Sativex® Oromucosal Spray: Clinical and Reimbursement Information

Medicines Management Programme

✓ Delta-9-tetrahydrocannabinol (THC)/cannabidiol (CBD) (Sativex®) is available as an oromucosal spray in a 10 ml vial which is reimbursed under the High Tech Arrangement with a Managed Access approach. The 10 ml vial allows for delivery after priming of up to 90 sprays of 100 microlitres per spray. Each single 100 microlitre spray contains 2.7 mg THC and 2.5 mg CBD from *Cannabis sativa* L. Refer to the Summary of Product Characteristics (SmPC) for full prescribing information.

✓ THC/CBD (Sativex®) oromucosal spray contains a substance that is listed in Schedule 4, Part 1 of the Misuse of Drugs Regulation 2017.

Medicinal Product	THC/CBD (Sativex®)	Managed Access Protocol (MAP) requirements
Reimbursed indication	THC/CBD (Sativex®) is indicated as treatment for 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.	• A Managed Access Protocol (MAP) is in place for THC/CBD (Sativex®). This outlines the criteria that must be satisfied in order for a patient to be recommended for reimbursement of THC/CBD (Sativex®) under the High Tech Arrangement. • The prescribing of THC/CBD (Sativex®) under the High Tech Arrangement is confined to consultant neurologists registered with the Irish Medical Council, who have agreed to the terms of the MAP and have been approved by the HSE. • A copy of the HSE-MAP for THC/CBD (Sativex®) can be accessed at www.hse.ie/mmp.
Presentation	THC/CBD (Sativex®) oromucosal spray with each pack containing 3 x 10 ml spray vials. Each 10 ml spray vial allows for delivery after priming of up to 90 sprays.	
Titration and dosing	A titration period is required to reach optimum dose (see SmPC for further information). Patients should gradually increase the dose, from one spray in the evening on the first day, until they achieve optimum symptom relief, up to a maximum of 12 sprays per day. The median dose in clinical trials for patients with MS was 8 sprays per day. Dosing for titration is divided into “morning sprays” and “evening sprays” (see SmPC for further information). The number and timing of sprays will vary between patients. There should be at least a 15 minute gap between sprays. Once the optimum dose has been achieved, patients may spread the doses throughout the day according to individual response and tolerability.	
Prescribing and Dispensing Information	• One 10 mL spray vial allows for delivery after priming of up to 90 sprays of 100 microlitres. Accordingly, one 10 mL spray vial should have sufficient sprays for **10 days in an individual using 9 sprays per day**. In this example, one pack of THC/CBD (Sativex®) oromucosal spray containing 3 x 10 ml spray vials would be required every 30 days. • For individuals on a maintenance dose of 12 sprays per day of THC/CBD (Sativex®), 4 x 10 ml spray vials would be required every 30 days. • THC/CBD (Sativex®) contains a substance that is listed in Schedule 4, Part 1 of the Misuse of Drugs Regulations 2017, therefore the associated **Controlled Drug Prescription Requirements apply, including the requirement for the total quantity of spray vials prescribed to be outlined in both words and figures**. • **Ensure that the number of sprays prescribed per day corresponds to the number of vials prescribed**.	
Storage	Store in a refrigerator (2-8 °C). Once the spray vial is opened and in use, refrigerated storage is not necessary. When a spray vial is opened it has a 42 day expiry.	
Administration	• The spray vial should be shaken before use and the sprays should be directed at different sites on the oromucosal surface, changing the application site at each use. • To minimise variability of bioavailability in the individual, administration of THC/CBD (Sativex®) should be standardised as far as possible in relation to food intake. • Starting or stopping of some concomitant medicinal products may require a new dose titration (see SmPC for further information).	

Abbreviations: CBD= Cannabidiol; MAP= Managed Access Protocol; MMP= Medicines Management Programme; SmPC= Summary of Product Characteristics; THC=Delta-9-tetrahydrocannabinol

References: 1. Summary of Product Characteristics (SmPC) Sativex® available on www.hpra.ie 2. Sativex® Oromucosal Spray Medicinal Product Authorisation Information available on www.hpra.ie 3. Medical Council and Pharmaceutical Society of Ireland. Safe Prescribing and Dispensing of Controlled Drugs Joint Guidance. October 2017.

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