

## 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.

### List of medicinal cannabis-based products which have been approved for the local market:

Product Name	Form	Registered Cannabinoid(s) Concentration (%w/w – for products in dried flower/granulate form; mg/mL – for products in oil/extract form)	Pack Sizes	Mode of Use
<i>Afghani*</i>	<i>Dried inflorescence</i>	<i>THC: 24% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Inhalation</i>
<i>Aphria 22/1, Variety Bienville*</i>	<i>Dried inflorescence</i>	<i>THC: 22% w/w CBD: ≤1% w/w</i>	<i>5 g</i>	<i>Oral / Inhalation</i>
<i>Aurora 22/1</i>	<i>Dried inflorescence</i>	<i>THC: 22% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral / Inhalation</i>
<i>BCANN THC 10: CBD 280</i>	<i>Sublingual drops</i>	<i>THC: 10 mg/mL CBD: 280 mg/mL</i>	<i>10 mL</i>	<i>Oral</i>
<i>BCANN THC 100: CBD 100</i>	<i>Sublingual drops</i>	<i>THC: 100 mg/mL CBD: 100 mg/mL</i>	<i>10 mL</i>	<i>Oral</i>
<i>BCANN THC 200: CBD 40</i>	<i>Sublingual drops</i>	<i>THC: 200 mg/mL CBD: 40 mg/mL</i>	<i>10 mL</i>	<i>Oral</i>
<i>bc green HGH 25:1</i>	<i>Dried inflorescence</i>	<i>THC: 25% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral</i>

Product Name	Form	Registered Cannabinoid(s) Concentration (%w/w – for products in dried flower/granulate form; mg/mL – for products in oil/extract form)	Pack Sizes	Mode of Use
<i>bc green HGH 27:1</i>	<i>Dried inflorescence</i>	<i>THC: 27% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral</i>
<i>Cannabis 1A 16/1 Flos*</i>	<i>Dried inflorescence</i>	<i>THC: 16% w/w CBD: ≤1% w/w</i>	<i>10 g</i>	<i>Inhalation</i>
<i>Cannabis 1A 18/1 Flos*</i>	<i>Dried inflorescence</i>	<i>THC: 18% w/w CBD: ≤1% w/w</i>	<i>10 g</i>	<i>Inhalation</i>
<i>Cannabis Flos WEECO 23/1*</i>	<i>Dried inflorescence</i>	<i>THC: 23 % w/w CBD: ≤1% w/w</i>	<i>10g</i>	<i>Inhalation</i>
<i>Cannabis Flos WEECO BR 22/1*</i>	<i>Dried inflorescence</i>	<i>THC: 22 % w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Inhalation</i>
<i>Cannabis Flos WEECO Duke 24/1 *</i>	<i>Dried inflorescence</i>	<i>THC: 24% w/w CBD: ≤1% w/w</i>	<i>10 g</i>	<i>Inhalation</i>
<i>Epidyolex</i>	<i>Oral Solution</i>	<i>THC: N/A CBD: 100 mg/mL</i>	<i>100 mL</i>	<i>Oral and Enteral Administration (nasogastric and gastrostomy tubes)</i>
<i>Materia 8 Ball Kush*</i>	<i>Dried inflorescence</i>	<i>THC: 25 % w/w CBD: ≤1% w/w</i>	<i>5 g; 10 g</i>	<i>Oral</i>
<i>Materia 8 Ball Kush H*</i>	<i>Dried inflorescence</i>	<i>THC: 30 % w/w CBD: ≤1% w/w</i>	<i>5 g; 10 g</i>	<i>Oral</i>
<i>Materia 8 Ball Kush Irr.*</i>	<i>Dried inflorescence</i>	<i>THC: 25% w/w CBD: ≤1% w/w</i>	<i>10g</i>	<i>Oral</i>
<i>Materia 8 Ball Kush H Irr.*</i>	<i>Dried inflorescence</i>	<i>THC: 30 % w/w CBD: ≤1% w/w</i>	<i>10g</i>	<i>Oral</i>

