Shared Care Prescribing Guideline

Sativex (delta-9-tetrahydrocannabinol/cannabidiol) oromucosal spray for treatment of spasticity in patients with multiple sclerosis

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of **Sativex** 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 *(please refer to Principles of Shared Care Agreements in point 2h)*. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. Refer to Principles of Shared Care document for full details, in summary:

- Transfer of monitoring and prescribing to Primary care is normally after the patient is on regular dose and with satisfactory investigation results for at least 4 weeks
- The duration of treatment will be determined by the specialist based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the GP/primary care clinician
- Termination of treatment will be the responsibility of the specialist.

PRESCRIBING INFORMATION

1. Background

Multiple Sclerosis (MS) is an acquired chronic immune-mediated inflammatory condition of the central nervous system, affecting both the brain and spinal cord. Spasticity is a common symptom of MS. Spasticity is usually associated with muscle spasms, reduced mobility, disturbed sleep and pain.

According to NICE clinical guideline (CG) 186 on the management of MS in adults (2014), baclofen or gabapentin should be considered as first-line drugs to treat spasticity in MS. A combination of baclofen and gabapentin should be considered if individual drugs do not provide adequate relief, or if side effects from individual drugs prevent the dose being increased. Tizanidine or dantrolene should be considered as second-line options and benzodiazepines as a third-line option.

Sativex is a cannabinoid based medicine that contains delta-tetrahydrocannabinol and cannabidiol. It is classified as a Schedule 4 (part 1) controlled drug. It is used to treat moderate to severe spasticity in people with MS who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Sativex is intended to be used in addition to the patient's current anti-spasticity medication.

According to NICE guideline (NG) 144: Cannabis-based medicinal products (November 2019), a 4-week trial of Sativex should be offered to treat moderate to severe spasticity in adults with MS, if other pharmacological treatments for spasticity are not effective (as set out in CG186) and the company provides Sativex according to its pay-for-responders scheme. After the 4-week trial, Sativex should be continued if the person has had a ≥20% reduction in

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spasticity-related symptoms on a 0 to 10 patient-reported NRS. Treatment with Sativex should be initiated and supervised by a physician with specialist expertise in treating spasticity due to MS, in line with its marketing authorisation

Sativex is only effective in approximately 50% of patients. The dose is gradually titrated up from one spray/day (to minimise side effects, typically dizziness and fatigue) to the optimum dose (typically 4-8 sprays/day; max 12) over 2 weeks and then the response assessed after 1 month. The optimal dose is the dose from which the best balance of effect and side-effect occurs; it is typically 4 – 6 sprays / day but can be as high as 12 and as low as 1.

2. Indications (*Please state whether licensed or unlicensed)*

Sativex is licensed as a treatment for symptom improvement in adults with moderate to severe spasticity due to MS who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

The PRGC recommendation approved within Kent and Medway states that a 4-week trial of Sativex to treat moderate to severe spasticity in adults with multiple sclerosis (MS) may be considered, if:

- Other pharmacological treatments (as set out in NICE CG186) for spasticity are not effective*. These treatments should have been tried at maximum tolerated doses prior to consideration of Sativex and must have been ineffective, as defined by a score of ≥4 on a 0 to 10 patient-reported numeric rating scale (NRS) of spasticity-related symptoms, **AND**
- Invasive interventions are being considered (i.e. where a successful trial of Sativex may avoid/ delay the need for invasive therapies), **AND**
- The company provides Sativex according to its pay-for-responders scheme.

After the 4-week trial, Sativex may be continued if the person has had ≥20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported NRS.

Sativex should be provided as part of a multi-disciplinary approach alongside neuro-physiotherapy and NOT as an isolated treatment

Treatment with Sativex should be initiated and supervised by a physician with specialist expertise in treating spasticity due to MS, in line with its marketing authorisation.

*Prior to consideration of Sativex, patients must have been treated in line with recommendations for the management of spasticity in NICE CG186 section 1.5.19 to 1.5.22 i.e.:

1.5.19 Consider baclofen or gabapentin as a first-line drug to treat spasticity in MS depending on contraindications and the person's comorbidities and preferences. If the person with MS cannot tolerate one of these drugs consider switching to the other.

