University Hospital of North Staffordshire NHS Trust | North Staffordshire Combined Healthcare NHS Trust | Staffordshire and Stoke on Trent Partnership NHS Trust | NHS North Staffordshire Clinical Commissioning Group | NHS Stoke-on-Trent Clinical Commissioning Group

Effective Shared Care Agreement for demeclocycline for the treatment of chronic hyponatraemia associated with the syndrome of inappropriate secretion of antidiuretic hormone (SIADH)

This shared care agreement outlines the ways in which the responsibilities for managing the prescribing of demeclocycline will be shared between the specialist and general practitioner (GP). If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition will remain with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practical.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Written by (clinician): Dr U Nayak Written by (pharmacist): Jennie Sleigh Date of issue: 1/10/13

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RESPONSIBILITIES and ROLES

Specialist responsibilities

1 Perform baseline tests (FBC, U&Es and LFTs).
2 Discuss the benefits and side effects of treatment with the patient.
3 Initiate and stabilise treatment with demeclocycline. Stabilisation will usually take 2 - 4 weeks.
4 Supply medication until care is transferred to GP.
5 Ask the GP whether he or she is willing to participate in shared care.
6 Ensure GP has access to blood results for information: no action would be required from the GP.
7 Periodically review the patient's condition in clinic every 3 to 4 months and communicate promptly with the GP when treatment is changed.
8 Advise the patient and GP on when to adjust the dose or stop treatment.
9 Report adverse events to the CSM and GP.
10 Ensure that clear backup arrangements exist for GPs to obtain advice and support.
11 If patient fails to attend for monitoring tests, inform GP who may then stop treatment.

General Practitioner responsibilities

1 Reply to the request for shared care as soon as possible.
2 Prescribe demeclocycline at the dose recommended once patient is established on treatment.
3 Ensure compatibility with other concomitant medication.
4 Adjust the dose as advised by the specialist.
5 Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
6 Report adverse events to the specialist and CSM.

Patient's / Carer's role

1 Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2 Share any concerns in relation to treatment with demeclocycline.
3 Inform specialist or GP of any other medication being taken, including over-the-counter products.
4 Report any adverse effects or warning symptoms to the specialist or GP whilst taking demeclocycline.

Monitoring requirements

Monitoring	Full blood count	LFTs	U&Es	GP or Consultant
Baseline	✓	✓	✓	Consultant
Every 2 weeks until stabilised	✓	✓	✓	Consultant
3-4 monthly	✓	✓	✓	Consultant

SUPPORTING INFORMATION EFFECTIVE SHARED CARE AGREEMENT

This information should be read in conjunction with the Summary of Product Characteristics for demeclocycline available from www.medicines.org.uk

Licensed indications

For the treatment of chronic hyponatraemia associated with the syndrome of inappropriate secretion of antidiuretic hormone (SIADH) secondary to malignant disease, where water restriction is ineffective and the patient does not have concomitant cirrhosis

Dosage and Administration

Adults only

Initially: 900mg-l200mg daily in divided doses (avoiding bedtime)

Maintenance dose: 600-900mg daily in divided doses (avoiding bedtime)

LEDERMYCIN should be swallowed whole with plenty of fluid while sitting or standing. Doses should be taken an hour before or 2 hours after meals as absorption of LEDERMYCIN is impaired by milk and food. Patients should be advised to avoid direct exposure of the skin to sunlight.

LEDERMYCIN therapy in the treatment of chronic hyponatraemia due to SIADH should not be withdrawn without commencing other methods of control.

Contraindications

Demeclocycline is contraindicated in patients with acute porphyria; patients who are pregnant or breast-feeding; children under 12 years of age; patients with a history of hypersensitivity to tetracyclines or patients with renal impairment.

Monitoring

LEDERMYCIN should be used with caution in patients with renal or hepatic dysfunction, or in conjunction with other potentially hepatotoxic or nephrotoxic drugs. Concurrent use with the anaesthetic methoxyflurane increases the risk of kidney failure. The anti-anabolic action of the tetracyclines may cause an increase in BUN. The treatment of chronic hyponatraemia may necessitate the administration of high doses of LEDERMYCIN for prolonged periods, so increasing the potential for nephrotoxicity (manifested by rises in plasma urea and creatinine) and photoallergic reactions.

Side Effects

Gastrointestinal disturbances including nausea, vomiting, diarrhoea and rarely dysphagia have been reported. There have been a few cases of oesophagitis and oesphageal ulceration in patients taking oral tetracyclines in solid dose form, usually where medication was taken immediately before retiring or with inadequate fluids.

In common with other tetracyclines, transient increases in liver function test values, hepatitis, jaundice and hepatic failure have been reported rarely. A few cases of pancreatitis have been reported.

The most commonly reported dermatological reaction is photosensitivity. Erythematous, and maculo-papular rashes, pruritus, bullous dermatoses, exfoliative dermatitis and skin discolouration have occurred occasionally but serious skin reactions are rare.

Headache, dizziness, visual disturbances and rarely impaired hearing have been reported with tetracyclines. Bulging fontanelles in infants and benign intracranial hypertension in juveniles and adults have been reported. Treatment should cease if evidence of raised intracranial pressure, such as severe or persistant headache or blurred vision are noted. While the condition and related symptoms usually resolve soon after discontinuation of the tetracycline, the possibility of permanent sequelae exists. There have been isolated cases of myasthenia.

Hypersensitivity reactions including urticaria, Stevens-Johnson syndrome, angioneurotic oedema, anaphylaxis, anaphylactoid purpura, pericarditis and exacerbation of systemic lupus erythmatosus may occur.

Renal dysfunction, especially in patients with pre-existing renal impairment, and rarely, acute renal failure or nephritis, have been reported with tetracyclines.

Reversible nephrogenic diabetes insipidus can occur especially if treatment is prolonged and/or at high dosages.

Haemolytic anaemia, thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and eosinophilia have been reported rarely. When given over prolonged periods, tetracyclines have been reported to produce brown-black discoloration of the thyroid gland. No abnormalities of thyroid function are known to occur.

Drug Interactions

LEDERMYCIN should not be used with penicillins.

Tetracyclines depress plasma prothrombin activity and reduced doses of concomitant anti-coagulants such as Coumarins and phenindione may be required.

Absorption of LEDERMYCIN is impaired by the concomitant administration of milk and dairy products, food, iron, calcium, zinc, magnesium and particularly aluminium salts commonly used as antacids.

Absorption of tetracyclines is possibly reduced by kaolin, quinapril tablets (quinapril tablets contain magnesium carbonate), strontium ranelate, sucralfate, tripotassium dicitratobismuthate. The concomitant use of tetracyclines may reduce the efficacy of oral contraceptives; an increased incidence of breakthrough bleeding may also be experienced.

There is a possible increased risk of benign intracranial hypertension with concomitant use of tetracyclines and retinoids, e.g. acitretin, isotretinoin, tretinoin. There is an increased risk of ergotism when tetracyclines are given with ergotamine and methysergide.

Typhoid Vaccine (oral): Antibacterials inactivate oral typhoid vaccine and therefore Ledermycin should be avoided for 3 days before and after oral typhoid vaccine.

Primary Care Costs

Demeclocycline 150mg 28 capsules cost £70.86

References

1 Summary of Product Characteristics Demeclocycline Hydrochloride 150mg Capsules. Amdipharm Mercury Company Limited. Last revised 30/11/2012. Accessed via www.medicines.org.uk

2 Drug Tariff July 2013 accessed via: http://www.ppa.org.uk

BACK-UP ADVICE AND SUPPORT

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