SHARED CARE PRESCRIBING GUIDELINE

Management of Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia in adults

Stimulant therapy: modafinil, methylphenidate and dexamfetamine

Anti-cataplectic agents: venlafaxine XL, clomipramine, fluoxetine and sodium oxybate

NOTES to the GP

The information in the shared care guideline has been developed in consultation with CCGs in South East London and it has been agreed that it is suitable for shared care.

This document should provide sufficient information to enable you to make an informed decision regarding the clinical and legal responsibility for prescribing the following medication for the **management of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adults.**

Stimulant therapy: modafinil, methylphenidate and dexamfetamine

Anti-cataplectic agents: venlafaxine XL, clomipramine, fluoxetine and sodium oxybate.

The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.

If the answer is NO to any of these questions you should contact the requesting consultant or your local CCG Medicines Management Team. There may be implications for the patient where the invitation to share care is declined. For example, the patient may need to be changed to an alternative treatment regimen. It would not normally be expected that shared care prescribing would be declined on the basis of cost.

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**.

Prescribing should follow requirements in the South East London Interface Prescribing Policy.
The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient's best interests are always paramount.

Contents

Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia treatment and licensing

Please also refer to the treatment pathways for:

(i) Pharmacological Management of Excessive Daytime Sleepiness due to Narcolepsy

(ii) Pharmacological Management of Cataplexy associated with Narcolepsy

Narcolepsy (+/- cataplexy) and idiopathic hypersomnia are both long-term and debilitating sleep conditions which are similar in their clinical presentation, differ in their diagnosis but may be managed in a parallel manner.

Narcolepsy is a long-term condition that causes excessive sleepiness during the day and may also disrupt your sleep at night. You can also have sleep attacks where you fall asleep at inappropriate times during the day without any warning. The Epworth Sleepiness Scale is a questionnaire intended to measure daytime sleepiness. Narcolepsy is generally associated with an ESS of >12, even after adequate night-time sleep.

Cataplexy is a condition associated with narcolepsy that results in sudden muscle weakness triggered by strong emotions such as laughter, anger, fright or surprise. Muscle weakness can vary in severity and cataplexy attacks can differ in both nature and duration.

Idiopathic Hypersomnia (IH) is a sleep disorder in which a person is excessively sleepy during the day and has great difficulty being awakened from sleep. Idiopathic means there is no clear cause. IH is similar to narcolepsy in that you are extremely sleepy but also different from narcolepsy because IH does not usually involve suddenly falling asleep (sleep attacks) or losing muscle control due to strong emotions (cataplexy). Furthermore, unlike narcolepsy, naps in idiopathic hypersomnia are usually not refreshing.

The purpose of this document is to demonstrate the clinical use of stimulant and anti-cataplectic agents in the treatment of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adult patients. It is not within the scope of this document to provide guidance on diagnosis of this condition.

O = 'off-label' but considered routine treatment option
X = unlicensed and not currently considered a routine option

	Narcolepsy	Narcolepsy with Cataplexy	Idiopathic Hypersomnia
Modafinil	***Licensed***	***Licensed***	***O***
Methylphenidate XL	***O***	***O***	***O***
Methylphenidate IR	***O***	***O***	***O***
Dexamfetamine	***Licensed***	***Licensed***	***O***
Sodium oxybate	***O***	***Licensed***	***X***
Venlafaxine XL	***X***	***O***	***X***
Clomipramine	***X***	***O***	***X***
Fluoxetine	***X***	***O***	***X***
The agent below is red listed and is NOT included in this shared care arrangement. Prescribing will remain with the sleep centre.			
Pitolisant (NOT FOR SHARED CARE)	***Licensed***	***Licensed***	***O***

Once you have read the shared care guideline and considered the information above, please complete the GP decision form on the next page and email back to the requesting clinician if you are in agreement to participate in shared care.

1. GP DECISION FORM

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of **stimulant therapy: modafinil, methylphenidate and dexamfetamine plus anti-cataplectic agents: venlafaxine XL, clomipramine, fluoxetine and sodium oxybate** for the **management of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adults** can be shared between the specialist and general practitioner (GP). GPs are invited to participate. 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 remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

AGREEMENT TO PARTICIPATE IN SHARED CARE

Management of Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia in Adults.