1.5.20 Consider a combination of baclofen and gabapentin for people with MS if:

- individual drugs do not provide adequate relief or
- side effects from individual drugs prevent the dose being increased.

1.5.21 Consider tizanidine or dantrolene as a second-line option to treat spasticity in people with MS.

1.5.22 Consider benzodiazepines as a third-line option to treat spasticity in MS and be aware of their potential benefit in treating nocturnal spasms.

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3. Pharmaceutical aspects

Route of administration: Oromucosal

Formulation:
Oromucosal spray with each 100 microlitre spray containing 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD). Each spray vial of Sativex contains 90 actuations

Administration details:
The patient self-administers Sativex by spraying it into their mouth - cheek or under the tongue. Dosage is between 1-12 sprays per day spread out according to the patient's needs with a minimum of 15 minutes between sprays. Many patients take more in the evening to help with sleep.

Other important information:

- Sativex is intended to be used in addition to the patient's current anti-spasticity medication.
- Prescribers should note that Sativex is a classified as Schedule 4 Part 1 Controlled Drug. Prescriptions must comply with the regulations for Schedule 4 part 1 controlled drugs – refer to the "CD and drug dependence" section of the most current edition of the BNF.

4. Exclusions or contraindications

Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.

Sativex may only be initiated in patients meeting the criteria as outlined in the PRGC recommendation (listed in section 2) and continued following a successful 4-week trial.

Sativex is contraindicated in patients:

- With hypersensitivity to cannabinoids or to any of the excipients
- With any known or suspected history or family history of schizophrenia, or other psychotic illness; history of severe personality disorder or other significant psychiatric disorder other than depression associated with their underlying condition.
- Who are breast feeding (in view of the considerable levels of cannabinoids likely in maternal breast milk and the potential adverse developmental effects in infants).

Use of Sativex is not recommended in patients with serious cardiovascular disease.

5. Initiation and ongoing dose regime (by specialist)

Note -

- *Transfer of monitoring and prescribing to Primary care is normally **after the patient is stable on a regular dose** and with satisfactory investigation results for period of time as agreed by the specialist.*
- *The duration of treatment will be determined by the specialist based on clinical response and tolerability.*
- *Specialist to specify the length of treatment supplied to the patient in order to indicate to primary care when new supply will be required for forward planning.*
- *All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician*
- *Termination of treatment will be the responsibility of the specialist.*

Consultant responsibilities

- To confirm that the patient is suitable for treatment with Sativex in line with both the

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PRGC recommendation and the Summary of Product Characteristics (SPC) for the drug.

- To confirm that the patient:
  - Does not have hypersensitivity to cannabinoids or any of the excipients contained in Sativex
  - Does not have a history of severe mental disorder, including psychotic illness
  - Is not breastfeeding
  - Does not have serious cardiovascular disease
- To carry out any necessary baseline monitoring prior to initiation of Sativex, including baseline record of the NRS and blood pressure.
- To inform patients of practical issues related to the use of Sativex, such as storage, maximum dose and contraception – see Section 11 “Advice to patients and carers” section on page 7
- To liaise with the GP as necessary to ensure that the patient is on a suitable form of contraception during their treatment with Sativex and for three months after discontinuation.
- To initiate, stabilise and prescribe Sativex until the patient has completed dose titration and is on a stable dose.
- Provide the patient with instructions on how to prime the vial, administer spray and titrate the dose to the optimum amount (typically 4-8 sprays/day; max 12) over 2 weeks (see Appendix 2). During this first 2 week titration period the patient will be advised not to drive. Once the optimum dose has been determined, treatment can be used at any time of the day or night depending on symptoms, but leaving at least a 15-minute gap between sprays.
- To provide patients with written instructions / diary and advice on how the diary should be completed.
- At the time of initiating Sativex, notify GP & MS nurse/physiotherapist in writing that Sativex has been prescribed as a trial.
- The GP should be invited to share care if the trial is successful. Information provided to the GP should include*:*
  - A copy of the shared care guidelines with appendix 1 fully completed with the details of the individual patient
  - Confirmation that a prescription for the first month’s supply has been given
  - Information on when the patient will next be reviewed and by whom.
  - A request that the GP continue prescribing once it has been confirmed that benefit has been obtained from Sativex following the trial and that the patient is on a stable dose.
  - Confirmation of the dose the patient has been stabilised on and the number of vials that should be prescribed by the GP each month.
- If the GP is willing to participate in shared care, to discuss the shared care arrangements with the patient.
- To review patient at the request of GP / MS nurse/physiotherapist should any problems arise (side-effects / lack of efficacy) – routine hospital out-patient follow-up by the consultant is not essential if this will prove difficult for the patient as long as an MS nurse/physiotherapist is able to review the patient in the community
- To communicate promptly with the GP/MS Nurse/physiotherapist if treatment is changed.
- If specialist review results in a dose change a prescription should be issued to reflect the change and communicated promptly to the GP.
- To inform the GP if the patient does not attend a review appointment and provide a plan for how the patient should be managed in light of this.
- To report any suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk

