Weekly methotrexate for CTCL

Indication
Long term therapy with low dose weekly oral Methotrexate for the treatment of stage IA - IVB cutaneous T-cell lymphoma (CTCL), erythrodermic CTCL and Sézary syndrome

Regimen details
Methotrexate variable dose (usually 10mg – 30mg) taken orally weekly

Cycle frequency
Given weekly on a 28 day cycle

Number of cycles
Until disease progression or unacceptable toxicity

Administration
Tablets must be taken on the same day each week – state day on prescription
Issue patient with methotrexate card

Pre-medication
N/A

Emetogenicity
Minimal

Additional supportive medication
None routinely prescribed

Extravasation
N/A

Investigations – pre first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days

Investigations –pre subsequent cycles
FBC, U+E (including creatinine), LFT (including AST)

Standard limits for administration to go ahead
If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	Limit
Neutrophil count	≥ 1.0 x 10^9/L
Platelet count	≥ 100 x 10^9/L
Creatinine clearance	≥ 50 mL/min
Bilirubin	≤ 1.5 x ULN

AST	< 3 x ULN

Dose modifications

Renal Impairment

Creatinine Clearance (ml/min)	Methotrexate Dose
> 50	100% dose
20 - 50	50 - 100% dose
10 – 20	50% dose
< 10	contra-indicated

Hepatic Impairment reduce dose, particularly in patients with concomitantly renal impairment. In severe hepatic impairment – contraindicated

Bilirubin (micromol/l)	AST(IU/l)	Methotrexate dose
<50	and <180	100%
>51-85	or >180	75%
>85		omit

Adverse effects –

for full details consult product literature/ reference texts

Pulmonary reactions
Interstitial pneumonitis
GI toxicity
Haematopoietic suppression
Lymphomas
Mucositis
Nausea – dose related
Anorexia
Diarrhoea
Fatigue
Elevation of liver enzymes and liver toxicity
Renal toxicity
Rash
Pruritus
Photosensitivity
Radiation recall reactions

Significant drug interactions

– for full details consult product literature/ reference texts

Drugs with antifolate properties (e.g. co-trimoxazole, trimethoprim)
NSAIDS- increased methotrexate toxicity
Digoxin – decreased efficiency
Theophylline, phenytoin- increased effect/ toxicity
Probenecid, penicillins- increased effect of methotrexate
Quinolones
Hepatotoxic and nephrotoxic drugs- care
PPIs
Vitamin products containing folic acid may alter response
Avoid use of live vaccines

Additional comments

Adequate contraceptive methods should be used during and at least 6 months after the therapy.

References

Treatment Protocol for Methotrexate in CTCL – Christie Hospital

MHRA alert: https://www.gov.uk/drug-safety-update/methotrexate-once-weekly-for-autoimmune-diseases-new-measures-to-reduce-risk-of-fatal-overdose-due-to-inadvertent-daily-instead-of-weekly-dosing

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THIS PROTOCOL HAS BEEN DIRECTED BY DR CHARNLEY, CONSULTANT CLINICAL ONCOLOGIST

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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