Stimulant therapy: modafinil, methylphenidate and dexamfetamine

Anti-cataplectic agents: venlafaxine XL, clomipramine, fluoxetine and sodium oxybate

Consultant/Specialist Name:	**Patient name:**
Consultant/Specialist signature:	**Patient Hospital Number:** **Patient NHS Number:**
Date completed:	**Patient Agreement:**
Hospital requesting shared care:	Patient agrees to shared care ☐ Patient does not agree to shared care ☐

GP Name:

This is to confirm that I agree to participate in shared care for

Stimulant therapy: modafinil, methylphenidate, dexamfetamine*.

Anti-cataplectic agents: sodium oxybate, venlafaxine XL, clomipramine and fluoxetine*

***Delete as appropriate**

for the treatment of Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia in adults **for this patient as outlined in this shared care document**

GP Signature:

Date signed:

ACTION

1. HOSPITAL CONSULTANT **Tick to confirm**

- Explain shared care to patient and obtain agreement Date agreement obtained: _____ ☐
- Indicate requesting hospital ☐
- Complete and sign agreement ☐
- Email full shared care guideline (including signed agreement to GP) ☐
- Place original in patient's notes ☐

2. GP PRACTICE

- If **in agreement** to participate in shared care, sign and email (via secure NHS.net) this sheet back **within 2 weeks** of receipt **of request from specialist** to: gst-tr.gsttsleepreferrals@nhs.net

- If **do not agree** to participate in shared care, contact consultant and local Primary Care CCG Medicines Management Team within 2 weeks of receipt to discuss. If after discussion it is agreed not to undertake shared care for this patient, both the consultant and the local Primary Care CCG Medicines Management team should be informed.
  Once decision reached file a copy in the Patient's medical notes.

Management of Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia in adults
Stimulant therapy: modafinil, methylphenidate and dexamfetamine

Anti-cataplectic agents: venlafaxine XL, clomipramine, fluoxetine and sodium oxybate

CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient's condition is stable or predictable.
- The hospital will provide the patient with **an ongoing supply until** shared care agreement is in place.
- Stimulant medication including methylphenidate XL and IR preparations, dexamfetamine plus anti-cataplectic agent sodium oxybate are controlled drugs therefore 30 day supply at each prescription issue will demonstrate good practice.

2 Areas of responsibility

Consultant / Specialist team responsibilities

- Ensuring patient fits criteria for use of stimulant +/- anti-cataplectic agents (e.g. no contraindications, cautions, fits local agreement for use of the drug).
- Baseline monitoring tests- Blood pressure, heart rate, weight, Epworth Sleep Score. ECG for initiation of methylphenidate and dexamfetamine only.
- To initiate, stabilise and supply treatment for at least 6 months.
- To inform patients of practical issues related to the use of stimulant +/- anti-cataplectic agents, such as administration, storage and maximum dose – see "Information provided to patient" section on page 27.
- At the time of initiating, notify GP in writing that stimulant +/- anti-cataplectic agents has been prescribed. The GP should ONLY be invited to share care once the patient is stable. Information provided to the GP should include:
  - A copy of the shared care guidelines
  - Information on when the patient will next be reviewed and by whom.
  - A request that the GP continue prescribing the medication beyond the first 6 months on initiation of transfer.
  - That a monthly prescription for 6 months will be issued at transfer of shared care.
- Any continuous monitoring that will remain under the consultant's responsibility
- To review patient at the request of GP should any problems arise (side-effects / lack of efficacy). Within 2 weeks
- To communicate promptly with the GP if patient does not attend clinic appointment or if treatment or management of condition is changed. Within 2 weeks
- To report any suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk

General Practitioner responsibilities

- To consider shared care proposal within 2 weeks of receipt. If agree to request to continue prescribing as detailed in shared care guideline. Confirmation to the requesting consultant is required **within 2 weeks** of receipt of this guideline by completing and returning the agreement on page 6.
- If do not agree to shared care discuss with requesting consultant or local primary care medicines management team within 2 weeks of receipt of shared care request.
- To provide ongoing prescriptions for stimulant +/- anti-cataplectic agents after **6** months. To adjust the dose as advised by the specialist.
- To agree monitoring requirements with specialist – see page 9-25 of this document for GP monitoring requirements.
- To report and seek advice regarding any concerns, for example: side-effects, co-morbidities, pregnancy, or lack of efficacy to the specialist team.
- To advise the specialist if non-compliance is suspected.
- To refer back to specialist if the patient's condition deteriorates.
- To stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- To report any suspected adverse effects to the MHRA via the Yellow Card scheme: http://www.yellowcard.gov.uk