MS Nurse/MS Physiotherapist/AHP responsibilities

- To provide patients with written instructions / diary and advice on how the diary should be completed.
- To inform patients of practical issues related to the use of Sativex, such as storage and maximum dose – see Section 11 “Advice to patients and carers” section on page 7
- To contact the patient during the initial 4 week titration period to ensure they have received their prescription and are clear how to administer Sativex (ensure they have received a diary from MS clinic and are completing it and if not provide this and if necessary advise on how to complete).
- To contact patient after 4 weeks to determine if Sativex has been beneficial (20% or greater improvement in NRS)
- To inform the GP (by fax or email) and consultant of outcome of evaluation and whether or not Sativex treatment is being continued long-term or withdrawn following the 4 week trial.
- To arrange a second prescription of 3 x 10ml of Sativex® following the four week assessment if at this point the patient has less than 28 days’ supply remaining to cover the transition period.
- To contact patient again at month 3 by telephone to review response to treatment and side effects, and write to GP and consultant to inform them of outcome of evaluation.
- To promptly communicate information on the patient’s progress with treatment or any changes in treatment, including current dose, to the GP.
- To monitor for efficacy and significant side-effects at least every 3- 6 months whilst the patient remains on Sativex and inform the consultant if concerns arise.
- To inform the GP if the patient does not attend a review appointment and provide a plan for how the patient should be managed in light of this.
- Report any suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk

6. Specialist responsibilities for monitoring (including frequency)

The specialist team will review and monitor for efficacy, significant side-effects and overuse at 1 month, 3 months (telephone consultation) and then at least every 6 months whilst the patient remains on Sativex. The patient will have an annual review with the consultant to ensure ongoing efficacy and appropriateness of treatment. The specialist team will communicate the outcome of patient reviews and any resulting changes to the patient’s treatment plan to the GP in a timely manner.

The consultant will review the patient at the request of GP or MS nurse/physiotherapist should any problems arise (side-effects / lack of efficacy).

7. GP responsibility

- To consider shared care proposal within 2 weeks of receipt. If in agreement to continue prescribing as detailed in the shared care guideline to confirm this to the requesting consultant within 2 weeks of receipt of this guideline by completing and returning the agreement on page 13
- If do not agree to shared care discuss with requesting consultant or CCG medicines optimisation team within 2 weeks of receipt of shared care request
- To provide ongoing prescriptions for Sativex for patients who have been found to benefit following the initial 4-week treatment period.
- To adjust the dose as advised by the specialist.
- To agree monitoring requirements with specialist – see below for GP monitoring requirements.
- To report and seek advice regarding any concerns, for example: side-effects

(possible allergic reactions, excessive somnolence, dizziness), co-morbidities (seizures, severe cardiovascular disease, mental illness), pregnancy, or lack of efficacy to the MS specialist team (MS nurse/physiotherapist or consultant).

- To monitor ongoing use of Sativex to ensure appropriate quantities are ordered and to contact the MS nurse/physiotherapist or consultant if there are any issues of concern. This includes if the patient requests excessive repeat prescriptions (i.e. using more than one 10ml vial every 10 days or more than 3 vials a month).
- To refer back to specialist if non-compliance or over-use is suspected
- To refer back to specialist if the patient's condition deteriorates.
- To refer back to specialist if there is any change in the patient's cardiovascular status.
- 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

Monitoring (including frequency):

- To report any concerns about side-effects (possible allergic reactions, excessive somnolence, dizziness), co-morbidities (seizures, severe cardiovascular disease, mental illness), pregnancy, overuse or lack of efficacy to the MS specialist team (MS nurse/physiotherapist or consultant)
- There is no need to routinely monitor any blood parameters.
- No routine reviews of the patient are required in between the 6 monthly specialist reviews.

