



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2025
EMA/34446/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): promethazine

Procedure No. PSUSA/00002545/202404



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Prothazin 25 mg potahované tablety	not available	24/815/99-C	TEOFARMA S.R.L.	CZ
Atosil Filmdabletten 25 mg	not available	6245842.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Atosil Filmdabletten 25 mg	not available	6245842.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Atosil Injektionslösung N, 28,2 mg/ml	not available	6245368.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Atosil Tropfen, 22,6 mg/ml, Tropfen zum Einnehmen, Lösung	not available	6245291.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Promethazin-neuraxpharm 100 mg Filmdabletten	not available	43872.01.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Promethazin-neuraxpharm 50 mg Filmdabletten	not available	43872.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Promethazin-neuraxpharm 75 mg Filmdabletten	not available	53297.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Promethazin-neuraxpharm forte Tropfen zum Einnehmen, Lösung 100 mg/ml	not available	51344.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Prothazin® 25 mg Filmdabletten	not available	3000237.00.00	TEOFARMA S.R.L.	DE
Phenergan, filmoveertrukne tableer	not available	10097	OPELLA HEALTHCARE FRANCE SAS	DK
Fenergán® crema Prometazina	not available	17471	TEOFARMA S.R.L.	ES
PHENERGAN 25 mg, comprimé enrobe.	not available	34009 301 879 3 7	LABORATOIRES FRILAB	FR
Phenergan 25 mg Film-Coated Tablets	not available	PA23180/011/002	OPELLA HEALTHCARE FRANCE SAS	IE
Phenergan 25 mg Film-Coated Tablets	not available	PA23180/011/002	OPELLA HEALTHCARE FRANCE SAS	IE

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Phenergan 25 mg Film-Coated Tablets	not available	PA23180/011/002	OPELLA HEALTHCARE FRANCE SAS	IE
Phenergan 25 mg Film-Coated Tablets	not available	PA23180/011/002	OPELLA HEALTHCARE FRANCE SAS	IE
Phenergan 25 mg Film-Coated Tablets	not available	PA23180/011/002	OPELLA HEALTHCARE FRANCE SAS	IE
Phenergan 5mg/5ml Oral Solution	not available	PA23180/011/001	OPELLA HEALTHCARE FRANCE SAS	IE
Phenergan 25 mg filmuhúðaðar töflur.	not available	870134	OPELLA HEALTHCARE FRANCE SAS	IS
FARGANESSE	not available	026964039	ANSERIS FARMA SRL	IT
FARGANESSE	not available	026964015	ANSERIS FARMA SRL	IT
FENAZIL 2% crema	not available	003311053	SELLA	IT
FENAZIL 2% crema	not available	003311053	SELLA	IT
FENAZIL 2% crema	not available	003311053	SELLA	IT
FENAZIL 2% crema	not available	003311053	SELLA	IT
FENAZIL 2% matita cutanea	not available	003311038	SELLA	IT
REACTIFARGAN	not available	002516045	JOHNSON & JOHNSON S.P.A.	IT
REACTIFARGAN	not available	002516060	JOHNSON & JOHNSON S.P.A.	IT
Phenergan 25 mg tabletter	not available	2366	OPELLA HEALTHCARE FRANCE SAS	NO
Lergigan 1 mg/ml oral lösning	not available	4172	VIATRIS AB	SE
Lergigan 25 mg filmdragerade tabletter	not available	4171	VIATRIS AB	SE
Lergigan mite 5 mg filmdragerade tabletter	not available	4174	VIATRIS AB	SE
Prothazin 25 mg	not available	14/0289/01-S	TEOFARMA S.R.L.	SK
Avomine 25mg Tablets	not available	PL 15833/0003	MANX PHARMA LTD	XI
Careway Nausea Relief 25mg Tablets	not available	PL 15833/0003	MANX PHARMA LTD	XI
Careway Travel Sickness and Nausea 25mg Tablets	not available	PL 15833/0003	MANX PHARMA LTD	XI
LloydsPharmacy Nausea	not available	PL 15833/0003	MANX PHARMA LTD	XI

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Relief 25mg Tablets				
Lloydspharmacy Travel Sickness and Nausea 25mg Tablets	not available	PL 15833/0003	MANX PHARMA LTD	XI
Numark Travel Sickness Relief 25mg Tablets	not available	PL 15833/0003	MANX PHARMA LTD	XI
Phenergan 25 mg Tablets	not available	PL 53886/0055	OPELLA HEALTHCARE UK LIMITED, TRADING AS SANOFI	XI
Phenergan 25 mg/ml Solution for Injection	not available	PL 53886/0056	OPELLA HEALTHCARE UK LIMITED, TRADING AS SANOFI	XI
Phenergan 25 mg/ml Solution for Injection	not available	PL 53886/0056	OPELLA HEALTHCARE UK LIMITED, TRADING AS SANOFI	XI
Phenergan Elixir 5 mg/5 ml Oral Solution	not available	PL 53886/0057	OPELLA HEALTHCARE UK LIMITED, TRADING AS SANOFI	XI
Phenergan Night Time 25 mg Film-coated Tablets	not available	PL 53886/0058	OPELLA HEALTHCARE UK LIMITED, TRADING AS SANOFI	XI
Promethazine Teoclate 25mg Tablets	not available	PL 15833/0003	MANX PHARMA LTD	XI
Vertigon® 25mg Tablets	not available	PL 15833/0028	MANX PHARMA LTD	XI