

Pharmatropia Methylene Blue 25 mg Capsules

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

Pharmatropia Methylene Blue 25mg – Hard Gelatin Capsules

COMPOSITION

Each capsule contains:

- **Methylthioninium Chloride:** 25mg.
- Excipients: Lactose, Ascorbic Acid, Microcrystalline

INDICATIONS

Pharmatropia Methylene Blue may assist with:

- Enhancing cellular energy production and mitochondrial function, supporting overall vitality and endurance.
- Promoting DNA repair and protection from oxidative damage.
- Improving cognitive function, memory and mental clarity.
- Providing neuroprotective support for long-term brain health.
- Supporting antioxidant defense to protect against free radical damage.
- Enhancing metabolic efficiency and tissue oxygenation.
- Assisting in detoxification processes by reducing cellular stress and damage.
- Antiviral, antibacterial, and antiparasitic support, potentially beneficial in reducing the severity and duration of infections.
- Supporting urinary tract health and assisting in the management of urinary tract infections (UTIs).
- Helping to inhibit the growth of harmful pathogens in the body.

PHARMACOLOGICAL ACTION

Methylene Blue is a heterocyclic aromatic compound known for its diverse pharmacological properties, including acting as an electron donor in mitochondrial respiration and a redox cycling agent. It enhances ATP production, promotes antioxidant activity by scavenging free radicals and has demonstrated neuroprotective properties in several clinical settings.

Methylene Blue also exhibits strong antimicrobial effects, shown to inhibit the replication of bacteria, viruses and certain parasites. It has shown efficacy in managing various infections, including UTIs.

Methylene Blue has shown efficacy in supporting brain function, memory retention, immune defense, and neuroprotection in preclinical and clinical studies.

PHARMACOKINETIC PROPERTIES

- **Absorption:** Rapidly absorbed in the gastrointestinal tract after oral administration.
- **Distribution:** Distributed widely in tissues, including the brain and urinary system.
- **Metabolism:** Primarily metabolized in the liver by N-demethylation.
- **Elimination:** Excreted in the urine (as methylene blue and its metabolites) and bile.

CONTRAINDICATIONS

- Hypersensitivity to methylene blue or any excipients.
- Known glucose-6-phosphate dehydrogenase (G6PD) deficiency (risk of hemolytic anemia).
- Pregnancy and lactation.

Special Caution: Methylene blue has monoamine oxidase inhibitor (MAOI) properties. It should be used with caution in patients taking medications that affect serotonin levels, such as SSRIs, SNRIs, TCAs, or MAOIs. Concurrent use may increase the risk of serotonin syndrome.

WARNINGS AND PRECAUTIONS

- **Serotonin Syndrome Risk:** Monitor for symptoms of serotonin syndrome (e.g., confusion, hyperreflexia, autonomic instability, and agitation) when combining methylene blue with serotonergic medications.
- **MAOI Action:** Due to its mild MAOI properties, methylene blue can interact with serotonergic medications and enhance serotonin activity.
- **Psychiatric Disorders:** Use with caution in patients with a history of mood disorders.
- **Psychedelic Use:** This product should **never** be taken with psychedelics.
- **Infection Support:** Although it has antimicrobial properties, methylene blue should not replace antibiotics for severe infections without medical supervision.
- **Pregnancy and Lactation:** Not safe to use during pregnancy or lactation

DOSAGE AND DIRECTIONS FOR USE

Refer to the dosage table for weight-specific dosing recommendations. Clinical studies suggest the most effective dose range is between **0.5 to 2 mg per kilogram of body weight**, depending on the intended use. **Do not exceed a maximum dose of 4 mg per kilogram of body weight.**

It is recommended to start with the lowest effective dose and gradually adjust based on individual response and guidance from a healthcare professional.

Recommended Dosage:

Weight (kg)	Low Dose (mg)	Low Dose (Capsules)	Medium Dose (mg)	Medium Dose (Capsules)
50	25.0	1	50.0	2
55	27.5	2	55.0	3
60	30.0	2	60.0	3
65	32.5	2	65.0	3
70	35.0	2	70.0	3
75	37.5	2	75.0	3
80	40.0	2	80.0	4
85	42.5	2	85.0	4
90	45.0	2	90.0	4
95	47.5	2	95.0	4
100	50.0	2	100.0	4

SIDE EFFECTS

Common side effects:

- Dizziness or headache.
- Blue or green discoloration of urine.

Rare side effects:

- Gastrointestinal discomfort (nausea, vomiting, diarrhea).
- Hemolytic anemia (especially in G6PD-deficient individuals).
- Serotonin syndrome (when combined with serotonergic drugs).
- Photosensitivity reactions (in cases of light exposure).

INTERACTIONS

- **MAOIs and Serotonergic Agents:** Methylene blue may potentiate the effects of serotonergic agents (e.g., SSRIs, SNRIs, TCAs, MAOIs), increasing the risk of serotonin syndrome.

- **Psychedelics:** Extreme caution is advised. This product should **never** be combined with psychedelics.
- **Antimicrobials:** While methylene blue has broad-spectrum antimicrobial properties, its interactions with other antimicrobials should be monitored.
- **CYP450 Enzyme Inhibitors:** Potential for altered drug metabolism.

PREGNANCY AND LACTATION

Not safe to use during pregnancy or lactation.

OVERDOSE

Symptoms of overdose may include nausea, vomiting, dizziness, confusion, and disorientation. Seek immediate medical attention if an overdose is suspected.

STORAGE INSTRUCTIONS

Store in a cool, dry place below 25°C. Keep out of reach of children.

IDENTIFICATION

Clear gelatin capsules

PRESENTATION

Capsules in a black PET plastic bottle with tamper-evident seal.

REGISTRATION NUMBER

22/04/2021

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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DISCLAIMER

Consult your healthcare provider before use, especially if you are taking any prescription medications or have a medical condition. This is a complementary health product and not intended to diagnose, treat, cure, or prevent any disease.

This unregistered product has not been evaluated by SAHPRA for quality, or safety or intended to diagnose, treat, cure, or prevent any disease. Please consult your health practitioner before consuming any of our products. Consult your doctor if you are pregnant or breastfeeding.