Nordimet (methotrexate) Solution for injection in pre-filled pen

Please refer to the Summary of Product Characteristics for full prescribing information

Presentation: Pre-filled pen containing 7.5 mg (in 0.3 ml), 10 mg (in 0.4 ml), 12.5 mg (in 0.5 ml), 15 mg (in 0.6 ml), 17.5 mg (in 0.7 ml), 20 mg (in 0.8 ml), 22.5 mg (in 0.9 ml) and 25 mg (1.0 ml) methotrexate in solution for injection. **Indications:** Active rheumatoid arthritis in adult patients. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate. Severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, retinoids and severe psoriatic arthritis in adult patients. **Dosage and administration:** Nordimet should only be prescribed by physicians with experience in the various properties of the medicinal product and its mode of action. Nordimet is injected once weekly, administered subcutaneously.

Important warning about the dosage of Nordimet
In the treatment of rheumatoid arthritis, active juvenile idiopathic arthritis, psoriasis and psoriatic arthritis requiring dosing once a week, Nordimet **must only be used once a week**. Dosage errors in the use of Nordimet can result in serious adverse reactions, including death. Please read this section of the Summary of Product Characteristics very carefully.

Rheumatoid arthritis: The recommended initial dose is 7.5 mg of methotrexate once weekly. Depending on the individual activity of the disease & patient tolerability, the initial dose may be increased. A weekly dose of 25 mg should in general not be exceeded. Once the desired therapeutic result has been achieved, the dose should be reduced gradually to the lowest possible effective maintenance dose. Polyarthritic forms of severe, active juvenile idiopathic arthritis: The recommended dose is 10-15 mg/m² BSA per week. In therapy-refractory cases, the weekly dose may be increased up to 20 mg/m² BSA per week. Use in children < 3 years of age is not recommended. Psoriasis vulgaris and psoriatic arthritis: A test dose of 5 - 10 mg subcutaneously administered one week prior to initiation of therapy is recommended. The recommended initial dose is 7.5 mg methotrexate once weekly. Dose is to be increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate. Once the desired therapeutic result has been achieved, dose should be reduced gradually to the lowest possible effective maintenance dose. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. Renal impairment, hepatic impairment or elderly patients: Please refer to SmPC. Note: When switching from oral to parenteral use, a reduction in the dose may be required, due to the variable bioavailability of methotrexate after oral administration. **Contraindications:** Hypersensitivity to methotrexate or to any of the excipients. Severe hepatic impairment, if serum bilirubin is > 5 mg/dl (85.5 µmol/l). Alcohol abuse. Severe renal impairment (creatinine clearance < 30 ml/min). Pre-existing blood dyscrasias (e.g. bone marrow hypoplasia, leukopenia, thrombocytopenia or significant anaemia). Immunodeficiency. Serious, acute or chronic infections such as tuberculosis & HIV. Stomatitis. Ulcers of the oral cavity and known active gastrointestinal ulcer disease. Pregnancy. Breast-feeding. Concurrent vaccination with live vaccines. **Special warnings and precautions:** Patients must be clearly advised that the therapy is to be administered once a week, and not every day. Patients receiving therapy should be appropriately monitored. Doses exceeding 20 mg/week can be associated with significant increase in toxicity, especially bone marrow suppression. The possible risks of effects on reproduction, pregnancy loss and congenital malformations should be discussed with male and female patients of childbearing potential. Methotrexate contact with skin and mucosal membranes is to be avoided; in cases of contamination rinse the area with plenty of water. **Undesirable effects: See SmPCs for full list of undesirable effects.** Very common: Stomatitis. Dyspepsia. Appetite loss. Abdominal pain. Nausea. Raised liver enzymes. Common: Leukopenia. Anaemia. Thrombopenia. Headache. Tiredness. Drowsiness. Pneumonia. Interstitial alveolitis/pneumonitis. Oral ulcers. Diarrhoea. Exanthema. Erythema. Pruritus. Uncommon: Pharyngitis. Pancytopenia. Precipitation of diabetes mellitus. Depression. Enteritis. Pancreatitis. Gastrointestinal ulceration and bleeding. Cirrhosis. Fibrosis and fatty degeneration of liver. Inflammation and ulceration of bladder. Renal impairment. Rare: Infection. Conjunctivitis. Sepsis. Allergic reactions. Anaphylactic shock. Hypogammaglobulinaemia. Visual disturbances. Pericarditis. Pericardial effusion. Pericardial tamponade. Thromboembolic events. Pulmonary fibrosis. Pneumocystis carinii pneumonia. Shortness of breath and bronchial asthma. Pleural effusion. Acute hepatitis. Renal failure. Anuria. Very rare: Lymphoma. Agranulocytosis. Lymphoproliferative disorders. Severe courses of bone marrow depression. Acute aseptic meningitis. Convulsions. Paralysis. Impaired vision. Retinopathy. Haematemesis. Toxic megacolon. Hepatic failure. Stevens-Johnson syndrome. Toxic epidermal necrolysis. Not known: Eosinophilia. Encephalopathy/Leukoencephalopathy. Jaw osteonecrosis (secondary to lymphoproliferative disorders). Pulmonary alveolar haemorrhage. Injection site necrosis. **Cost (for single Nordimet Pen):** 7.5 mg: £13.37, 10 mg: £13.77, 12.5 mg: £14.85, 15 mg: £14.92, 17.5 mg: £15.75, 20 mg: £16.06, 22.5 mg: £16.61 and 25 mg: £16.64 **Legal classification:** POM. **MA numbers: Nordimet:** EU/1/16/1124/001 – 008. **Further information available from:** Nordic Pharma Ltd, Unit 3 Commerce Park, Brunel Way, Theale, Reading, Berkshire, RG7 4AB. **Date of prescribing information:** Jan 2020. **Item code:** NOR/20/012

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk.

Adverse events should also be reported to Nordic Pharma on 0800 121 8924