8. Dose Management (by primary care)

See section 10.

9. Significant medicine interactions – *prescriber must consider interactions with any and all repeat medication the patient is taking at the time of initiation*

There is a theoretical risk that there may be an additive effect with other muscle-relaxing agents such as baclofen and benzodiazepines, thereby increasing the risk of somnolence, weakness and falls.

Sativex is metabolised by the Cytochrome P-450 enzyme system, therefore enzyme inducers or inhibitors may decrease or increase the concentration of Sativex in the circulation. Seek specialist advice if necessary.

Sativex may reduce effectiveness of systemically acting hormonal contraceptives, therefore women using systemically acting hormonal contraception for example the oral contraceptive pill or contraceptive implant should use an additional method of contraception for the duration of therapy and for three months after discontinuation.

Care should be taken with hypnotics, sedatives alcohol due to the additive side effects.

For a full list of drug interactions, refer to the Summary of Product Characteristics.

10. Adverse effect management

Specialist to detail action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first

to GPs.

The commonest side-effects are dizziness and somnolence. These are most common on starting treatment. Patients should not drive, operate machinery or engage in any hazardous activity if they are experiencing any significant CNS effects such as dizziness or somnolence.

Possible adverse effects and what to do if they occur:
• Dizziness
• Psychiatric disorders
• Somnolence
• Light headedness
• Oral irritation
• Weakness or falls
• Rarely low mood can be reported
See Summary of Product Characteristics for a full list of adverse effects.

If side effects occur the dose should be lowered by 1-2 sprays/day, in the case of oral irritation the patient should be advised to vary the site of the spray around the mouth and avoid any ulcers or irritated areas. If the GP has any concern regarding dose changes, they may wish to contact the specialist team for advice (See Section 13)

Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the CHM.

Criteria for stopping treatment
- Hypersensitivity to active ingredients or excipients
- Side effects are intolerable
- If as part of ongoing review it is recognised that response has deteriorated and dose titration does not improve symptom management

11. Advice to patients and carers

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice

The specialist team will advise/make the patient aware of:
- The potential CNS effects such as dizziness or somnolence and the need to avoid driving/using machinery if affected by these.
- Provide advice to patients on driving and the law eg the leaflet Driving Advice for Sativex Users - https://www.mstrust.org.uk/sites/default/files/DfT-New%20Drug%20Driving%20Rules-Sativex-A5.pdf
- That there have been a few cases of loss of consciousness with Sativex use
- Contraception should be advised for men and women of child bearing potential whilst taking Sativex and for three months after discontinuation. Sativex may reduce the effectiveness of systemically acting hormonal contraceptives, therefore women using systemically acting hormonal contraception for example the oral contraceptive pill or contraceptive implant should use an additional alternative non-hormonal/reliable barrier method of contraception for the duration of therapy and for three months after discontinuation.
- When travelling abroad patient will need to check with the Home Office (see reference) if Sativex is legal in the country they are due to visit and they should request a letter from their MS specialist
- Sativex should be stored in the fridge but once opened it can be kept out of the fridge for up to 42 days (10ml vial only), but should not be stored above 25 degrees C. It

should be kept upright.
- The afternoon/evening dose should be taken at any time between 4 pm and bedtime. When the morning dose is introduced, it should be taken at any time between waking and midday.
- The maximum number of sprays per day is 12. A minimum of 15 minutes between sprays
- In general, alcoholic beverages should be avoided whilst using Sativex especially at the beginning of treatment or when changing dose. If patients do drink alcohol while using Sativex, they should be aware that using Sativex and alcohol together may increase their effects (such as loss of balance or ability to respond quickly) which could increase the risk of falls and other accidents.
- As there may be a potential for oral discomfort with the use of Sativex, the patient should be advised to change the area in their mouth where they spray each time. This helps to stop any discomfort in one place.

