

Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Methionine 250mg capsule

2. Qualitative and quantitative composition

Each Capsule contains 250mg of Methionine.

Excipient with known effect:

Each tablet contains 134 mg of Lactose

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Hard Gelatin Capsule.

A maroon colored cap and body with “NEROS” printed on 360 degree band on the cap in white ink and “METHIONINE” printed on 360 degree band on the body in white ink.

4. Clinical particulars

4.1 Therapeutic indications

Used for protein synthesis including the formation of SAMe, L-homocysteine, L-cysteine, taurine, and sulfate.

4.2 Posology and method of administration

Posology

The daily recommended intake of methionine plus cysteine is 8.6 mg/lb (19 mg/kg) per day for adults, which is around 1.3 grams for someone weighing 150 pounds (68 kilograms)

Adults: 4-8 capsules per day.

Children: 2-4 capsules per day

Method of administration

For oral administration.

4.3 Contraindications

Methionine is contraindicated for those who have:

- Liver damage
- Hepatic encephalopathy (a decrease in the function of the brain caused by liver damage)
- Severe liver disease (such as cirrhosis of the liver)
- Acidosis (an excessive acid condition of the body and it's the acidity of the blood)

- Atherosclerosis (hardening of the arteries): Methionine may worsen atherosclerosis. The nutritional supplement has been associated with an increased risk for heart disease.
- Schizophrenia: Large doses of methionine (over 20 g per day for five days) have been known to cause confusion, delirium, and agitation in those with schizophrenia.
- Methylenetetrahydrofolate reductase (MTHFR) deficiency (a hereditary disease involving an abnormal method of processing of risk of heart disease)

4.4 Special warnings and precautions for use

Children: Methionine is POSSIBLY SAFE for children when given by mouth or injected intravenously (by IV) to treat acetaminophen poisoning, but only under the supervision of a healthcare professional. Methionine is POSSIBLY UNSAFE when injected intravenously into infants that are receiving parenteral nutrition.

Pregnancy and breast-feeding: There is not enough reliable information about the safety of taking methionine if you are pregnant or breast-feeding. Stay on the safe side and avoid use.

Acidosis: Methionine can cause changes in acidity of the blood and should not be used in people with a condition called acidosis.

“Hardening of the arteries” (atherosclerosis): There is some concern that methionine might make atherosclerosis worse. Methionine can increase blood levels of a chemical called homocysteine, especially in people who don't have enough folate, vitamin B12, or vitamin B6 in their bodies, or in people whose bodies have trouble processing homocysteine. Too much homocysteine is linked to an increased risk for diseases of the heart and blood vessels.

Liver disease, including cirrhosis: Methionine might make liver disease worse.

Methylenetetrahydrofolate reductase (MTHFR) deficiency: This is an inherited disorder. It changes the way the body processes homocysteine. People who have this disorder should not take methionine supplements because methionine might cause homocysteine to build up in these people. Too much homocysteine might increase the chance of developing diseases of the heart or blood vessels.

Schizophrenia: Large doses of methionine (e.g., 20 g/day for 5 days) might cause confusion, disorientation, delirium, agitation, listlessness, and other similar symptoms in people with schizophrenia.

4.5 Interaction with other medicinal products and other forms of interaction

Levodopa: The effects of it can be reduced by methionine.

4.6 Fertility, pregnancy and lactation

Pregnancy

METHIONINE 250mg Capsules | NEROS PHARMACEUTICALS LTD

METHIONINE should only be used during pregnancy only if the possible benefit outweighs the possible risk to the unborn baby. Methionine should be given to a pregnant woman only if clearly needed

High dosage regimen should be avoided in pregnancy.

Establishing safety and efficacy of the treatment in pregnancy remains priority

Breast-feeding

There is not enough reliable information about the safety of taking methionine if you are pregnant or breast, no evidence exists suggesting such excretion is hazardous to the infant.

4.7 Effects on ability to drive and use machines

On the basis of the product's pharmacodynamic profile and reported adverse events, methionine has no known effect on an individual's ability to drive or operate machinery.

4.8 Undesirable effects

Methionine is well tolerated at this dosage strength. Abnormally high levels of METHIONINE may lead to brain damage and death. Methionine can also increase the blood levels of homocysteine, which may increase risk of cardiovascular disease.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

Symptoms

At very high doses, Methionine may cause adverse effects like brain damage, Acidosis and Atherosclerosis

Management

The first step in case of over dosage is to stop the drug.
Treatment should involve haemodialysis to remove Methionine from the system

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC code: V03AB26

L-Methionine is a principle supplier of sulfur which prevents disorders of the hair, skin and nails; helps lower cholesterol levels by increasing the liver's production of lecithin; reduces liver fat and protects the kidneys; a natural chelating agent for heavy metals; regulates the formation of ammonia and creates ammonia-free urine which reduces bladder irritation; influences hair follicles and promotes hair growth. L-methionine may protect against the toxic effects of hepatotoxins, such as acetaminophen. Methionine may have antioxidant activity.

5.2 Pharmacokinetic properties

Absorption

Absorbed from the lumen of the small intestine into the enterocytes by an active transport process.

Distribution

Absorbed amino acids pass into the liver, where a portion of the amino acids are taken up and used; the remainder pass through into the systemic circulation and are utilized by the peripheral tissues.

Elimination

Protein secretion into the intestine continues even under conditions of protein-free feeding, and fecal nitrogen losses (ie, nitrogen lost as bacteria in the faeces) may account for 25% of the obligatory loss of nitrogen. Under this dietary circumstance, the amino acids secreted into the intestine as components of proteolytic enzymes and from sloughed mucosal cells are the only sources of amino acids for the maintenance of the intestinal bacterial biomass. ... Other routes of loss of intact amino acids are via the urine and through skin and hair loss. These losses are small by comparison with those described above, but nonetheless may have a significant impact on estimates of requirements, especially in disease states.

5.3 Preclinical safety data

There are no other preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch

Lactose

Sodium Starch Glycollate

Colloidal Silicon Dioxide

Talc

Magnesium Stearate

Empty Capsule Shells, Size 1

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Bottle of 100 capsules, Box of 1 bottle.

6.6 Special precautions for disposal and other handling

No special requirements

7. Applicant

NEROS Pharmaceuticals Ltd.
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By Singer Bus Stop
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8. Reference/Authorisation number(s)

Not applicable

9. Date of first authorisation/renewal of the authorisation

Not applicable

10. Date of revision of the text

23 August 2020.

PREGNANCY AND LACTATION:

- **METHIONINE** should be used during pregnancy only if the possible benefit outweighs the possible risk to the unborn baby. Methionine should be given to a pregnant woman only if clearly needed.

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STORAGE:

Store in a cool dry place, away from light below 30°C

PRESENTATION:

Bottle of 100 capsules, Box of 1 bottle.