

## 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	Cannabinoid Concentration (%w/w – for products in dried flower/granulate form; mg/mL – for products in oil/extract form)	Pack Sizes	Mode of Use
<i>Aurora 20/1</i>	<i>Dried Flower</i>	<i>THC: 20% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral / Inhalation</i>
<i>Aurora 22/1</i>	<i>Dried Flower</i>	<i>THC: 22% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral / Inhalation</i>
<i>Bediol*</i>	<i>Dried Flower Granulate</i>	<i>THC: 6.3% w/w CBD: 8% w/w</i>	<i>5 g</i>	<i>Inhalation</i>
<i>Bedrocan*</i>	<i>Dried Flower</i>	<i>THC: 22% w/w CBD: &lt;1% w/w</i>	<i>5 g</i>	<i>Inhalation</i>
<i>Cannabis 1A 18/1</i>	<i>Dried Flower</i>	<i>THC: 18% w/w CBD: ≤1% w/w</i>	<i>10 g</i>	<i>Inhalation</i>
<i>Cannabis Flos WEECO 25/1*</i>	<i>Dried Flower</i>	<i>THC: 25% w/w CBD: ≤1% w/w</i>	<i>10 g</i>	<i>Inhalation</i>

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
<i>Carbasi Verde, Cannabis Flower, Strain code: ASID 005/2019-1001*</i>	<i>Dried Flower</i>	<i>THC: 20% w/w CBD: ≤1% w/w</i>	<i>5 g; 15 g</i>	<i>Oral / Inhalation</i>
<i>Materia Vanilla Cake Irr.*</i>	<i>Dried Flower</i>	<i>THC: 23% w/w CBD: ≤1% w/w</i>	<i>5 g</i>	<i>Oral</i>
<i>Medi-Glue Intense 23/1</i>	<i>Dried Flower</i>	<i>THC: 23% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Inhalation</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>30 mL</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>30 mL</i>	<i>Oral</i>
<i>Panaxir THC25/CBD25</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 25 mg/mL CBD: 25 mg/mL</i>	<i>30 mL</i>	<i>Oral</i>
<i>Panaxir THC50</i>	<i>Cannabis extract standardized in MCT oil</i>	<i>THC: 50 mg/mL CBD: ≤3 mg/mL</i>	<i>30 mL</i>	<i>Oral</i>
<i>Pedantos 8/8</i>	<i>Dried Flower</i>	<i>THC: 8% w/w CBD: 8% w/w</i>	<i>10 g</i>	<i>Oral / Inhalation</i>
<i>Pedantos 20/1</i>	<i>Dried Flower</i>	<i>THC: 20% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral / Inhalation</i>
<i>Pedantos 22/1</i>	<i>Dried Flower</i>	<i>THC: 22% w/w CBD: &lt;1% w/w</i>	<i>10 g</i>	<i>Oral / Inhalation</i>
<i>Salus Biopharma Medical Cannabis Flower</i>	<i>Dried Flower</i>	<i>THC: 20% w/w CBD: &lt;1% w/w</i>	<i>5 g; 10 g</i>	<i>Oral / Inhalation</i>

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
ZeraMed ZeraUltra s22:0	Dried Flower	THC: 22% w/w CBD: <1% w/w	10 g	Oral / Inhalation

*\* Products approved for batch-specific assay labelling where the cannabinoid(s) concentration might exceed the  $\pm 10\%$  relative deviation of the stated content.*

*Unit packs of products manufactured in Malta display a 10-alphanumeric serialisation codes (e.g. 123MTXXXXX). Unit packs of products sourced to Malta display a 7-alphanumeric serialisation codes (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 serialisation codes of unit product packs up to the dispensing stage (including at producer, importer, distributor and pharmacy level).

**Updated on 26 March 2024**

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