Pending CCG approval

NHS
Pan Mersey
Area Prescribing Committee

Prescribing Support Information

Cannabis Extract oromucosal spray (Sativex®)

For the symptomatic treatment of moderate to severe spasticity in adult patients with multiple sclerosis when other pharmacological treatments for spasticity are ineffective.

AMBER patient retained by specialist

Your patient has been identified as being suitable to receive Sativex® in accordance with the indication detailed below, and has been started on treatment and has been reviewed to assess the efficacy and adverse effects of the treatment by the specialist team.

Sativex® has been considered as appropriate for prescribing in primary care and the information contained in this document has been provided to support you to prescribe the medicine for your patient in the community. Your patient's dose is now stable and is detailed in the attached clinic letter.

Your patient will remain under the care of the specialist team whilst receiving this medicine.

Diagnosis and Initiation
Neurology specialists with a special interest in multiple sclerosis will assess and select patients with multiple sclerosis who are suitable for Sativex® therapy in accordance with NICE NG144[1].

Indication and mode of action
Sativex® is licensed for symptomatic treatment of moderate to severe spasticity in adult patients with multiple sclerosis when other pharmacological treatments for spasticity are not effective[2].

Delta-9-tetrahydrocannabinol (THC) is a partial agonist at CB1 and CB2 receptors, mimicking the effect of endocannabinoid, thereby reducing the effect of excitatory neurotransmitters. In animal models CB receptor agonists have been shown to reduce limb stiffness and improve motor function[2].

Dosage and administration
Sativex® is only available as an oromucosal spray and contains a combination of delta-9-tetrahydrocannabinol (THC) 2.7mg and cannabidiol 2.5mg per dose.

The dose requires titration until optimum symptom relief is achieved. This may take up to two weeks. The maximum licensed dose is 12 sprays per day.

The following table gives the manufacturers dosing advice[2]:

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

The specialist will communicate the patient's dose to the GP once stabilised.

Evening doses should be taken at any time between 4 pm and bedtime and morning doses at any time between waking and midday. There should be at least a 15-minute gap between sprays[2].

Once the optimum dose has been achieved, patients may spread the doses throughout the day according to individual response and tolerability[2].

Contra-indications

- Personal or family history of psychosis or other severe psychiatric disorder.
- Breast-feeding
- Hypersensitivity

Adverse effects

- Dizziness
- Fatigue
- Altered taste
- Oral disorders
- Paranoia
- Suicidal ideation

Please note this list is not exhaustive – refer to the summary of product characteristic (SPC) for the complete list.

Special warnings/cautions

- Significant cardiovascular disease
- History of epilepsy or recurrent seizures
- Significant renal impairment – risk of prolonged or enhanced effect
- Moderate-severe hepatic impairment – risk of accumulation

Please note this list is not exhaustive – refer to the SPC for the complete list of warnings and precautions.

Interaction with other medicines

Sativex® is metabolised by the cytochrome P_{450} enzyme system and therefore has the potential to affect and be affected by other medicines that also use the CYP_{450} system.

Sativex® is known to reduce the effectiveness of hormonal contraceptives. The manufacturers recommend effective contraception during and for 3 months after stopping treatment in both men and women[2].

There may be an additive sedative and muscle relaxing effect with hypnotics, sedatives and drugs with potential sedating effects.

Please note this list is not exhaustive – refer to the SPC for the complete list.

Monitoring

There is no specific monitoring required for Sativex®, however in certain patients with renal or hepatic impairment the specialist should advise the GP if it is necessary to monitor renal or hepatic function and state the frequency to carry this out.

Transfer of prescribing into primary care

The tertiary centre will review the outcome of the trial at four weeks and ensure the patient is established and stable on treatment before transferring prescribing to primary care. A prescription for a further one month's supply will be issued to the patient to facilitate the transition to primary care.

The patient will remain under the care of the referring trust for the duration of the Sativex® treatment and NOT be discharged to primary care.

Guidance for GPs taking on prescribing

Treatment should be interrupted if the patient develops persistent soreness or lesions of the oral mucosa.

Contact details for advice

Consider seeking specialist advice if the patient reports any adverse effects or any deterioration in symptoms. Patients and GPs can contact the specialist via the Walton Centre NHS Foundation Trust MS nurse advice line (tel. 0151 556 4008) or by the contact details on the clinic letter. GPs can also contact the MS team by email: wcf-tr.msnursewcft@nhs.net.

References

1. NICE clinical guideline 144: Cannabis-based medicinal products. November 2019. Accessed 26/11/19.
2. Summary of product characteristics: Sativex Oromucosal Spray. Last updated April 2019 Accessed 26/11/19.