
Technical Information

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Supersedes issue dated November 2008

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Dexpanthenol Ph.Eur.

Ph. Eur., USP

1. Medical indication

Dexpanthenol increases the healing of wounds, stimulates the epithelization, and has anti-inflammatory properties, which is why it is applied locally.

The substance is applied orally (with other vitamins) as food supplement, or as therapeutic supportive for the treatment of inflammation of the oral cavity and the throat (lozenges).

Furthermore, Dexpanthenol is applied parenterally in combination with other vitamins for the prophylaxis or therapy of malnutrition and drastic lack of vitamins, disorders of the vitamin absorption from the gastrointestinal tract, and vitamin-consuming diseases. In addition, such injectable vitamin preparations with Dexpanthenol are used for completing parenteral nutrition.

Pharmaceutical formulations which are available on the market include:

• Topical formulations (local application)

- Creams, gels, ointments, solutions and foam spray (skin)
- Eye drops, gels, and ointments
- Nose sprays and gels
- Ear drops
- Mouth sprays

• Oral dosage forms

- Tablets and lozenges
- Soft gelatin capsules
- Oral solutions
- Syrups

• Injectables

- Injection solutions for i.m. and i.v. application
- Infusion solutions

Application

Dexpanthenol is an active pharmaceutical ingredient for topical, oral, and injectable application.

Pharmacology

Dexpanthenol is the corresponding alcohol to Pantothenic acid (Pantoyl- β -alanine, Vitamin B₅).

Pantothenic acid is a compound of Coenzyme A, which is a cofactor for a number of biochemical and enzyme-catalyzed reactions for the transfer of acetyl groups: Composition and decomposition of fatty acids, oxidative metabolism of carbohydrates, biosynthesis of steroids etc.

Pharmacokinetics

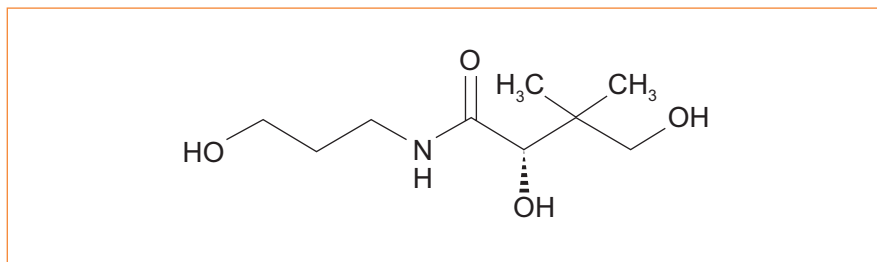
Coenzyme A is a food compound and is hydrolyzed in the intestines to Pantothenic acid. Dexpanthenol and D-Pantothenic acid are absorbed rapidly and completely from the small intestines. In the blood, Pantothenic acid is bound to plasma proteins. Inside the cells, Pantothenic acid is transformed to coenzyme A. The substance is eliminated via the kidneys.

2. Chemical information

Synonyms

Panthenol, Pantothenyl alcohol

Structural formula



Molecular formula

C₉H₁₉O₄N

Molar mass

205.3 g/mol

CAS-No.

81-13-0

Description

Dexpanthenol Ph.Eur. is a colorless to slightly yellowish, viscous liquid or semi-crystalline substance.

3. Grades

PRD-No.	
30276997	Dexpanthenol Ph.Eur. 25 kg 0.25 kg (sample)

Retests period

See separate documentation: "Q&R PI (not for regulatory purposes)" available at BASF's WorldAccount: <https://worldaccount.basf.com> (registered access).

4. Specification

See separate document: "Standard Specification (not for regulatory purposes)" available via BASF's WorldAccount: <https://worldaccount.basf.com> (registered access).

5. Regulatory status

Meets current Ph. Eur. and USP monographs.
CEP is available and can be issued to customers on request.
EDMF and JDMF are available upon request and when necessary.

6. Storage

Dexpanthenol Ph.Eur. should be stored in the original container or in airtight, well-filled containers, and protected from light and humidity.

7. Formulations

Dexpanthenol is very hygroscopic and can thus be easily dissolved in water for the production of liquid or semi-solid formulations.

The following example is given for a gel-cream:

Dexpanthenol Gel-Cream (5%)

1. Formulation

Dexpanthenol Ph.Eur. (BASF)	5 g
Liquid paraffin.....	10 g
Lutrol E 400 (BASF)	15 g
Lutrol F 127 (BASF)	18 g
Water	52 g

2. Manufacturing

Dissolve Dexpanthenol Ph.Eur. and Lutrol E 400 in water, add liquid paraffin and stir while heating to 60 – 70 °C. Add Lutrol F 127 slowly and stir until it is dissolved. Cool to room temperature while stirring continuously until the air bubbles disappear.

3. Properties of the gel

Soft turbid gel-cream.

4. Physical stability (3 months, 40 °C)

No change of the appearance and viscosity.

Note

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