



**LINCOLNSHIRE Clinical Commissioning Groups in association with
UNITED LINCOLNSHIRE HOSPITALS TRUST**

SHARED CARE GUIDELINE:

**Nabilone unlicensed use in the management of chronic neuropathic pain
that has failed to respond to other first and second line treatments.**

General Principles

Shared Care Responsibilities:

In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (BNF 70, September 2015 – March 2016, pg.4)

Aims:

- (1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.
- (2) Specific shared care guidance should be available for any high cost drug, high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.
- (3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.
- (4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

Further copies

Further copies of any guidelines in this series are available from members of the Arden and GEM commissioning Support Unit – Lincolnshire Prescribing & Medicines Optimisation Team.

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Principles of shared care

The General Medical Council published their Good Practice In Prescribing And Managing Medicines and which came into effect 25th February 2013. A section of the guidance provides recommendations for the sharing of care which applies to any instance when care is shared between different services.

Good practice recommendation 35.

- Decisions about who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on patients best interest rather than on convenience or the cost of the medicine and associated monitoring or follow-up

Good practice recommendation 36.

- Shared care requires the agreement of all parties including the patient. Effective communication and continuing liaison between all parties to a shared care agreement is essential.

Good practice recommendation 37.

- If you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence.

Good practice recommendation 38.

- If you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required

Good practice recommendation 39.

- In both cases, you will be responsible for any prescription you sign.

Good practice recommendation 40.

- If you recommend that a colleague, for example a junior doctor or general practitioner, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required

Good practice recommendation 41

- If you share responsibility for a patient's care with a colleague , you must be competent to exercise your share of clinical responsibility.

You should:

- a) Keep yourself informed about the medicines that are to be prescribed for the patient
- b) Be able to recognise serious and frequently occurring adverse side effects
- c) Make sure appropriate clinical monitoring arrangements are in place and that the patient and the healthcare professionals involved understand them
- d) Keep up to date with relevance guidance on the use of the medicines and on the management of the patient's condition

Good practice recommendation 42

- In proposing a shared care arrangement, specialists may advise the patient's general practitioner which medicine to prescribe. If you are recommending a new or rarely prescribed medicine you should specify the dosage and means of administration and agree a protocol for treatment. You should explain the use of unlicensed medicines and departures from authoritative guidance or recommended treatments and provide both the general practitioner and the patient with sufficient information to permit the safe management of the patient's condition.

Good practice recommendation 43

- If you are uncertain about your competence to take responsibility for the patient's continuing care you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied you should explain this to the other clinician and to the patient and make appropriate arrangements for their continuing care.

Drug Details

Approved Name: Nabilone

Brand Name:

Form and Strength: 1mg capsules

Specialist Responsibilities

The specialist secondary/tertiary care service will:

1. Send a letter to the GP suggesting that shared care is agreed for this patient. Either enclose a copy of the shared care protocol or the GP should be signposted to where they can find a copy of the shared care protocol e.g. the PACEF website <http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-pacef>.
2. Ensure that the patient receives initial supplies of nabilone from the hospital until the GP formally agrees to share care.
3. Provide a comprehensive assessment of the patient.
4. Discuss treatment options with the patient to include an explanation of the unlicensed use of nabilone for the treatment of neuropathic pain obtaining consent to treatment.
5. Ensure that the patient is aware of possible side effects on mood and behavioural effects of nabilone.
6. Initiate treatment with nabilone or provide the GP with clear instructions as to the initial dose of including details of any dose titration that might be required and when the patient will next be reviewed in clinic.
7. Periodically review the patient's clinical condition
8. Communicate promptly any changes in nabilone dose or any other ongoing pain clinic intervention to the GP.
9. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.

10. Follow up any adverse drug reactions reported by the GP and report back to the GP.
11. Provide support to the GP and advice if treatment needs to be discontinued.

GP Responsibilities

The GP will:

1. Notify the consultant in writing, without undue delay, if they agree to share care
2. Initiate treatment with nabilone according to written instructions provided by the specialist service or continue to prescribe at the dose initiated by the specialist.
3. Monitor the patients overall health and wellbeing.
4. Monitor the patient for adverse drug reactions and remain vigilant to the risk of potential drug interactions.
5. Carry out any investigations that are communicated and deemed appropriate.
6. Refer back to the specialist if condition deteriorates as advised by specialist service.
7. Discontinue treatment (where necessary) on the advice of the specialist

Referral Criteria

1. Patients will have been stabilized on nabilone on an appropriate dose unless GP has agreed to initiate treatment according to instructions provided by the specialist service.
2. The specialist will have carried out an assessment of efficacy

Licensed Indications

Nabilone is licensed for nausea and vomiting caused by cytotoxic chemotherapy unresponsive to conventional anti-emetics. It is not licensed as an analgesic. Nabilone is prescribed by the Chronic Pain Management Team outside of product license.