Patient's / Carer's responsibilities

- To contact the specialist or GP if he or she does not have a clear understanding of any aspect of the treatment.
- ***Narcolepsy and Driving:*** You are obliged by law to notify the Driver and Vehicle Licensing Agency (DVLA) of the diagnosis of Narcolepsy. Group one licence holders (car, motorbike) must cease driving on the diagnosis of the narcolepsy. Driving will be permitted when satisfactory control of symptoms is achieved, then 1, 2 or 3 year licence with medical review, till 70 years of age. Licence restored after several years of satisfactory control. Group two licence holders (LGV/PCV) are generally considered unfit to drive this class of vehicle permanently. However, if a long period of symptom control has been established, licensing may be considered on an individual basis. Do not drive if feeling sleepy.
- To inform prescribing specialist, GP and other healthcare professionals of any other medication being taken, including over the counter products, alternative therapies or recreational drugs.
- To implement and maintain good sleep hygiene. *Taking medication is not a replacement for a good sleep routine. It is still important to aim to get around seven to eight hours of sleep at night if possible. You should aim to go to bed when sleepy/tired and get up at about the same time each day.*
- To inform community pharmacists that they are using stimulant +/- anti-cataplectic agents before purchasing medication over-the-counter.
- To attend all hospital and GP appointments.
- To take medicines as agreed and take steps to ensure that no doses are missed and not to share medicines with others.
- To read the patient information leaflet included with the medication.
- To report any adverse effects or warning symptoms to GP or hospital specialist.
- To report to GP and sleep centre team if pregnant or breastfeeding.
- To inform GP and hospital of any changes in addresses or telephone contact number

GP monitoring template for the management of Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia in adults.

Dear Dr……

The patient is on a stimulant medication for: the treatment of Narcolepsy (+/-Cataplexy) and Idiopathic Hypersomnia in adults. (delete as appropriate)

Stimulant initiated	**Tick selected**	**Date initiated**	**Dose on transfer**	**Intended duration of treatment**	**Date of next review**
Modafinil					
Methylphenidate XL					
Methylphenidate IR					
Dexamfetamine					
Anti-cataplectic agent initiated	**Tick selected**	**Date initiated**	**Dose on transfer**	**Intended duration of treatment**	**Date of next review**
Sodium Oxybate					

Stimulant/Anti-cataplectic Therapy

Is the patient receiving concomitant stimulant therapy? YES / NO	
Is the patient receiving anti-cataplectic therapy? YES / NO	Name and strength:

I will supply the first 6 months of therapy (in line with good practice recommendations for supply of controlled drugs) for this patient and am writing patient's on-going treatment from ….. /…../…….

All patients receiving stimulant therapy for narcolepsy (+/- cataplexy) and idiopathic hypersomnia should be reviewed at least annually throughout the treatment period by the initiating organisation's specialist sleep physician.

Baseline monitoring undertaken by specialist team:

Test	**Result**	**Date of test**	**GP to repeat test in:**	**Result**	**Date of test**
Blood Pressure			every 12 months		
Heart rate					
Weight			every 12 months		

Reported side effects:

……
……

Other relevant information:

……
……
……

Signed:…… Name of Clinician:…… Date: ……

3 CLINICAL INFORMATION

NOTE: The information here is not exhaustive. Please also consult the current Summary of Product Characteristics (SPC) for stimulant +/- anti-cataplectic agents prior to prescribing for up to date prescribing information, including detailed information on adverse effects, drug interactions, cautions and contraindications (available via www.medicines.org.uk)

Modafinil – refer to pathway for place in therapy (see links on pages 3 and 24)

Modafinil promotes wakefulness by stimulating the brain to increase alertness and reduce excessive sleepiness during the day.
Although there is no cure for narcolepsy, modafinil can help to control symptoms.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: modafinil 50-100mg/day gradually increasing over 4 to 6 weeks to maintenance dose of 400mg/day. **Renal impairment** GFR<10 Start at 50% normal dose and increase according to response. **Hepatic impairment** Reduce dose by half in patients with severe hepatic impairment. **Older people** Limited data available but potential for lower clearance and increased systemic exposure, it is recommended that	**Baseline** Blood pressure, heart rate, pregnancy test if necessary, Epworth Sleep Score. **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, Epworth Sleep Score Ask patient about any rashes or change in mood and behaviour at each visit. Ask patient about side effects such as headache, chest pain.	Blood pressure and heart check annually. Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.	Failure to respond to treatment or adverse effects necessitating withdrawal. Pregnancy Patient request **STOP** modafinil if rash develops, onset of chest pain, palpitations, breathlessness of unknown cause, and changes in mood, behaviour or thinking, suicidal thoughts. Inform named consultant urgently.	GP to monitor blood pressure, heart rate. Inform the named consultant of **any reported** adverse effects i.e rash, headache urgently.	**Specialist:** Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose, most recent blood pressure, Epworth Sleep Score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP** Request patient seen earlier if condition deterioration or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/modafinil.pdf

patients ≥ 65 years of age commence therapy at 100 mg daily. **Duration of Treatment** Indefinitely if patient is responding well to treatment and in absence of significant side effects.					

