

**Order no. 251  
of 08/04/2002**

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On approval of the List containing medicinal products for human and veterinary use containing substances which fall under the scope of Law 143/2000 on illicit drug traffic and consumption control

No. 251/240/292

The Ministry of Health and Family  
The Ministry for Food, Agriculture and Forestry  
The Ministry of Industry and Resources

The Ministry of Health and Family, the Ministry for Food, Agriculture and Forestry and the Ministry of Industry and Resources,

Taking into account the provisions of Law no. 143/2000 on illicit drug traffic and consumption control, as amended,

Based on Art. 2 (5) of Government Decision no. 1.359/2000 on approval of the Regulation for enforcement of provisions of Law no. 143/2000 on illicit drug traffic and consumption control,

Based on provisions of Government Decision no. 22/2001 on the organization and operation of the Ministry of Health and Family, as amended,

Based on provisions of Government Decision no. 362/2002 on the organisation and operation of the Ministry for Food, Agriculture and Forestry, as amended,

Based on provisions of Government Decision no. 19/2001 on the organisation and operation of the Ministry of Industry and Resources, as amended,

Based on Approval Report no. DB.3485 of 2 April 2002,  
Hereby issue the following Order:

**Art. 1.** - The List containing medicinal products for human and veterinary use containing substances which fall under the scope of Law 143/2000 on illicit drug traffic and consumption control is approved and attached in the Annex which is integral part of this Order.

**Art. 2.** – The List mentioned under Art. 1 contains the medicinal product containing conditioned active substance under any pharmaceutical form.

**Art. 3.** – Prescription by physicians and release by pharmacists of the medicinal products specified in this Annex under point A are performed in accordance with the provisions of Law no. 73/1969 on the regime of narcotic substances and products and of the Ministry of Health Directions no. 103/1970 for enforcement of the provisions of Law no. 73/1969 and in accordance with the classification of the medicinal products mentioned under Art. 3 of Emergency Government Ordinance no. 152/1999 on medicinal products for human use, as amended.

**Art. 4.** - **(1)** The prescription, release and use of medicinal products for human use specified in the Annex under point B are performed in accordance with the provisions of Law no. 73/1969 on the regime of narcotic substances and products and of the Ministry of Health Directions no. 103/1970 for enforcement of the provisions of Law no. 73/1969.

**(2)** Medicinal products for human use are prescribed and released by veterinaries in accordance with the provisions of this Annex, point B (last column of the table).

**Art. 5.** – The update of the List in the Annex to this Order shall be performed by the same authorities whenever required.

**Art. 6.** - The Ministry of Health and Family, The Ministry for Food, Agriculture and Forestry, The Ministry of Industry and Resources, via their special directorates, shall fulfil the provisions of this Order.

**Art. 7.** – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of Health and Family,  
Daniela Bartoş

Minister of for Food, Agriculture and Forestry,  
Ilie Sârbu

Minister of Industry and Resources,  
Mihai Berinde,  
Secretary of state

**LIST**

containing medicinal products for human and veterinary use containing substances which fall under the scope of Law 143/2000 on illicit drug traffic and consumption control

\*) The Annex is facsimiled.

**A. Medicinal products for human use recorded/authorised for marketing in Romania**

**a) Medicinal products containing substances from the second table of Law no. 143/2000**

No. crt.	Name of the active substance	Medicinal product containing the substance Commercial name	Pharm. form, strength	Manner of Prescription and release
1.	CODEINUM	CODEIN PHOSPHATE CODEINĂ CODEINĂ FOSFAT CODEINĂ FOSFORICĂ CODEINĂ FOSFORICĂ-EEL CODELIN FARMACOD FOSFAT DE CODEINĂ	tablets 15 mg. tablets 15 mg. tablets 15 mg. tablets 15 mg. tablets 15 mg. tablets 15 mg. tablets 15 mg. tablets 15 mg.	P-RF P-RF P-RF P-RF P-RF P-RF P-RF P-RF
2.	COMBINATIONS CONTAINING CODEIN	ALGOSTOP ANTALGIC	tablets tablets	OTC P-RF

