

Pharmaceutical form:

Injectable solution – intramuscular

Composition:

One ampoule contains:

Procaine hydrochloride.....	100 mg
Benzoic acid.....	6 mg
Disodium phosphate dodecahydrate.....	0.5 mg
Potassium metabisulfite.....	5 mg
Distilled water for injectable solutions...up to	5 ml

Pharmacotherapeutic group:

Alimentary tract and metabolism. Tonic preparations.

ATC code: A13 AN01

Therapeutic indications:

- Protection of the organism against aging phenomena.
- Depressive syndrome (light and moderate depression), in precocious stages, especially when conventional therapy is not well-tolerated or it has contraindications.
- Parkinsonian syndromes – where it can be used in monotherapy or associated with other antiparkinsonian drugs, especially with dopaminergic agents.
- Osteoarthritis (chronic degenerative rheumatism)
- Systemic arteriosclerosis with hypercholesterolemia, ischaemic heart disease, arteritis, cerebral atherosclerosis.

Contraindications:

Hypersensitivity to procaine in antecedents or tested.

Severe arterial hypotension.

Associated treatment with sulfonamides (except the antidiabetic ones) and with acetylcholinesterase agents: neostygmine, eserine (physostigmine) and pyridostigmine.

Precautions regarding medicinal product administration:

Before starting the treatment, a test for individual tolerance to procaine should be made (see under **Posology and method of administration**).

The treatment must take place under medical supervision, mainly in the first series of treatment, in order to establish the optimal dose.

The product should be administered with caution in patients with orthostatic hypotension.

Although procaine medication is not carcinogenic, it is not recommended to the patients with cancer, as its stimulating effect on mitotic potential of the neoplastic cell is not excluded.

Interactions with other medicinal products or other substances:

Gerovital® H³ should not be administered simultaneously with sulphonamides (antagonistic mechanism of action) – except the antidiabetic ones, anticholinesterases: neostygmine, eserine (physostigmine) and pyridostigmine.

Special warnings:

Pregnant and breast-feeding women:

The studies on animals did not show teratogenic effects. In absence of teratogenic effects on animals, malformative effects on humans are not expected. However, the clinical experience with Gerovital® H³ is mainly on patients over the procreation period. For these reasons we do not recommend the use of the product during pregnancy and lactation.

Potential effect on the ability to drive or to use machines:

The product does not interfere with these abilities.

Posology and method of administration:

Before starting the treatment with Gerovital® H³ it is compulsory to test individual sensitivity to procaine, as follows: 1 ml from the injectable solution of Gerovital® H³ will be administered subcutaneously and after 24 hours the test should be repeated with 1.5 ml solution intramuscularly. If any allergic reaction occurs, the treatment is not recommended.

- For protection of the organism against aging phenomena (standard schedule), alternative courses of injections and tablets of Gerovital® H³ should be administered, as follows:

Injectable solution: 1 intramuscular injection, 3 times a week (one ampoule every other day), over a period of 4 weeks (12 ampoules).

Sugar-coated tablets: 2 sugar-coated tablets/ day, after meals, in the morning and in the afternoon, for 12 days.

Series of injections and sugar-coated tablets should be alternated yearly, continuously or with one-month pause between them. The schedule and the frequency of pauses will be decided by the geriatrist, according with the aging status of the patient.

Curative treatment:

- Depressive syndrome:

1-st week: 1 ampoule i.m. /day, 3 times a week (i.e., on Monday, on Wednesday and on Friday);

2-nd and 3-rd week: 1 ½ ampoules i.m., 3 times a week;

4 – th week: 2 ampoules i.m., 3 times a week.

The treatment should be repeated 4-6 times a year.

- Parkinsonian syndromes:

Daily administration of 1 ampoule i.m. and two sugar-coated tablets, for 15 days.

- Osteoarthritis:

1 ampoule i.m. / day, for 15-21 days and then 1 ampoule i.m. 3 times a week (every other day), for 4 weeks, repeated of 4-5 times /year. During the pauses in injections series, 1-2 sugar-coated tablets / day, 12-18 days / month, can be administrated.

- Systemic arteriosclerosis:

Depending of the intensity and the localization of the process, the treatment should be as follows: 1 ampoule i.m. / day, 3 times a week, 4 weeks (12 ampoules), repeated 5-6 times /year. Between the injections series, oral treatment may be added - 2 sugar-coated tablets /day, 12 days. In some cases the treatment can be exclusively oral: 3 sugar-coated tablets/ day, 21 days in 6-8 series / year.

Adverse reactions, which can occur during the use of the medicinal product:

Administration of Gerovital® H³ may produce allergic reactions in patients with hypersensitivity to procaine like skin rash or pruritus. These effects impose an immediate stop of the treatment.

Minor effects may occur especially at the beginning of the treatment like: dizziness, weakness and palpitations. These effects can be avoided if after the injection the patient rests in bed for 10-15 minutes.

Overdose:

There are no reports of overdose related to administration of Gerovital® H³. In case of accidentally injection of high doses, severe hypotension, convulsions, coma, respiratory arrest may occur.

The treatment is symptomatic and support of vital functions.

Storage:

Store below 25⁰ C.

Keep out of the reach of children.

Do not use after the expiry date printed on the package.

Packaging:

Primary package: brown ampoule of 5 ml

Secondary package: folding box with 5 brown ampoules of 5 ml
folding box with 10 brown ampoules of 5 ml

The date of the last revision of the leaflet:

May, 2002