Modafinil
Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list) **:**

1. **Adverse Effects -** Patients should be advised to stop treatment if any sign of a rash occurs, any changes in mood, behaviour or thinking or you develop a fast heartbeat, chest pain or unexplained breathlessness. The side-effects mentioned above usually occur in the first 8 weeks of treatment and will be discussed by the doctor initiating the medication.
2. **Pregnancy and Breast Feeding –** Modafinil is not recommended for use in pregnancy or breastfeeding. Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.
3. **Effects on ability to drive or use machinery**
   Modafinil can cause blurred vision or dizziness in some people therefore it may affect their ability to drive or use machines. Sleepiness associated with condition may also add to this.
4. **Abuse, misuse and diversion**
   Patients should be carefully monitored for the risk of diversion, misuse and abuse of modafinil.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list) - http://www.medicines.org.uk/emc/medicine/28918

Modafinil is a weak enzyme inducer.
Hormonal contraceptives, including oral contraceptive pills, implants, intrauterine contraceptive devices (IUCDs) and contraceptive patches may be less effective when used with modafinil and therefore are not recommended. Advise to use additional barrier methods.

Methylphenidate - refer to pathway for place in therapy (see links on pages 3 and 24)

Methylphenidate belongs to a group of medicines called stimulants. Methylphenidate works by stimulating the brain to increase alertness and reduce excessive sleepiness during the day. Although there is no cure for narcolepsy, methylphenidate can help to control symptoms.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: Methylphenidate XL 18-72mg every morning Methylphenidate IR 10-60mg/day in divided doses. **Renal or hepatic insufficiency** There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency. **Older people** Methylphenidate should not be used in the elderly. Safety and efficacy has not been established in this age group. **Duration of Treatment** Indefinitely if patient is responding well to treatment and in absence of significant side effects If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.	**Baseline** Blood pressure, heart rate, ECG, Epworth Sleep Score Weight – to allow assessment of weight loss, pregnancy test if necessary **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, pulse, weight, Epworth Sleep Score Ask patient about any changes to mood, behaviour or thinking. Ask patient about any chest pain, fast heartbeat or unexplained breathlessness Ask patient about any suicidal thoughts or thoughts about harming yourself.	Check weight, blood pressure and pulse annually. Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.	Failure to respond to treatment or adverse effects necessitating withdrawal. Pregnancy Patient request **STOP** methylphenidate if changes in mood, behaviour or thinking or onset of suicidal thoughts. Inform named consultant urgently.	GP to monitor blood pressure, heart rate, weight. Inform the named consultant of **any reported** adverse effects such as chest pain, fast heartbeat and mood changes urgently.	**Specialist:** Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP:** Request patient seen earlier if condition deteriorates or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/methylphenidate.pdf

Methylphenidate (contd)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list)**:**

1. Adverse effects

- Changes to mood, behaviour or thinking
- Fast heartbeat, palpitations
- Unexplained breathlessness
- Weight loss

2. Pregnancy and Lactation

• Not recommended during pregnancy.
• Breast-feeding is not recommended when using Methylphenidate
Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

3. Contra-indications:

The list of contraindications is not exhaustive, please refer to the SPC for detail.
http://www.medicines.org.uk/emc/medicine/1316

4. Choice of formulation

The choice of formulation of methylphenidate-containing product will be decided by the treating specialist on an individual basis and depends on the intended duration of effect. Generic prescribing permitted.

5. Abuse, misuse and diversion

- Patients should be carefully monitored for the risk of diversion, misuse and abuse of methylphenidate.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list) - http://www.medicines.org.uk/emc/medicine/1316

- **Coumarins:** Methylphenidate can possibly enhance the effect of coumarins

Dexamfetamine - refer to pathway for place in therapy (see links on pages 3 and 24)