		ARDINEX CALMANT TUSE CODAMIN P EFERALGAN CODEINE FASCONAL M FASCONAL P FASCONORD GELONIDA GRIPECALM N-CALMANT N-TUSOCALM PARACOF PARAGRIP C PRODEINE SOLPADEINE SOLPADEINE SOLUBLE TUSINOGAL-A TUSOMAG	film-coated tablets tablets tablets effervescent tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets tablets effervescent tablets sirop sol. int.	P-RF P-RF OTC P-RF OTC OTC OTC OTC P-RF OTC OTC OTC OTC OTC OTC OTC OTC OTC OTC OTC OTC OTC OTC		
3.	EXTROPROPOXYPHENUM	DARVON N DARVON N DARVON N	capsules 100 mg capsules 50 mg capsules 65 mg	P-RF P-RF P-RF		
4.	DIHYDROCODEINUM	DHC CONTINUS DHC CONTINUS DHC CONTINUS	tablets ret. 120 mg tablets ret. 60 mg tablets ret. 90 mg	P-RF P-RF P-RF		
5.	FENTANYLUM	FENTANYL FENTANYL FENTANYL	solution for injection 0.05 mg/ml - 2 ml solution for injection 0.05 mg/ml - 10 ml solution for injection 0.05 mg/ml - 5 ml		S S S	
6.	HYDROMORPHONUM	HIDROMORFON	solution for injection 0.02% - 1 ml			P-TS
7.	COMBINATIONS CONTAINING HYDROMORFON	HIDROMORFON - ATROPINĂ HIDROMORFON - SCOPOLAMINA	solution for injection solution for injection			S/P-TS S/P-TS
8.	METHADONUM	METHADONE SINTALGON	oral solution 1 mg/ml tablets 2.5 mg			P-TS P-TS

9.	MORPHYNUM	DOLTARD - 100 mg	tablets ret. 100 mg	P-TS	P-TS
		DOLTARD - 30 mg	tablets ret. 30 mg	P-TS	
		DOLTARD - 60 mg	tablets ret. 60 mg	P-TS	
		MORFINĂ	solution for injection 2 mg/ml - 1 ml	P-TS	
		MST CONTINUS	tablets 100 mg	P-TS	
		MST CONTINUS	tablets 10 mg	P-TS	
		MST CONTINUS	tablets 200 mg	P-TS	
		MST CONTINUS	tablets 30 mg	P-TS	
		MST CONTINUS	tablets 60 mg	P-TS	
		SEVREDOL	film-coated tablets 10 mg	P-TS	
		SEVREDOL	film-coated tablets 20 mg	P-TS	
		SKENAN LP	capsules ret. 100 mg	P-TS	
		SKENAN LP	capsules ret. 10 mg	P-TS	
		SKENAN LP	capsules ret. 30 mg	P-TS	
		SKENAN LP	capsules ret. 60 mg	P-TS	
		VENDAL RETARD	tablets ret. 100 mg	P-TS	
VENDAL RETARD	tablets ret. 10 mg	P-TS			
VENDAL RETARD	tablets ret. 30 mg	P-TS			
VENDAL RETARD	tablets ret. 60 mg	P-TS			
10.	COMBINATIONS CONTAINING MORPHIN	ATROPIN MORPHIN	solution for injection		S/P-TS
11.	PETHIDINUM	MIALGIN	solution for injection 5 mg/ml - 2 ml		P-TS

**b) Pharmaceutical substances from table III of Law no. 143/2000**

No. crt.	Name of the active substance	Med. Prod. containing the substance Commercial name	Pharm. Form , strength	Manner of Prescription and release
1.	ALPRAZOLAMUM	ALPROX ALPROX ALPROX FRONTIN	tablets 0.25 mg tablets 0.5 mg tablets 1 mg tablets 0.25 mg	P-RF P-RF P-RF P-RF