Indications for initiating treatment:

Adults with distressing, intractable, neuropathic pain that has failed to respond to:

1. First line medications including: opioids (including strong opioids), antidepressants (e.g. amitriptyline) and anticonvulsants (e.g. gabapentin).
2. Other reasonable treatments under the care of the pain clinic (e.g. injectable therapies, complementary therapies and other treatments such as TENS).

Recommended Dosage and Administration

Usually up to 1mg twice a day. Some patients may require up to 2mg twice daily although this would be regarded as unusual. Some patients find very low doses beneficial (e.g. 0.5mg per day; this dosage requires the division of one capsule).

Background Pharmacology

Nabilone is a synthetic cannabinoid.

Preparations Available

1mg capsules.

Nabilone is not available from standard pharmaceutical wholesalers; dispensing practices and community pharmacies will need to source directly from the manufacturer.

Order contact details are:

Adverse Effects

Common or very common: ataxia, concentration difficulties, drowsiness, dry mouth, dysphoria, euphoria, headache, hypotension, nausea, sleep disturbances, vertigo, visual disturbance.

Frequency not known: abdominal pain, confusion, decreased appetite, decreased coordination, depression, disorientation, hallucinations, psychosis, tachycardia and tremors.

Patients should be warned that drowsiness and dizziness occur frequently with standard doses.

Patients should be made aware of possible changes of mood and other adverse behavioural effects.

For full list of reported adverse effects refer to SPC.

Drug Interactions

There is an increased sedative effect when nabilone is given with hypnotics, anxiolytics or alcohol.

Nabilone should be administered with caution to patients who are taking other psychoactive drugs or CNS depressants.

Nabilone should be administered with caution to patients who are taking other psychoactive drugs or CNS depressants, including alcohol, barbiturates and narcotic analgesics, or to those with a history of psychiatric disorder (including manic-depressive illness and schizophrenia). Nabilone has been shown to have an additive CNS depressant effect when given with either diazepam, secobarbitone sodium, alcohol or codeine.

Precautions and Contraindications

Contraindications

Nabilone is contra-indicated in patients with a known allergy to cannabinoid agents and in those with severe hepatic impairment.

There are no studies of nabilone use in pregnancy and breast feeding. Manufacturer recommends that nabilone should not be given to nursing mothers and only should be used in pregnancy if the benefits outweigh the potential risks.

Cautions

Patients receiving Nabilone should be closely observed, if possible, within an inpatient setting. This is especially important during the treatment of naive patients. However, even patients experienced with cannabinoid agents may have serious untoward responses not predicted by prior uneventful exposures. Patients should be made aware of possible changes of mood and other adverse behavioural effects of the drug.

Nabilone should be administered with caution to patients who are taking other psychoactive drugs or CNS depressants, including alcohol, barbiturates and narcotic analgesics, or to those with a history of psychiatric disorder (including manic-

SCA Nabilone Final Version

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depressive illness and schizophrenia). Adverse effects on mental state can persist for 48-72 hours after cessation of treatment.

Nabilone may elevate supine and standing heart rates and cause postural hypotension and the manufacturer advises it should be used with caution in the elderly and in patients with hypertension and heart disease.

Nabilone is an abusable substance and should be used with caution in patients with a history of drug or substance abuse.

Nabilone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as operating machinery or driving a car. Patients should be advised accordingly.

The effects of Nabilone may persist for a variable and unpredictable period of time following its oral administration.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine
- However, you would not be committing an offence (called 'statutory defence') if:
 - The medicine has been prescribed to treat a medical or dental problem,
 - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine, and
 - It was not affecting your ability to drive safely

Monitoring

Ongoing review will be provided by the Chronic Pain Management Team. GPs can refer patients back to the Team for review on request

Indication of Likely Cost of Therapy in Primary Care

January 2016

28 days supply at 1mg twice daily £352.35 annual cost - £4,581

28 days supply at 2mg twice daily £704.70 annual cost - £ 9,161

Information Given to the Patient

Contact Details

Pilgrim Hospital, Boston

Pain Management Clinic Secretaries – 01205 446612

Lincoln County Hospital, Lincoln

Pain Management Clinic Secretaries – 01522 573691

Or

Pain Management Nurse Specialist – 01522 512512 ext 3717

References

1. BNF 70 September 2015 – March 2016.
2. SPC Nabilone 1mg capsules Meda Pharmaceuticals.. Last updated 13th October 2014, accessed through eMC website on 28th January 2016.
- 3.PACE Bulletin Vol 9 No 7 – New drugs and driving legislation.

Updated.

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C.M.Johnson

Interface Lead Pharmacist

Arden GEM CSU