SATIVEX®
delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)

BAYER

Sativex Pay-for-Responder Order Form for Private Patients*

This form must be fully completed prior to the start of a patient's treatment with Sativex. Only one form to be completed per patient. If further information is required please call Bayer Customer Services on 0118 206 3131.

Section 1. PATIENT DETAILS

please tick

I confirm this is a new Sativex patient within the licensed MS Spasticity indication for Sativex who has not previously received a free pack** of Sativex. ☐

I understand the patient will receive 1 pack of Sativex via this scheme ☐

** 1 PACK = 3 x 10mls vial
(90 doses per vial, 270 doses per pack)

Section 2. PRIVATE FUNDING OF SATIVEX AGREED

please tick

I confirm that this patient understands that Sativex is being prescribed on a private basis and that they understand that following this initial pack they will be responsible for funding their treatment (if they respond to Sativex) while funding remains unavailable in their locality. ☐

please tick

Please confirm the patient understands that they will be responsible for covering the cost of dispensing this private prescription. **Please note that the cost varies widely depending on the pharmacy.** ☐

Section 3. DELIVERY CONTACT AND ADDRESS

Pharmacy name: ……

Pharmacy address: ……

……Postcode: ……

Pharmacy tel: ……

Contact name: ……

Section 4. TREATING CLINICIAN'S DETAILS AND CONFIRMATION

I confirm that I am an authorised person within the hospital to sign this form. I confirm that we are claiming an initial pack of Sativex free of charge for the patient who is starting on Sativex for the first time and that the patient has not previously received a free pack of Sativex. I understand that the costs of any subsequent packs of Sativex for this patient will not be met by Bayer and confirm that on-going funding has been secured as detailed in Section 2. This order is subject to Bayer's standard conditions of sale and the terms and conditions of the Bayer Pay-for-Responder scheme.

Clinician's name: ……Tel: ……

Signature: …… Date: ……

Position held: ……

Hospital name: ……

Hospital address: ……

……Postcode: ……

When complete, please fax to 0118 206 3429 or email to orders-uk@bayer.com

* Please note that Bayer has the right to refuse registration into the Pay-for Responder scheme if any of the above terms and conditions are not met. Bayer reserves the right to remove the scheme at any point.

Clinician's details provided in the form constitutes 'personal data' as defined under the Data Protection Act 1998. As such they shall only be used for the purposes of administering the Sativex Pay-for-Responder scheme and not for any other purpose.

Prescribing Information

Sativex® Oromucosal Spray (Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD))

Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 1mL contains: 38-44mg & 35-42mg of two extracts from *Cannabis sativa* L., (Cannabis leaf and flower) corresponding to 27mg delta-9-tetrahydrocannabinol (THC) and 25mg cannabidiol (CBD). Each 100 microlitre spray contains: 2.7mg THC and 2.5mg CBD. Each 100 microlitre spray also contains up to 0.04g ethanol. **Indication(s):** Symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (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. **Posology and method of administration:** Oromucosal use only. Treatment must be initiated and supervised by physician with specialist expertise in MS. Intended to be used in addition to patient's current anti-spasticity medication. Shake before use. Direct spray at different sites on oromucosal surface changing site each time product used. ***Adults:*** Number/timing of sprays will vary. Dose titration required. Number of sprays increased daily according to SmPC table, up to maximum of 12 sprays per day with minimum 15 minutes between sprays. May take up to 2 weeks to find optimal dose, review response after 4 weeks and stop if no clinically significant improvement. Standardise administration in relation to food intake. Re-titrate dose in response to patient's condition, adverse events or changes in concomitant medication. Review at intervals. ***Paediatric population:*** not recommended. ***Elderly:*** no specific studies but CNS side effects may be more likely. ***Significant hepatic or renal impairment:*** Administration to patients with moderate or severe hepatic impairment not advised. In impaired renal function, effects of Sativex may be exaggerated or prolonged. Frequent evaluation recommended. **Contra-indications:** Hypersensitivity to cannabinoids or excipients. Breast feeding. Known/suspected history or family history of schizophrenia/other psychotic illness, severe personality disorder or significant psychiatric disorders other than depression associated with MS. **Warnings and precautions:** Mild/moderate dizziness common in first few weeks. Pulse rate, blood pressure changes may occur during titration period. Fainting may occur. Not recommended in patients with serious cardiovascular disease. Caution in patients with history of epilepsy/recurrent seizures. Psychiatric symptoms (anxiety, illusions, mood changes, paranoid ideas) reported. Disorientation, confusion, hallucinations, delusional beliefs or transient psychotic reactions reported and causal association with suicidal ideation not ruled out: in any of these circumstances stop treatment immediately and monitor until fully resolved. Contains approx. 50%v/v ethanol. Risk of falls; could impact personal safety especially in elderly. Possible additive effect with muscle-relaxing agents; warn patients of risk of falls. Sativex may reduce effectiveness of hormonal contraceptives. Women of childbearing potential must use highly effective contraception and additional method of contraception with hormonal contraceptives during and for 3 months after stopping Sativex. Prior substance abuse may increase risk of abusing Sativex. Withdrawal may cause transient disturbances of sleep, emotion or appetite. No dose increase observed in long-term; self-reported 'intoxication' low; Mild/moderate stinging on application; possible leucoplakia; Vary site of application if discomfort or ulceration. Inspect mucous membrane regularly and stop treatment if persistent soreness. Advise patient to check legal status of Sativex before travelling outside UK. **Interactions:** Sativex reversibly inhibits CYP3A4, 1A2, 2B6, 2C9 and 2C19 at high concentrations; may inhibit CYP3A4 at clinically relevant concentrations. Review dosing regimen of CYP3A4 substrates if given with Sativex as plasma concentration of concomitant drug may increase. Sativex may induce CYP1A2, 2B6 and CYP3A4 and thus may reduce activity of other drugs metabolised by cytochrome P-450 e.g. coumarins, statins, beta-blockers and corticosteroids. Review dosing regimen of sensitive CYP substrates if co-administered with Sativex. Sativex inhibits the UGT enzymes UGT1A9 and UGT2B7 at therapeutic doses. Caution when prescribing Sativex with drugs solely metabolised by any of these UGTs (e.g. Propofol and certain antivirals). Use Sativex with caution in patients with genetic glucuronidation disorders (e.g. Gilbert's disease) as they may exhibit increased serum concentrations of bilirubin. Sativex is metabolised by cytochrome P-450 enzyme system. If concomitant treatment with CYP3A4 inhibitors (e.g. itraconazole, ritonavir, clarithromycin) is started or stopped during Sativex treatment, consider new dose titration. Fluconazole may inhibit metabolism of Sativex; care should be taken when co-administering Sativex with potent CYP2C9 inhibitors as may increase in exposure to THC, CBD and their metabolites. Avoid concomitant use of strong cytochrome P-450 enzyme inducers (e.g. rifampicin, carbamazepine, phenytoin, phenobarbital, St John's Wort) with Sativex; if use unavoidable, careful titration is recommended, especially in two weeks following discontinuation of the inducer. Refer to SmPC for more details. *General:* Caution with concomitant use of hypnotics and drugs with sedating effects: additive effect may increase risk of falls. Sativex may interact with alcohol, affecting co-ordination, concentration and ability to respond quickly. Avoid alcohol consumption whilst taking Sativex, especially at the beginning of treatment or when changing dose; additive CNS effects may impair ability to drive or use machines and increase fall risk. *Hormonal contraceptives:* Sativex may reduce effectiveness of systemic hormonal contraceptives: use additional barrier methods **Fertility, pregnancy and lactation:** Do not use in pregnancy unless benefit outweighs potential risks. Contra-indicated during breast feeding. Little data on reproductive effect but may affect spermatogenesis: men and women should use effective contraception during treatment and for 3 months after and use an additional method with hormonal contraception. **Effects on ability to drive and use machines:** Do not drive, operate machinery or engage in hazardous activity if experiencing significant CNS side effects; may cause loss of consciousness, impair cognitive function and affect ability to drive safely. Sativex use falls under Section 5a of the Road Traffic Act 1988. Patients should be made aware of how Sativex may affect them. **Side effects:** *Very common*: dizziness, fatigue; *common*: increased/decreased appetite, depression, disorientation, dissociation, euphoria, amnesia, balance disorder, disturbance in attention, dysarthria, dysgeusia, lethargy, impaired memory , somnolence, blurred vision, vertigo, constipation, diarrhoea, dry mouth, glossodynia, mouth ulcers, nausea, oral discomfort/pain, vomiting, application site pain, asthenia, feeling abnormal/drunk, malaise, fall; *Serious: cf. CI/Warnings & Precautions.* Consult SmPC for full information on side effects. **Overdose:** Symptomatic and supportive treatment required. **Special precautions for storage:** Store upright. Refrigerate (2 to 8ºC); once opened refrigeration is unnecessary but do not store above 25ºC. In-use stability (10ml): 42 days from date of first opening. Discard unused product in accordance with local requirements. **Legal category:** POM. **Package quantities and basic NHS costs:** 3 x 10mL £300.00. **MA holder:** GW Pharma Ltd, Sovereign House, Histon, Cambridge CB24 9BZ. **MA number(s):** PL 18024/0009. **Further information available from:** Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** December 2019. Sativex® is a registered trademark of GW Pharma Ltd.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk
Adverse events should also be reported to GW Pharma Ltd. Tel: 01223 233410, Fax: 01223 233319