Dexamfetamine belongs to a group of medicines called stimulants. Dexamfetamine works by stimulating the brain to increase alertness and reduce excessive sleepiness during the day. Although there is no cure for narcolepsy, dexamfetamine can help to control symptoms.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: Dexamfetamine 10-60mg daily in divided doses. **Renal or hepatic insufficiency** There is no experience with the use of dexamfetamine in these patients. Peak plasma levels could be higher and elimination could be prolonged. Dexamfetamine should be used with special caution in this patient group by taking care of titration and dosage. **Older people** Dexamfetamine should not be used in the elderly. Safety and efficacy of dexamfetamine has not been established in this age group. **Duration of Treatment** Indefinitely if patient is responding well to treatment and in absence of significant side effects. If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.	**Baseline** Blood pressure, heart rate, ECG, Epworth Sleep Score Weight – to allow assessment of weight loss, pregnancy test if necessary **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, pulse, weight, Epworth Sleep Score Ask patient about any changes to mood, behaviour or thinking. Ask patient about any chest pain, fast heartbeat or unexplained breathlessness Ask patient about any suicidal thoughts or thoughts about harming yourself.	Check weight, blood pressure and heart rate annually. Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.	Failure to respond to treatment or adverse effects necessitating withdrawal. Pregnancy Patient request **STOP** dexamfetamine if changes in mood, behaviour or thinking or onset of suicidal thoughts. Inform named consultant urgently.	GP to monitor blood pressure, heart rate, weight. Inform the named consultant of **any reported** adverse effects such as chest pain, fast heartbeat and mood changes urgently.	**Specialist:** Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP:** Request patient seen earlier if condition deteriorates or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/dexamfetamine.pdf

Dexamfetamine (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list)**:**

1. Adverse effects

- Changes to mood, behaviour or thinking
- Fast heartbeat, palpitations
- Unexplained breathlessness
- Weight loss

2. Pregnancy and Lactation

• Not recommended during pregnancy.
• Breast-feeding is not recommended when using dexamfetamine
Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

3. Contra-indications:

The list of contraindications is not exhaustive, please refer to the SPC for detail.
http://www.medicines.org.uk/emc/medicine/31119

4. Abuse, misuse and diversion

- Patients should be carefully monitored for the risk of diversion, misuse and abuse of dexamfetamine.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list) - http://www.medicines.org.uk/emc/medicine/31119

MAO-A and MAO-B inhibitors: Risk of hypertensive crisis if given with dexamfetamine

Venlafaxine XL - refer to pathway for place in therapy (see links on pages 3 and 24)

Venlafaxine belongs to a group of medicines called anti-depressants. It can be used to treat cataplexy in narcolepsy. Venlafaxine is thought to work by interfering with certain chemicals in the brain which may be involved in causing the symptoms of cataplexy.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: Venlafaxine XL 75-150mg in the morning. **Duration of Treatment** Indefinitely if patient is responding well to treatment and in absence of significant side effects. **Abrupt cessation:** Abrupt cessation of antidepressants can result in status-cataplecticus (particularly cessation of venlafaxine). They should be withdrawn slowly and overlapped with next treatment option. **Hepatic impairment** 50% dose reduction should be considered mild and moderate hepatic impairment. Risk versus benefit in patients with severe hepatic impairment. **Renal impairment** No change in dosage if caution is advised. Dose should be reduced by 50%	**Baseline** Blood pressure, heart rate, cataplexy severity, Epworth Sleep Score. **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, heart rate, cataplectic episodes, Epworth Sleep Score.	Blood pressure and heart rate annually.	Failure to respond to treatment or adverse effects necessitating withdrawal. Patient request Inform named consultant urgently. Sleep centre will advise appropriate weaning regimen.	GP to monitor blood pressure and heart rate. Inform the named consultant of **any reported** adverse effects such as hypertension, anxiety urgently.	**Specialist:** Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP:** Request patient seen earlier if condition deterioration or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/venlafaxine-XL.pdf

in haemodialysis and in severe renal impairment (GFR < 30 ml/min). **Older people:** No dose adjustment required. Caution should be exercised using lowest effective dose. Careful monitoring is required when an increase in the dose is required.					

Venlafaxine (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list)**:**

1. Choice of formulation
Modified release preparation should ONLY be prescribed for the management of cataplexy. Using the immediate release preparation may increase the risk of rebound cataplexy or the onset of status cataplecticus.

2. Adverse effects
- Abnormal dreams, insomnia,
- Anxiety; particularly on withdrawal
- Dizziness, drowsiness, confusion, nervousness
- Sweating, nausea & vomiting
- Hypertension, palpitations

3. Effects on Ability to Drive and use Machines
- Any psychoactive medicinal product may impair judgment, thinking, and motor skills. Therefore, any patient receiving venlafaxine should be cautioned about their ability to drive or operate hazardous machinery.