		FRONTIN FRONTIN HELEX HELEX HELEX XANAX XANAX XANAX XANAX ZOLAREM 0.5	tablets 0.5 mg tablets 1 mg tablets 0.25 mg tablets 0.5 mg tablets 1 mg tablets 0.25 mg tablets 0.5 mg tablets 1 mg tablets 2 mg tablets 0.5 mg	P-RF P-RF P-RF P-RF P-RF P-RF P-RF P-RF P-RF P-RF
2.	AMFEPRAMONUM	REGENON	capsules 25 mg	P-RF
3.	AMOBARBITALUM	AMOBARBITAL AMITAL 200	tablets 100 mg tablets 200 mg	P-RF P-RF
4.	BROMAZEPAMUM	BROMAZEPAM BROMAZEPAM CALMEPAM (R) CALMEPAM (R) LEXOTANIL LEXOTANIL (R) LEXOTANIL (R) LEXOTANIL (R)	tablets 1.5 mg tablets 3 mg tablets 1.5 mg tablets 3 mg tablets 3 mg tablets 1.5 mg tablets 3 mg tablets 6 mg	P-RF P-RF P-RF P-RF P-RF P-RF P-RF P-RF
5.	CHLORDIAZEPOXIDUM	NAPOTON	drajeuri 10 mg	P-RF
6.	CLONAZEPAMUM	CLONAZEPAM RIVOTRIL RIVOTRIL	tablets 2 mg tablets 0.5 mg tablets 2 mg	P-6L P-6L P-6L
7.	CLORAZEPAS DIKALII	TRANXENE (R) 10 TRANXENE (R) 5	Capsules 10 mg Capsules 5 mg	P-RF P-RF
8.	COMBINAȚII CONȚINÂND PHENOBARBITAL	CALMANT TUSE DISTONOCALM EXTRAVERAL EXTRAVERAL EXTRAVERAL IAȘI FASCONAL M FASCONAL P LIZADON P	tablets film-coated tablets tablets tablets tablets tablets tablets capsules	P-RF P-6L OTC OTC P-RF OTC S P-6L

9.	CYCLOBARBITALUM	CICLOBARBITAL SARE DE CALCIU	tablets 200 mg	P-RF	
10.	DIAZEPAMUM	DIAZEPAM DIAZEPAM DIAZEPAM DIAZEPAM DIAZEPAM DIAZEPAM	tablets 10 mg tablets 2 mg tablets 5 mg solution for injection 5 mg/ml - 2 ml rectal solution 10 mg/2.5 ml rectal solution 5 mg/2.5 ml	P-RF P-RF P-RF P-RF P-RF P-RF	P-RF
11.	FLUNITRAZEPAMUM	NILIUM ROHYPNOL FLUNITRAZEPAM FLUNITRAZEPAM	tablets 2 mg tablets 1 mg tablets 1 mg tablets 2 mg	P-RF P-RF P-RF P-RF	
12.	GLUTETHIMIDUM	GLUTETIMID	tablets 250 mg	P-RF	
13.	LORAZEPAMUM	LORIVAN MERLIT	tablets 1 mg tablets 2 mg	P-RF P-RF	
14.	MEDAZEPAMUM	ANSILAN EUROZEPAM MEDAZEPAM MEDAZEPAM 10 mg RUDOTEL	capsules 10 mg capsules 10 mg tablets 10 mg tablets 10 mg tablets 10 mg	P-RF P-RF P-RF P-RF P-RF	
15.	MEPROBAMATUM	MEPROBAMAT	tablets 400 mg	P-RF	
16.	MIDAZOLAMUM	DORMICUM DORMICUM DORMICUM FULSED INJECTION FULSED INJECTION FULSED INJECTION	film-coated tablets 7.5 mg solution for injection 1 mg/ml - 5 ml solution for injection 5 mg/ml - 1 ml solution for injection 1 mg/ml - 10 ml solution for injection 1 mg/ml - 5 ml solution for injection 5 mg/ml - 1 ml	P-RF S S S S S	
17.	NITRAZEPAMUM	NITRAZEPAM NITRAZEPAM	tablets 2.5 mg tablets 5 mg	P-RF P-RF	
18.	OXAZEPAMUM	OXAZEPAM	tablets 10 mg	P-RF	
19.	PENTAZOCINUM	FORTRAL	tablets 50 mg	S/P-RF	



		FORTRAL	solution for injection 30 mg/ml	P-RF
20.	PHENOBARBI-TALUM	FENOBARBITAL FENOBARBITAL FENOBARBITAL FENOBARBITAL	tablets 100 mg tablets 15 mg solution for injection 10% - 2 ml solution for injection 4% - 1 ml	P-RF P-RF P-RF P-RF
21.	TETRAZEPAMUM	MYOLASTAN RELAXAM	film-coated tablets 50 mg film-coated tablets 50 mg	P-RF P-RF

c) Pharmaceutical substances containing substances from table IV of Law no. 143/2000