Further information for the patient can be found in the patient information leaflet for Sativex, which can be downloaded from:
http://www.medicines.org.uk/EMC/medicine/23228/PIL/Sativex+Oromucosal+Spray/

Patients should also be advised of their responsibilities under shared care by the specialist team:
- To contact the specialist team if he or she does not have a clear understanding of any aspect of the treatment.
- 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 inform community pharmacists that they are using Sativex 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.
- Avoid driving/using machinery if affected by dizziness or somnolence.
- To monitor dosing requirements of Sativex using a patient diary
- To report any adverse effects or warning symptoms to GP or hospital specialist
- To report to GP and MS team if pregnant or breastfeeding.
- To inform GP and hospital of any changes in addresses or telephone contact numbers.
- When travelling abroad, to check with the Home Office if Sativex is legal in the country they are due to visit and to request a letter from the MS specialist

12. Pregnancy and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.

Sativex is contraindicated in patients who are breast feeding (in view of the considerable levels of cannabinoids likely in maternal breast milk and the potential adverse developmental effects in infants).

Sativex should not be used in pregnancy unless benefit of treatment outweighs risk to the foetus.

Sativex may reduce effectiveness of systemically acting hormonal contraceptives, therefore women using systemically acting hormonal contraception for example the oral contraceptive pill or contraceptive implant should use an additional alternative non-hormonal/reliable barrier method of contraception for the duration of therapy and for three months after discontinuation.

13. Specialist contact information

Medway Maritime Hospital (MFT)

Specialist name	Contact details
MS Specialist Nurses: Dorcas Gweshe Sylvie Hurst	
Consultant Dr Dana Chirosca-Vasileiou	

Maidstone and Tunbridge Wells (MTW)

Specialist name	Contact details
Maidstone area: MS nurse Tina Hill Neurology secretaries	
TW & Sevenoaks area: MS nurse Geraldine Brand Neurology secretaries	

Darent Valley Hospital (DVH)

Specialist name	Contact details
Specialist Nurses : Debbie McMillan (Tues-Thurs) Ola Okunowo (Mon-Fri)	
Consultants : Dr Kirstin Weyrich (maternity leave till Sept 2021) Dr Guru Kumar	

East Kent Hospitals University NHS Foundation Trust (EKHUFT)
EKHUFT aim to respond to routine email requests within 5-7 working days. For urgent queries please contact the MS secretaries directly or the on call neurology service.

Specialist name	Contact details
Nikki Guck ESP Physio in MS Clare Langham MS nurse specialist (Ashford and SKC) Bethan Tredwell MS nurse specialist (Canterbury and Coastal, Faversham and out of area) Carole Day MS nurse specialist (Thanet)	

Dr Harikrishan Consultant Neurologist Dr Redmond Consultant Neurologist	
Neurology registrar on call (for weekends or evenings)	

14. Additional information

Sativex is a Schedule 4 Part 1 controlled drug. Please refer to the "CD and Drug Dependence" section of the current BNF for further information.

Sativex does not typically cause a 'high' comparable with recreational cannabis use.

Each 10ml vial contains approximately 90 sprays and will last around 10-15 days on average. It should be stored in the fridge but once opened it can be kept out of the fridge for up to 42 days (Only 10ml vials will be used), but should not be stored above 25 degrees C. It should be kept upright.

There is a risk of an increase in incidence of falls in patients whose spasticity has been reduced and whose muscle strength is insufficient to maintain posture or gait. In addition to an increased risk of falls, the CNS adverse reactions of Sativex could potentially have an impact on various aspects of personal safety, such as with food and hot drink preparation.

15. References

NICE guidance: Cannabis-based medicinal products.
https://www.nice.org.uk/guidance/NG144 Accessed 17/03/21

NICE guidance: Multiple sclerosis in adults: Management.
https://www.nice.org.uk/guidance/cg186/ Accessed 17/03/21

Sativex Oromucosal Spray, GW Pharma Ltd.. Last updated 25/08/2020, hyperlink
https://www.medicines.org.uk/emc/product/602/smpc Accessed 17/3/21

Drugs and Driving: The Law. https://www.gov.uk/drug-driving-law Accessed 17/3/21

Appendix 1
REQUEST TO SHARE CARE AND AGREEMENT FORM

Sativex (delta-9-tetrahydrocannabinol/cannabidiol) oromucosal spray for treatment of spasticity in patients with multiple sclerosis