4. Contraindications
- Conditions associated with high risk of cardiac arrhythmia; uncontrolled hypertension

5. Pregnancy and Lactation
- Avoid unless potential benefit outweighs risk. Risk of withdrawal effects in neonate.
- Present in breast milk- avoid
- Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list)
The list of significant drug interactions is not exhaustive, please refer to the SPC for detail.
https://www.medicines.org.uk/emc/product/2686/smpc

Clomipramine - refer to pathway for place in therapy (see links on pages 3 and 24)

Clomipramine belongs to a group of medicines called anti-depressants. It can be used to treat cataplexy in narcolepsy. Clomipramine works by interfering with certain chemicals in the brain which may be involved in causing the symptoms of cataplexy.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: Clomipramine 10-75mg at night. **Duration of Treatment** Indefinitely if patient is responding well to treatment and in absence of significant side effects. **Treatment cessation** Withdrawal effects such as nausea, vomiting, abdominal pain, diarrhoea, insomnia, headache, nervousness and anxiety may occur within 5 days of stopping treatment. May be mild and self-limiting, can be severe. The risk of withdrawal symptoms is increased if treatment stopped suddenly after regular administration for ≥ 6 weeks .Reduce gradually over 4 weeks, or longer if	**Baseline** Blood pressure, heart rate, cataplexy severity, Epworth Sleep Score. **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, heart rate, cataplectic episodes, Epworth Sleep Score.	Blood pressure and heart rate annually.	Failure to respond to treatment or adverse effects such as hallucinations, disorientation, agitation or anxiety necessitating withdrawal. Patient request Inform named consultant urgently. Sleep centre will advise appropriate weaning regimen.	GP to monitor blood pressure and heart rate. Inform the named consultant of **any reported** adverse effects such as hallucinations, disorientation, agitation or anxiety urgently.	**Specialist:** Subject to response to treatment: 3 monthly, 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP:** Request patient seen earlier if condition deterioration or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/clomipramine.pdf

withdrawal symptoms emerge Tricyclic and related antidepressants should be withdrawn slowly. **Renal impairment** Use with caution **Hepatic impairment** Sedative effects are increased in hepatic impairment. Avoid in severe liver disease. **Older people** May show a stronger response to clomipramine. Use with caution. Doses should be increased cautiously.					

Clomipramine (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list) **:**

1. Adverse effects

- Abdominal pain, constipation (diarrhoea associated with withdrawal)
- Fatigue, impaired memory
- Aggression, restlessness
- Hypertension
- Flushing, muscle weakness/twitching

2. Effects on Ability to Drive and use Machines

• Drowsiness may affect the performance of skilled tasks (e.g. driving).

3. Contraindications

- Arrhythmias
- Acute porphyrias
- during the manic phase of bipolar disorder
- major depression
- heart block
- immediate recovery period after myocardial infarction

4. Pregnancy and Lactation

- Clomipramine is not recommended for use in women not using contraception
- Neonatal withdrawal symptoms reported if used during third trimester
- The quantity of clomipramine secreted into breast milk is small. Nursing mothers should be advised to withdraw from the medication or cease breast-feeding.
- Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

5. Anticholinergic burden

Elderly patients are particularly sensitive to anticholinergic, neurological, psychiatric, or cardiovascular effects. Their ability to metabolise and eliminate drugs may be reduced, leading to a risk of elevated plasma concentrations at therapeutic doses. Dose range in pathway is appropriate for older people (10-75mg daily)

Clinically Significant Drug Interactions (refer to BNF/SPC for full list)

The list of significant drug interactions is not exhaustive, please refer to the SPC for detail.
https://www.medicines.org.uk/emc/product/2550

Fluoxetine - refer to pathway for place in therapy (see links on pages 3 and 24)

Fluoxetine belongs to a group of medicines called anti-depressants. It can be used to treat cataplexy in narcolepsy. Fluoxetine works by interfering with certain chemicals in the brain which may be involved in causing the symptoms of cataplexy.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: Fluoxetine 20-60mg daily in the morning. **Hepatic impairment** Reduce dose or increase dosing interval. **Older people** Caution is recommended when increasing the dose. Daily dose should generally not exceed 40 mg. Maximum recommended dose is 60 mg/day. **Duration of Treatment** Indefinitely if patient is responding well to treatment and in absence of significant side effects. If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.	**Baseline** Blood pressure, heart rate, cataplexy severity, Epworth Sleep Score. Weight – to allow assessment of weight loss **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, heart rate, cataplectic episodes, Epworth Sleep Score.	Blood pressure and heart rate annually.	Failure to respond to treatment or adverse effects necessitating withdrawal. Patient request Inform named consultant urgently. Sleep centre will advise appropriate weaning regimen.	GP to monitor blood pressure and heart rate. Inform the named consultant of **any reported** adverse effects such as palpitations, anxiety, urinary frequency/retention, weight loss urgently.	**Specialist:** Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP:** Request patient seen earlier if condition deterioration or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/fluoxetine.pdf