No. crt.	Name of the active substance	Med. Prod. containing the substance Commercial name	Pharm. Form, strength	Manner of prescription and release
1.	COMBINAȚII CONȚINÂND PSEUDOEFEDRINĂ	ACTIFED CLARINASE CLARINASE REPETABS HUMEX RĂCEALĂ ȘI GRIPĂ MAXIMUM STRENGTH SINUS MULTI SYMPTOM F. TYLENOL COLD NUROFEN RĂCEALĂ ȘI GRIPĂ PARACETAMOL SINUS RINOALERSIN RINOALERSIN FORTE	tablets film-coated tablets film-coated tablets tablets + capsules  film-coated tablets  tablets film-coated tablets  tablets tablets tablets	OTC  P-6L P-6L OTC  OTC  OTC  OTC OTC OTC
2.	EPHEDRINI HYDROCHLORIDUM	EFEDRINĂ EFEDRINĂ EFEDRINĂ	tablets 50 mg solution for injection 10 mg/ml - 1 ml solution for injection 50 mg/ml - 1 ml	P-RF S S
3.	ERGOMETRINUM	ERGOMET	solution for injection 0.2 mg/ml - 1 ml	P-RF

4.	COMBINAȚII CU ERGOTAMINĂ	COFEDOL	lozenges	P-6L
5.	PSEUDOEFEDRINUM	PSEUDOEPHEDRINE SUDAFED	tablets 30 mg film-coated tablets 60 mg	OTC OTC
6.	COMBINAȚII CONȚINÂND EFEDRINĂ	BIXTONIM NAZOCIN RHINOIL RINONEF-T UVOFED	solution for external use solution for nasal irrigation solution for external use solution for external use solution for external use	OTC OTC OTC OTC OTC

**NOTE:**

The last section, "Manner of prescription and release" contains the manner of release established in accordance with Art. 3 and 4 of Emergency Government Ordinance [no. 152/1999](#) on medicinal products for human use, as amended, the coded manner of release in accordance with the Scientific Council Decision of the National Medicines Agency no. 9 of 15 April 1999, as follows:

- S = medicinal products used only in specialised institutions (hospitals, clinics etc.);
- P-6L = medicinal products released in pharmacies based on medical prescription with a 6-month availability;
- P-RF = medicinal products released in pharmacies based on medical prescription which is retained by the pharmacy;
- P-TS = medicinal products released in pharmacies based on embossed stamp prescription;
- OTC = medicinal products which may be released in pharmacies or drugstores without medical prescription.

**B. Medicinal products for veterinary use recorded in Romania**

No. crt.	Name of the active substance	Medicinal product containing the substance Commercial	Pharmaceutical form, strength	Manner of prescription and release
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		name		
1.	APOMORFINA	FILTALON	solution for injection vials x 2 ml	P-TS
2.	ACEPROMAZINA MALEAT	NEUROTRANQ	solution for injection ampoules x 50 ml	P-RF
3.	KETAMINA CLORHIDRAT	KETAMINE 10% KETAMINE IMALGENE 500 IMALGENE 1000 VETASED KETAMINOL 5 KETAMINOL 10 KETALROM KETAMIDOR 10%	solution for injection ampoules x 10 ml and 25 ml P-RF solution for injection ampoules x 10 ml P-RF solution for injection ampoules x 10 ml P-RF solution for injection ampoules x 10 ml P-RF solution for injection ampoules x 20 ml P-RF solution for injection ampoules x 20 ml P-RF solution for injection ampoules x 10 ml şi 20 ml P-RF solution for injection ampoules x 10 ml P-RF	P-RF P-RF P-RF P-RF P-RF P-RF
4.	MEDETOMIDINA CLORHIDRAT	DOMOSEDAN DOMITOR	solution for injection ampoules x 10 ml solution for injection ampoules x 10 ml	P-RF P-RF
5.	PENTOBARBITAL SODIC	EUTHANYL	solution for injection ampoules x 250 ml	P-RF
6.	PETIDINA CLORHIDRAT	MIALGIN 5%	solution for injection ampoules x 250 ml	P-TS
7.	PROMETAZINA	ALERGOTRAT 3% ALERGOTRAT B	solution for injection ampoules x 10 ml, 20 ml, 50 ml P-RF solution for injection ampoules x 20 ml and 50 ml P-RF	P-RF P-RF
8.	PROPIONIL PROMAZIN FOSFAT	COMBELEN	solution for injection ampoules x 25 ml and 100 ml P-RF	P-RF
9.	TIOPENTAL SODIC	ROMPENTAL	solution for injection ampoules x 20 ml	P-RF
10.	XILAZINA	XYLAJECT 2%	solution for injection ampoules x 25 ml	P-RF

NOTE:

- P-TS = embossed stamp prescription;
- P-RF = medical prescription which retained by the pharmacy.