

DECISION

No. 22/12.08.2013

on approval of abbreviated Romanian Standard Terms for the labelling of parenteral, eye, ear and nasal preparations, in line with European Pharmacopoeia approved terms

The Scientific Council of the National Agency for Medicines and Medical Devices, established based on Order of the Minister of Health No. 158/18.02.2013, in accordance with the Regulation on the organisation and operation of the Scientific Council of the NAMMD, Article 8 (1), hereby adopts through written procedure the following

DECISION

Sole article - The abbreviated Romanian Standard Terms for the labelling of parenteral, eye, ear and nasal preparations in line with European Pharmacopoeia approved terms are approved, according to the annex which is integral part of this decision.

PRESIDENT

of the Scientific Council

of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ABBREVIATED ROMANIAN STANDARD TERMS

For parenteral, eye, ear and nasal preparations, in line with

abbreviated European Standard Terms

(Short /Patient friendly Terms)

approved by

*the European Pharmacopoeia Commission,
the European Directorate for the Quality of Medicines (EDQM),
the European Council, Strasbourg*

The Lists of European Standard Terms have been set up by the European Pharmacopoeia Commission at the request of the European Commission, to ensure their harmonised use in Marketing Authorisations (MAs), Summary of Product Characteristics (SmPCs), leaflets, labelling and European electronic medicinal product databases.

Standard terms serve a double purpose: to inform the patient/user/physician and make a difference between products with the same invented name. Given the object of the leaflet and labelling, all standard terms and combinations of standard terms must take account of the patient's condition.

Standard terms must express vital information about the properties and use of medicinal products. Vital information to be provided for all medicinal products is the „pharmaceutical form”, defined as follows:

The EDQM *Standard Terms Introduction and Guidance for Use* states:

„A *pharmaceutical form* is a combination between the form of a medicinal product presentation by the manufacturer (*presentation form*) and its manner of administration, including its physical form (*administration form*)”.

The List of European standard terms for pharmaceutical forms represents the basic terms required for characterisation of pharmaceutical forms. Standard terms can be used for medicinal products for human and veterinary use. These terms are called *full standard terms*.

Since the size of the label of certain pharmaceutical forms does not allow use of a full standard term, the use of *short standard terms* is exceptionally allowed, as approved by the *European Pharmacopoeia Commission*.

The following **Abbreviated Romanian Standard Terms** can only be used for the labelling of certain pharmaceutical forms, if the label size does not allow print of a full standard term.

Preparate oftalmice				
Eye preparations				
Whole Standard Terms		No.1) monogr. of Ph. Eur.	Abbreviated Standard Terms	
Romanian	English		Romanian	English

Cream oftalmică	<i>Eye cream</i>	No. 1163	-	-
Gel oftalmic	<i>Eye gel</i>	No. 1163	-	-
Unguent oftalmic	<i>Eye ointment</i>	No. 1163	-	-
Picături oftalmice, soluție	<i>Eye drops, solution</i>	No. 1163	Picături oftalmice*	<i>Eye drops*</i>
Picături oftalmice, suspensie	<i>Eye drops, suspension</i>	No. 1163	Picături oftalmice*	<i>Eye drops*</i>
Picături oftalmice, pulbere și solvent pentru soluție	<i>Eye drops, powder and solvent for solution</i>	No. 1163	-	-
Picături oftalmice, pulbere și solvent pentru suspensie	<i>Eye drops, powder and solvent for suspension</i>	No. 1163	-	-
Solvent oftalmic pentru reconstituire	<i>Eye drops, solvent for reconstitution</i>	-	-	-
Picături oftalmice cu eliberare prelungită	<i>Eye drops, prolonged-release</i>	No. 1163	-	-
Soluție pentru baie oculară	<i>Eye lotion</i>	No. 1163	-	-
Solvent pentru baie oculară	<i>Eye lotion, solvent for reconstitution</i>	-	-	-
Insert oftalmic	<i>Ophthalmic insert</i>	No. 1163	-	-
Bandă oftalmică	<i>Ophthalmic strip</i>	-	-	-

Preparate auriculare <i>Ear preparations</i>				
Whole Standard Terms		No.1) monogr. of Ph. Eur.	Abbreviated Standard Terms	
Romanian	English		Romanian	English
Cream auriculară	<i>Ear cream</i>	No. 652	-	-
Gel auricular	<i>Ear gel</i>	No. 652	-	-

Unguent auricular	<i>Ear ointment</i>	No. 652	-	-
Picături auriculare, soluție	<i>Ear drops, solution</i>	No. 652	Picături auriculare *	<i>Ear drops</i> *
Picături auriculare, suspensie	<i>Ear drops, suspension</i>	No. 652	Picături auriculare *	<i>Ear drops</i> *
Picături auriculare, pulbere și solvent pentru suspensie	<i>Ear drops, powder and solvent for suspension</i>	No. 652	-	-
Picături auriculare, emulsie	<i>Ear drops, emulsion</i>	No. 652	Picături auriculare *	<i>Ear drops</i> *
Pulbere auriculară	<i>Ear powder</i>	No. 652	-	-
Spray auricular, soluție	<i>Ear spray, solution</i>	No. 652	Spray auricular *	<i>Ear spray</i> *
Spray auricular, suspensie	<i>Ear spray, suspension</i>	No. 652	Spray auricular *	<i>Ear spray</i> *
Spray auricular, emulsie	<i>Ear spray, emulsion</i>	No. 652	Spray auricular *	<i>Ear spray</i> *
Soluție pentru spălări auriculare	<i>Ear wash, solution</i>	No. 652	Spălări auriculare *	<i>Ear wash</i> *
Emulsie pentru spălări auriculare	<i>Ear wash, emulsion</i>	No. 652	Spălări auriculare *	<i>Ear wash</i> *
Tampon auricular	<i>Ear tampon</i>	No. 1155	-	-
Creion auricular	<i>Ear stick</i>	No. 1154	-	-

Preparate nazale <i>Nasal preparations</i>				
Whole Standard Terms		No.1) monogr. of Ph. Eur.	Abbreviated Standard Terms	
Romanian	English		Romanian	English
Cream nazală	<i>Nasal cream</i>	No. 676	-	-
Gel nazal	<i>Nasal gel</i>	No. 676	-	-

Unguent nazal	<i>Nasal ointment</i>	No. 676	-	-
Picături nazale, soluție	<i>Nasal drops, solution</i>	No. 676	Picături nazale*	<i>Nasal drops*</i>
Picături nazale, suspensie	<i>Nasal drops, suspension</i>	No. 676	Picături nazale*	<i>Nasal drops*</i>
Picături nazale, emulsie	<i>Nasal drops, emulsion</i>	No. 676	Picături nazale*	<i>Nasal drops*</i>
Pulbere nazală	<i>Nasal powder</i>	No. 676	-	-
Spray nazal, soluție	<i>Nasal spray, solution</i>	No. 676	Spray nazal*	<i>Nasal spray*</i>
Spray nazal, suspensie	<i>Nasal spray, suspension</i>	No. 676	Spray nazal*	<i>Nasal spray*</i>
Spray nazal, emulsie	<i>Nasal spray, emulsion</i>	No. 676	Spray nazal*	<i>Nasal spray*</i>
Soluție pentru spălări nazale	<i>Nasal wash</i>	No. 676	-	-
Creion nazal	<i>Nasal stick</i>	No. 676	-	-