Fluoxetine (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list)**:**

1. Adverse effects

- Abdominal pain, diarrhoea, constipation
- Nausea & vomiting, GI effects, dyspepsia
- Dizziness, drowsiness, visual disturbances, hallucinations
- Urinary retention, sexual dysfunction
- Bleeding disorders
- Anxiety, nervousness

2. Effects on Ability to Drive and use Machines

• May also impair performance of skilled tasks (e.g. driving, operating machinery)

3. Contraindications

The list of contraindications is not exhaustive, please refer to the SPC for detail.
https://www.medicines.org.uk/emc/product/6013

4. Pregnancy and Lactation

Manufacturers advise to avoid during pregnancy unless the potential benefit outweighs the risk. There is a small increased risk of congenital heart defects when taken during early pregnancy. If used during the third trimester there is a risk of neonatal withdrawal symptoms, and persistent pulmonary hypertension in the newborn has been reported.
Present in breast milk- avoid

Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list)

The list of significant drug interactions is not exhaustive, please refer to the SPC for detail.
https://www.medicines.org.uk/emc/product/6013

Sodium Oxybate - refer to pathway for place in therapy (see links on pages 3 and 24)

Sodium Oxybate is used to treat narcolepsy when cataplexy is also a problem. Sodium Oxybate promotes deep sleep and improves night-time sleep. It helps with excessive daytime sleepiness as well as helping the symptoms of cataplexy. It is sometimes used in combination with other medicines for narcolepsy. Although there is no cure for narcolepsy, sodium oxybate can help to control symptoms.

Route, Dose, Duration	Monitoring Undertaken by Specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Stopping Criteria	Monitoring following dose changes	Follow Up
Oral: The recommended starting dose is 4.5 g/day sodium oxybate (9 ml Xyrem®) divided into two equal doses of 2.25 g/dose (4.5 ml/dose). The dose should be titrated to effect based on efficacy and tolerability up to a maximum of 9 g/day divided into two equal doses of 4.5g/dose (9ml/dose) by adjusting up or down in dose increments of 1.5 g/day (i.e. 0.75 g/dose or 1.5 ml/dose). A minimum of two weeks is recommended between dosage increments. • Each dose of Xyrem® must be diluted with 60 ml of water in the dosing cup prior to ingestion. Single doses of 4.5g should not be given unless the patient has been titrated previously to that dose level. • Because food significantly reduces the bioavailability of sodium oxybate, patients should eat at least several (2-3) hours before taking the first dose of Xyrem® at bedtime. Patients should always observe the same timing of dosing in relation to meals. Xyrem® should be taken orally upon getting into bed and again between 2.5 to 4 hours later. Patients advised to set an alarm and to remain in bed while they take their second dose.	**Baseline** Blood pressure, heart rate, Epworth Sleep Score, pregnancy test if necessary, weight – to allow assessment of weight loss, severity of cataplectic episodes. ?oximetry (?only avoid in severe OSA) ?mood **Ongoing at 6 and 12 monthly clinic appointments** Blood pressure, heart rate, Epworth Sleep Score, pregnancy test if necessary, weight – to allow assessment of weight loss. Cataplexy epsiodes. Ask the patient about any changes in mood, behaviour or side effects such as nocturnal enuresis, sleep walking. Any change in breathing i.e increased snoring, reports of apnoea.	Check weight, blood pressure and pulse annually. Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.	Failure to respond to treatment or adverse effects necessitating withdrawal. Pregnancy Patient request **STOP** sodium oxybate if changes in mood, behaviour or thinking or onset of suicidal thoughts. Inform named consultant urgently. Sleep centre will advise an appropriate weaning regimen.	Check weight, blood pressure and pulse annually. Inform the named consultant **of any reported** adverse effects such as sleep walking, nocturnal enuresis urgently.	**Specialist:** Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable. Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic. **GP:** Request patient seen earlier if condition deterioration or adverse effects experienced between appointments. https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/sodium-oxybate.pdf

Discontinuation of Xyrem®: The discontinuation effects of sodium oxybate have not been systematically evaluated in controlled clinical trials. If the patient stops medication for more than 14 consecutive days, titration should be restarted as per initiation regimen. **Patients with hepatic impairment:** The starting dose should be halved in patients with hepatic impairment, and response to dose increments monitored closely. **Patients with renal impairment:** Patients with impaired renal function should consider a dietary recommendation to reduce sodium intake. **Elderly patients:** Elderly patients should be monitored closely for impaired motor and/or cognitive function when taking sodium oxybate. **Duration of Treatment:** Indefinitely if patient is responding well to treatment and in absence of significant side effects.					

