This is to make sure that the pen is not accidentally activated and that the needle stays clean.



6) Make a fold in the skin by gently pinching the skin of the injection place with your forefinger and thumb. Make sure you hold the skin fold throughout the injection.

7) Move the pen towards the skin fold (site of injection) with the needle shield pointing directly at the site of injection. Place the yellow needle shield against the area of injection so that the entire rim of the needle shield is touching the skin.

8) Apply downward pressure on the pen on to your skin until you hear and feel a "click".

This activates the pen and the solution will inject automatically into the skin.

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 accidently 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 jiroveci* pneumonia, interruption of breathing, asthma, accumulation of fluid in the sac around the lungs, inflamed gums, acute hepatitis (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/ leucencephalopathy), 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 or 6 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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