Product Name	Form	Registered Cannabinoid(s) Concentration (%w/w – for products in dried flower/granulate form; mg/mL – for products in oil/extract form)	Pack Sizes	Mode of Use
<i>Materia Cherry Pie*</i>	<i>Dried inflorescence</i>	<i>THC: 17 % w/w CBD: ≤1% w/w</i>	<i>10 g</i>	<i>Oral use</i>
<i>Materia Cherry Pie H*</i>	<i>Dried inflorescence</i>	<i>THC: 20 % w/w CBD: ≤1% w/w</i>	<i>10g</i>	<i>Oral use</i>
<i>Materia Dark Shadow Haze*</i>	<i>Dried inflorescence</i>	<i>THC: 28% w/w CBD: ≤1% w/w</i>	<i>5 g; 10 g</i>	<i>Oral</i>
<i>Materia Dark Shadow Haze Irr.*</i>	<i>Dried inflorescence</i>	<i>THC: 28% w/w CBD: ≤1% w/w</i>	<i>5 g; 10 g</i>	<i>Oral / Inhalation</i>
<i>Materia Full Spectrum Cannabis Extract 10:10</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 1% w/w CBD: 1%w/w</i>	<i>30mL</i>	<i>Oral</i>
<i>Materia Full Spectrum Cannabis Extract 20:0</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 2% w/w CBD: ≤0.1%w/w</i>	<i>10mL; 30mL</i>	<i>Oral</i>
<i>Materia Gelato H Irr.*</i>	<i>Dried inflorescence</i>	<i>THC: 29% w/w CBD: ≤1% w/w</i>	<i>10g</i>	<i>Oral</i>
<i>Materia Gelato Irr.*</i>	<i>Dried inflorescence</i>	<i>THC: 24% w/w CBD: ≤1% w/w</i>	<i>10g</i>	<i>Oral</i>
<i>Materia Vanilla Cake Irr.*</i>	<i>Dried inflorescence</i>	<i>THC: 23% w/w CBD: ≤1% w/w</i>	<i>5g; 10g</i>	<i>Oral</i>
<i>Panaxir CBD25</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: ≤1.5 mg/mL CBD: 25 mg/mL</i>	<i>30mL</i>	<i>Oral</i>
<i>Panaxir THC25</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 25 mg/mL CBD: ≤1.5 mg/mL</i>	<i>30mL</i>	<i>Oral</i>

Product Name	Form	Registered Cannabinoid(s) Concentration (%w/w – for products in dried flower/granulate form; mg/mL – for products in oil/extract form)	Pack Sizes	Mode of Use
<i>Panaxir THC25/CBD25</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 25 mg/mL CBD: 25 mg/mL</i>	<i>30mL</i>	<i>Oral</i>
<i>Panaxir THC50</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 50 mg/mL CBD: ≤0.3 mg/mL</i>	<i>30mL</i>	<i>Oral</i>
<i>Peace Naturals™ 31/1 GMO Cookies</i>	<i>Dried inflorescence</i>	<i>THC: 31% w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Oral</i>
<i>Pedanios 22/1</i>	<i>Dried inflorescence</i>	<i>THC: 22% w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Oral / Inhalation</i>
<i>Pedanios 27/1 FRG-CA</i>	<i>Dried inflorescence</i>	<i>THC: 27% w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Oral / Inhalation</i>
<i>Pedanios 29/1 SRD-CA</i>	<i>Dried inflorescence</i>	<i>THC: 29% w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Oral / Inhalation</i>
<i>ZeraMed ZeraMax 25:1</i>	<i>Dried inflorescence</i>	<i>THC: 25% w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Oral</i>
<i>ZeraMed ZeraMax 27:1</i>	<i>Dried inflorescence</i>	<i>THC: 27% w/w CBD: &lt;1% w/w</i>	<i>10g</i>	<i>Oral</i>

\* Products approved for batch-specific assay labelling where the labelled content may have a relative deviation of up to ±20% from the registered cannabinoid(s) concentration.

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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