

Medicinal cannabis-based products

The Malta Medicines Authority reviews submissions and issues recommendations for activities relating to cannabis for medicinal and research purposes which go through approval processes in line with the relevant legislation, including the Drug Dependence (Treatment not Imprisonment) Act, Cap 537 of the Laws of Malta, and the Production of Cannabis for Medicinal and Research Purposes Act, Cap 578 of the Laws of Malta. Production, importation, wholesale distribution, prescribing and dispensing of medicinal cannabis-based products are subject to the relevant procedures, including licenses, approvals and permits, issued by the Superintendence of Public Health.

<u>List of medicinal cannabis-based products which have been approved for the local market:</u>

Product Name	Form	Cannabinoid Concentration (%w/w - for products in dried flower/granulate form; mg/mL - for products in oil/extract form)	Pack Sizes	Mode of Use
Afghani*	Dried inflorescence	THC: 24% w/w CBD: <1% w/w	10 g	Inhalation
Aphria 22/1, Variety Bienville*	Dried inflorescence	THC: 22% w/w CBD: ≤1% w/w	5 g	Oral / Inhalation
Aurora 20/1	Dried inflorescence	THC: 20% w/w CBD: <1% w/w	10 g	Oral / Inhalation
Aurora 22/1	Dried inflorescence	THC: 22% w/w CBD: <1% w/w	10 g	Oral / Inhalation
BCANN oil Medical Cannabis oil Sublingual drops THC 1% CBD 28% CBD Rich	Sublingual drops	THC: 10 mg/mL CBD: 280 mg/mL	10 mL	Oral
BCANN oil Medical Cannabis oil Sublingual drops THC 10% CBD 10% THC/CBD Balanced	Sublingual drops	THC: 100 mg/mL CBD: 100 mg/mL	10 mL	Oral









Product Name	Form	Cannabinoid Concentration (%w/w - for products in dried flower/granulate form; mg/mL - for products in oil/extract form)	Pack Sizes	Mode of Use
BCANN oil Medical Cannabis oil Sublingual drops THC 20% CBD 4% THC Rich	Sublingual drops	THC: 200 mg/mL CBD: 40 mg/mL	10 mL	Oral
Cannabis 1A 18/1*	Dried inflorescence	THC: 18% w/w CBD: ≤1% w/w	10 g	Inhalation
Cannabis Flos WEECO 25/1*	Dried inflorescence	THC: 25% w/w CBD: ≤1% w/w	10 g	Inhalation
Carbasi Verde, Cannabis Flower, Strain code: ASID 005/2019-1001*	Dried inflorescence	THC: 20% w/w CBD: ≤1% w/w	5 g; 15 g	Oral / Inhalation
Materia Dark Shadow Haze*	Dried inflorescence	THC: 28% w/w CBD: ≤1% w/w	5 g; 10 g	Oral
Materia Dark Shadow Haze Irr.*	Dried inflorescence	THC: 28% w/w CBD: ≤1% w/w	5 g; 10 g	Oral / Inhalation
Materia Vanilla Cake Irr.*	Dried inflorescence	THC: 23% w/w CBD: ≤1% w/w	5 g	Oral
Medi-Glue Intense 23/1	Dried inflorescence	THC: 23% w/w CBD: <1% w/w	10 g	Inhalation
Panaxir CBD25	Cannabis extract standardized in MCT oil	THC: ≤1.5 mg/mL CBD: 25 mg/mL	30 mL	Oral
Panaxir THC25	Cannabis extract standardized in MCT oil	THC: 25 mg/mL CBD: ≤1.5 mg/mL	30 mL	Oral









Product Name	Form	Cannabinoid Concentration (%w/w - for products in dried flower/granulate form; mg/mL - for products in oil/extract form)	Pack Sizes	Mode of Use
Panaxir THC25/CBD25	Cannabis extract standardized in MCT oil	THC: 25 mg/mL CBD: 25 mg/mL	30 mL	Oral
Panaxir THC50	Cannabis extract standardized in MCT oil	THC: 50 mg/mL CBD: ≤0.3 mg/mL	30 mL	Oral
Pedanios 20/1	Dried inflorescence	THC: 20% w/w CBD: <1% w/w	10 g	Oral / Inhalation
Pedanios 22/1	Dried inflorescence	THC: 22% w/w CBD: <1% w/w	10 g	Oral / Inhalation
Salus Biopharma Medical Cannabis Flower	Dried inflorescence	THC: 20% w/w CBD: <1% w/w	5 g; 10 g	Oral / Inhalation

^{*} Products approved for batch-specific assay labelling where the cannabinoid(s) concentration might exceed the ±10% relative deviation of the stated content.

Unit packs of products manufactured in Malta display a 10-alphanumeric serial number (e.g. 123MTXXXXX). Unit packs of products sourced to Malta display a 7-alphanumeric serial number (e.g. A111111).

All stakeholders involved in the supply chain making medicinal cannabis-based products accessible to patients shall collaborate to ensure traceability and reconciliation practices are maintained throughout; this includes keeping records of the serial numbers of unit product packs up to the dispensing stage (including at producer, importer, distributor and pharmacy level).

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