LEFLUNOMIDE TABLETS USP

movelef 10mg, 20mg Tablets

Composition:
Leflunonmide Tablets (Movelef) 10 mg: Each film coated tablet contain Leflunomide USP 10 mg
Leflunonmide Tablets (Movelef) 20 mg: Each film coated tablet contain Leflunomide USP 20 mg

Description:
Movelef (Leflunomide tablet USP) is a pyrimidine synthesis inhibitor. The clinical name of leflunomide is N-(4tri fluoromethylphenyl)-5-methylisoxazole-4-carboxamide. Movelef is available for oral administration as Tablets containing 10mg and 20 mg active drug.

Indications*:
(specialist use only) moderate to severe active rheumatoid arthritis; active psoriatic arthritis

Cautions*:
Renal impairment (avoid if moderate or severe; Manufacturer advises avoid in moderate or severe impairment-no information available); impaired bone-marrow function including anaemia, leucopenia or thrombocytopenia (avoid if significant and due to causes other than rheumatoid arthritis); recent treatment with other hepatotoxic or myelotoxic disease-modifying antirheumatic drugs; washout procedures recommended for serious adverse effects or before switching to other disease modifying antirheumatic drugs (consult product literature and see Washout Procedure, below); history of tuberculosis; exclude pregnancy before treatment; effective contraception essential during treatment and for at least 2 years after treatment in women and at least 3 months after treatment in men (plasma concentration monitoring required; waiting time before conception may be reduced with washout procedure-consult product literature and see Washout Procedure, below); monitor full blood count (including differential white cell count and platelet count) before treatment and every 2 weeks for 6 months then every 8 weeks; monitor liver function see Hepatotoxicity, below; monitor blood pressure;

Interactions*:
Note: Increased risk of toxicity with other haematotoxic and hepatotoxic drugs.
Antibacterials: plasma concentration of active metabolite of leflunomide possibly increased by rifampicin.
Anticoagulants: leflunomide possibly enhances anticoagulant effect of warfarin.
Antidiabetics: leflunomide possibly enhances hypoglycaemic effect of tolbutamide.
Antiepileptics: leflunomide possibly increases plasma concentration of phenytoin.

Cytotoxics: risk of toxicity when leflunomide given with methotrexate.
Lipid-regulating Drugs: the effect of leflunomide is significantly decreased by colestyramine (enhance-delimination)-avoid unless drug elimination desired.
Vaccines: avoid concomitant use of Leflunomide with live. Vaccines

Hepatotoxicity*:
Potentially life-threatening hepatotoxicity reported usually in the first 6 months; monitor liver function before treatment and every 2 weeks for first 6 months then every 8 weeks. Discontinue treatment (and institute washout procedure—consult product literature and see Washout Procedure below) or reduce dose according to liver-function abnormality;
if liver-function abnormality persists after dose reduction, discontinue treatment and institute washout procedure.

Washout procedure*:
To aid drug elimination in case of serious adverse effect, or before starting another disease modifying antirheumatic drug, or before conception (Avoid-active metabolite teratogenic in animal studies; effective contraception essential during treatment and for at least 2 years after treatment in women and at least 3 months after treatment in men), stop treatment and give either colestyramine 8 g 3 times daily for 11 days or activated charcoal 50 g 4 times daily for 11 days; the concentration of the active metabolite after washout should be less than 20 micrograms/litre (measured on 2 occasions 14 days apart) in men or women before conception—consult product literature

Contra-indications*:
severe immunodeficiency; severe hypoproteinaemia; serious infection; hepatic impairment (Avoid-active metabolite may accumulate); pregnancy (important teratogenic risk: see Cautions and Avoid-active metabolite teratogenic in animal studies; effective contraception essential during treatment and for at least 2 years after treatment in women and at least 3 months after treatment in men); breastfeeding (Present in milk in animal studies-manufacturer advises avoid).

Side-effects*:
Diarrhea, nausea, vomiting, anorexia, oral mucosal disorders, abdominal pain; increased blood pressure; headache, dizziness, asthenia, paraesthesia; leucopenia; tenosynovitis; alopecia,rash, dry skin, pruritus; less commonly taste disturbance, anxiety, hypokalemia, hypophosphatemia, anemia, thrombocytopenia, and tendon rupture; rarely hepatitis, jaundice (see Hepatotoxicity, above), interstitial lung disease, severe infection, eosinophilia,
Andsentation: pancytopenia; very rarely pancreatitis, hepatic failure (see Hepatotoxicity, above), peripheral neuropathy, vasculities, Stevens-Johnson syndrome, and toxic epidermal necrolysis; hyperlipidemia and renal failure also reported; important: discontinue treatment and institute washout procedure (see Washout Procedure under Cautions) in case of serious side effect

Dose*:
Rheumatoid arthritis: ADULT over 18 years, initially 100 mg once daily for 3 days, then 10–20 mg once daily.

Psoriatic arthritis: ADULT over 18 years, initially 100 mg once daily for 3 days, then 20 mg once daily.

Presentation:
LEFLUNOMIDE TABLETS USP 10mg:
(Movelef Tablets 10mg) is available in alu-alu blister pack of 30's (1x30's) and 510's (17x30's) tablets.

LEFLUNOMIDE TABLETS USP 20mg:
(Movelef Tablets 20mg) is available in alu-alu blister pack of 30's tablets.

Storage:
Store at temperature below 30°C.
Protect from heat, light and moisture.
Keep all medicines out of the reach of children.

***Reference to BNF 58**

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