The expectation is that this information, along with the full shared care protocol, provides sufficient information to enable GP* to be confident to take on clinical and legal responsibility for prescribing and monitoring. GP* to review and must respond to provider trust request to share care within two weeks, using form provided.
**This may be any primary care prescribing clinician.*

For completion by specialist (with shared care agreement form)	
Patient name	
DOB	
NHS Number	
Patient weight (kg)	
Diagnosis (please indicate if unlicensed or "off-label")	
Confirmation from specialist that patient meets the criteria for initiation and continuation of Sativex i.e.: ○ Other pharmacological treatments (as set out in NICE CG186) for spasticity are not effective. These treatments should have been tried at maximum tolerated doses prior to consideration of Sativex and must have been ineffective, as defined by a score of ≥4 on a 0 to 10 patient-reported numeric rating scale (NRS) of spasticity-related symptoms, **AND** ○ Invasive interventions are being considered (i.e. where a successful trial of Sativex may avoid/ delay the need for invasive therapies). ○ Sativex is being provided as part of a multi-disciplinary approach alongside neuro-physiotherapy and NOT as an isolated treatment ○ Treatment with Sativex has been initiated and will be supervised by a physician with specialist expertise in treating spasticity due to MS, in line with its marketing authorisation. ○ The patient has had ≥20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported NRS following the initial 4 week trial.	
Specialist signature to confirm the above criteria	
Specialist to tick box to confirm that the patient shows no evidence of serious cardiovascular disease	☐
Date of first prescription by specialist	
Drug, dose, frequency, and route at handover and date of most recent prescription if different to above	
Number of Sativex vials required on prescription (every 28 days)	

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Date of the next review appointment with the specialist team			
Estimated date for prescribing responsibility to be with GP* (at least 28 days after first prescribing)			
Special prescribing advice for this patient, to include any other medication patient is taking for same condition			
KEY PRIMARY CARE INFORMATION (refer to full shared care guideline for full details)			
GP* Responsibilities	As per section 7 in full guidance: Ongoing prescribing, dose adjustment following specialist advice, report concerns to specialist e.g. side effects, compliance, pregnancy, lack of efficacy or patient deterioration		
MONITORING (as per Shared Care document unless stated below)			
Frequency of GP* monitoring			
Frequency of specialist review			
TEST	NORMAL RANGE	Pre-Treatment Baseline Result (specialist responsibility)	Initiation of treatment Result (specialist responsibility)
ACTION TO BE TAKEN IF ABNORMAL RESULT			
TEST	RESULT	ACTION	

SHARED CARE AGREEMENT FORM

This form is used to agree shared care between specialist, patient and GP*.

Specialist and patient agreement

By signing below we accept:

- The Kent and Medway CCG shared care principles
- The requirements and responsibility defined in this drug specific shared care protocol
- To provide medication for the transition period (at least 28 days)

Specialist name:	Patient name:
Designation:	DOB:
Provider Trust:	NHS number:
Direct telephone number:	
Email:	
Specialist signature:	Patient signature:
Date:	Date:

GP* response to shared care request

Please return to specialist within **2 weeks** of receipt of request to share.
This form is to be completed by the GP* who is requested to share care.

I agree to accept shared care as set out in this shared care protocol and KMCCG shared care principles. ☐

I have not received adequate support to take over prescribing therefore I do not accept shared care for this patient. ☐

My reasons for not accepting are:

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility.

GP* name	
Designation	
Direct telephone number	
Email	
Practice address	
GP* signature	
Date	

Specialist to retain a copy in the patients' hospital notes
Copy to be given to patient
GP* to retain a copy in primary care notes

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Appendix 2 Sativex Titration Schedule over first 2 weeks of treatment:

Day	**Number of sprays in the morning**	**Number of sprays in the evening**	(Total number of sprays per day)
1	**0**	**1**	1
2	**0**	**1**	1
3	**0**	**2**	2
4	**0**	**2**	2
5	**1**	**2**	3
6	**1**	**3**	4
7	**1**	**4**	5
8	**2**	**4**	6
9	**2**	**5**	7
10	**3**	**5**	8
11	**3**	**6**	9
12	**4**	**6**	10
13	**4**	**7**	11
14	**5**	**7**	12

(Source Sativex SPC https://www.medicines.org.uk/emc/product/602/smpc)