Sodium Oxybate (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list)**:**

1. Storage

Sodium oxybate comes in a bottle with two containers for mixing the medication. Both the bottle and storage containers have child proofed caps. The mixed solution should be kept in a bed side drawer just before going to sleep. If there are children in the house, this draw should be locked or be out of the reach of children. Discard diluted solution after 24 hours.

2. Adverse effects

- Sleep walking
- Urinary incontinence
- Drowsiness, dizziness, blurred vision
- Nausea, vomiting, weight loss, abdominal pain
- Hypertension, palpitations

3. Effects on Ability to Drive and use Machines

• Sodium oxybate has a major effect on the ability to drive and use machines. These patients should already be known to the DVLA
• For at least 6 hours after taking sodium oxybate, patients must not undertake activities requiring complete mental alertness or motor coordination, such as operating machinery or driving.
• When patients first start taking sodium oxybate, they should take extreme care when driving, operating heavy machines or performing any other task which is dangerous or requires full mental alertness.

4. Contraindications

The list of contraindications is not exhaustive, please refer to the SPC for detail.
https://www.medicines.org.uk/emc/product/178

5. Pregnancy and Lactation

• Not recommended during pregnancy.
• Breast-feeding is not recommended when using Sodium oxybate.
Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list) - https://www.medicines.org.uk/emc/product/178

- **Alcohol:** The combined use of alcohol with sodium oxybate may result in potentiation of the central nervous system-depressant effects of sodium oxybate.
- **Sedative hypnotics or other CNS depressants:** Sodium oxybate should not be used in combination
- Since sodium oxybate is metabolised by GHB dehydrogenase there is a potential risk of an interaction with drugs that stimulate or inhibit this enzyme (e.g. valproate, phenytoin or ethosuximide). No interaction studies have been conducted in human subjects, although if sodium oxybate and valproate are used concomitantly, a decrease in sodium oxybate dose by 20% is recommended.
- Possible additive effect of antidepressants and sodium oxybate cannot be excluded. The rates of adverse events are increased when sodium oxybate is co-administered with tricyclic antidepressants.
- There is a higher risk of sleep apnoea in patients with BMI ≥ 40kg/m2.

TREATMENT PATHWAYS

Pathway for the Pharmacological Management of Excessive Daytime Sleepiness due to Narcolepsy

Pathway for the Pharmacological Management of Cataplexy associated with Narcolepsy

Pathways include important information on the administration of sodium oxybate.

Information provided to the patient

1) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/modafinil.pdf
2) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/methylphenidate.pdf
3) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/dexamfetamine.pdf
4) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/venlafaxine-XL.pdf
5) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/clomipramine.pdf
6) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/fluoxetine.pdf
7) https://www.guysandstthomas.nhs.uk/resources/patient-information/pharmacy/sodium-oxybate.pdf

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4. COMMUNICATION AND SUPPORT

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Consultant/specialist team **Guy Leschziner** **Brian Kent**	**Tel:** 0207 188 3430 **Email:** gst-tr.gsttsleepreferrals@nhs.net
Medication – Prescribing advice, interactions, availability of medicines **Elaine Lyons** **Grainne d'Ancona** **Medicines Information** Guy's Hospital Medicines Information Department If you have any questions or concerns about these medicines, please call our helpline. **Guy's Hospital Sleep Disorder Centre** Open Mon-Fri 9am-5pm	 **Tel:** 0207 188 3430 **Email:** gst-tr.gsttsleepreferrals@nhs.net **Tel:** 0207 188 3855/3853 **Email:** medicinesinformation@gstt.nhs.uk **Tel:** 0207188 3430 **Email:** gst-tr.gsttsleepreferrals@nhs.net
Language and accessible support services If you need an interpreter or information about the pharmacological management of these conditions in a different language or format, please get in touch. **NHS 111** Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day. **NHS Choices** Provides online information and guidance on all aspects of health and healthcare.	**Tel:** 020 7188 8815 **Email:** languagesupport@gstt.nhs.uk **Tel:** 111 **Website:** www.nhs.uk