



## TECHNICAL DATA SHEET

009673-TDS-ENG-2023

DEXPANTENOL PH.EUR. (D-PANTENOL)		
DESCRIPTION DCI: DEXPANTENOL		DESCRIPTION DOE: DEXPANTHENOL
CAS N°: 81-13-0	EC N°: 201-327-3	AEMPS CODE: ---
MOL. WEIGHT: 205.25	MOL. FORMULA: C <sub>9</sub> H <sub>19</sub> NO <sub>4</sub>	ARTICLE CODE: 009673

ATTRIBUTES	SHOULD BE
Appearance	Colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 %) and practically insoluble in heptane
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6
pH	= < 10.5
Specific optical rotation	+29.0 / +32.0
Impurity A and other amino compounds	= < 1.0 %
Related substances	
Impurity C	= < 1.0 %
Impurity B	= < 0.5 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 2.0 %
Water	= < 1.0 %
Sulfated ash	= < 0.1 %
Assay	98.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

### REMARKS

Dexpantenol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

### Properties and uses

It is a vitamin factor of the group of vitamins B, acting as a precursor of coenzyme A, a substance required in numerous biochemical processes, such as the production of energy and the metabolism of fats, carbohydrates and proteins. When administered orally, it rapidly oxidizes to the acid form (pantothenic acid or vitamin B5). The dexpantenol solutions are stable at pH = 4-7 (with an optimum pH of 6). It is used in the treatment of intestinal atony, constipation, paralytic ileus, alopecia, and skin regeneration. It is generally used in liquid multivitamin preparations, replacing the pantothenate. It



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typically has a healing, anti-seborrheic, and eutrophic action on the hair follicle (from which it derives its use in lotions for seborrheic alopecia). It is used in the form of ointments, ointments, creams, lotions, or solutions, in the therapy of burns, various dermatoses, and infected ulcers. It has also been administered for the purpose of reducing the adverse reactions of streptomycin and salicylates. It is also used in cosmetic preparations for its moisturizing and moisturizing action, and for its stimulation effect on epithelial metabolism.

### Dosage

Intramuscular route for the prevention or control of gastrointestinal atony, in doses of approximately 250 - 500 mg (the necessary dose has not yet been established). Topical route, usually at 0.5 - 5%.

### Side effects

In general, they are mild and transient, and can rarely cause allergic reactions because they are a hypersensitizing agent.

### Contraindications

It is contraindicated in hemophilic patients and in individuals with mechanical intestinal obstruction.

### Precautions

It should be used with caution when used together or immediately after parasympathomimetic drugs or suxamethonium.

### Incompatibilities

Strong acids and alkalis.

### Other observations

It is thermolabile. During storage it can crystallize.

### Formulation examples

#### *Solution for vitiligo*

DEXPANTHENOL - **5 %**

Hydroalcoholic solution 25 % c.s.p. - **100 mL**

Modus operandi: Dissolve the DEXPANTHENOL with part of the alcohol, and then incorporate the remaining water and alcohol.