

EDA PSUR Supplementary List V.6 dated 02-08-2023

Active Ingredient	Suggested Reference From EURD list	PSUR submission Frequency	DLP	Submission date	Next DLP	Next submission date	Notes
Lubiprostone	Lubiprostone from removed entries in EURD list	1 year	29\08\2023	07\11\2023	29\08\2024	07\11\2024	
Daclatasvir	Sofosbuvir	3 years	05\12\2024	05\03\2025		05\03\2028	
Limaprost	Limaprost from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Mitiglinide	Mitiglinide from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Dalfampridine	Fampridine	3 years	21\01\2023	21\04\2023		21\04\2026	
Omeprazole + Sodium bi-carbonate	Omeprazole	5 years	15\04\2027	14\07\2027		14\07\2032	
Bupivacaine Hydrochloride + Fentanyl (Injection)	Fentanyl (transdermal patches, solution for injection - nationally authorised product only)	1 year	30\04\2024	09\07\2024	30\04\2025	09\07\2025	PSUR frequency updated
Edaravone	Japan only	1 year	12\12\2023	20\02\2024	12\12\2024	20\02\2025	
Loxoprofen	ibuprofen, ibuprofen lysine (not indicated in ductus arteriosus), ibuprofen / caffeine	3 years	18\02\2023	19\05\2023		19\05\2026	
Vilazodone	Trazodone	6 years	03\08\2023	01\11\2023		01\11\2029	PSUR frequency and DLP updated

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Gentamicin + Miconazole + Mometasone	Mometasone	3 years	22\05\2023	20\08\2023		20\08\2026	
Finerenone	Spironolactone	3 years	08\03\2024	06\06\2024		06\06\2027	
Moxifloxacin HCL+ Dexamethasone (Ophthalmic)	Levofloxacin + Dexamethasone (ocular use)	3 years	12\06\2025	10\09\2025		10\09\2028	PSUR frequency updated
Alcaftadine (Ophthalmic)	As the Innovator + FDA only	1 year	27\07\2022	05\10\2022	27\07\2023	05\10\2023	
Carboxymethyl Cellulose + Glycerin (Ophthalmic)	Carmellose (eye preparation)	13 years	01\10\2025	30\12\2025		30\12\2038	
Dexamethasone + Chlorpheniramine	Dexamethasone + Diphenhydramine hydrochloride	13 years	01\01\2025	01\04\2025		01\04\2038	
Gatifloxacin sesquihydrate (Ophthalmic)	Ofloxacin (Topical use)	3 years	16\04\2024	15\07\2024		15\07\2027	
Gemifloxacin	Levofloxacin (intravenous and oral use)	2 years	01\10\2023	30\12\2023		30\12\2025	PSUR frequency updated
Minodronic acid	Risedronate (Japan only)	1 year	01\05\2023	10\07\2023	01\05\2024	10\07\2024	
Rebamipide	Rebamipide from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Guaifenesin + Oxomemazine + Carbocisteine	Carbocisteine	13 years	14\09\2025	13\12\2025		13\12\2038	
Butenafine	Terbinafine	3 years	30\09\2025	29\12\2025		29\12\2028	
Retigabine	Retigabine from removed entries in EURD list	1 year	28\09\2023	07\12\2023	28\09\2024	07\12\2024	
Ferrous sulphate + Folic acid + Riboflavine +	Ascorbic acid + Biotin + Cyanocobalamin	10 years	27\09\2027	26\12\2027		26\12\2037	

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Pyridoxine HCl + Zinc sulfate + Nicotinamide + Ascorbic acid +Thiamine	+ Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine						
Neomycin sulfate + Nystatin + Triamcinolone acetone + Gramicidin	Neomycin sulfate + Nystatin + Triamcinolone acetone	13 years	01\01\2025	01\04\2025		01\04\2038	
Aluminium hydroxide gel + Magnesium hydroxide + Oxethazaine	Aluminium hydroxide gel + Dimeticone + Magnesium hydroxide	13 years	01\01\2025	01\04\2025		01\04\2038	
Glycerin + Carboxymethylcellulose + Sodium Hyaluronate	Glycerol	13 years	01\01\2025	01\04\2025		01\04\2038	
Ascorbic acid + Zinc	Ascorbic acid	13 years	25\02\2025	26\05\2025		26\05\2038	
Pipazethate	Non reference	1 year	01\05\2023	10\07\2023	01\05\2024	10\07\2024	
Favipravir	Remdesivir	6 months	06\05\2023	15\07\2023	06\11\2023	15/01/2024	
Artesunate + Sulfamethoxypyrazine + Pyrimethamine	Artesunate	6 months	22\12\2022	02\03\2023	22\06\2023	31\08\2023	
Naphazoline HCL + Pheniramine maleate	Naphazoline	12 years	31\07\2024	29\10\2024		29\10\2036	
Sulphamethoxazole + Trimethoprim + light Kaolin + Pectin	Sulphamethoxazole + Trimethoprim	8 years	31\03\2027	29\06\2027		29\06\2035	
Aluminium hydroxide gel + Magnesium hydroxide + Simeticone	Aluminium oxide + Magnesium hydroxide + Simeticone	13 years	01\01\2025	01\04\2025		01\04\2038	

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Ethanolamine Oleic acid	Ethanolamine	13 years	01\01\2025	01\04\2025		01\04\2038	
Metformin Hydrochloride + Repaglinide	Metformin	3 years	01\04\2024	30\06\2024		30\06\2027	
Paracetamol + Pseudoephedrine + Diphenhydramine	Paracetamol + Pseudoephedrine + Chlorpheniramine	13 years	01\01\2025	01\04\2025		01\04\2038	
Metoclopramide + Pyridoxine	Metoclopramide	3 years	17\11\2024	15\02\2025		15\02\2028	
Levodopa + Entacapone	Carbidopa + Entacapone + levodopa	3 years	17\10\2024	15\01\2025		15\01\2028	
Pemirolast	Japan only	1 year	30\04\2023	29\07\2023	30\04\2024	29\07\2024	
Tolmetin sodium	Aceclofenac	3 years	31\03\2023	29\06\2023		29\06\2026	
Sulfacetamide + Prednisolone	Prednisolone	6 years	03\08\2023	01\11\2023		01\11\2029	PSUR frequency and DLP were updated
Eperisone	Tolperisone	2 years	01\06\2024	30\08\2024		30\08\2026	PSUR frequency updated
Phenylephrine Hydrochloride + Hypromellose (Ophthalmic Solution)	Phenylephrine (Ophthalmic formulations)	5 years	01\01\2025	01\04\2025		01\04\2030	
Carbazochrome + Troxerutin	Carbazochrome	13 years	19\03\2025	17\06\2025		17\06\2038	
Meclofenoxate	Japan only	1 year	30\04\2023	09\07\2023	30\04\2024	09\07\2024	
Loratidine + Paracetamol + Pseudoephedrine	Paracetamol + Pseudoephedrine	5 years	28\06\2023	26\09\2023		26\09\2028	

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Ursodeoxychloic acid + Silymarin	Ursodeoxycholic acid, tauroursodeoxyc holic acid	10 years	30\11\2026	28\02\2027		28\02\2037	
Nitazoxanide	FDA only	1 year	29\07\2023	07\10\2023	29\07\2024	07\10\2024	
Imeglimin Hydrochloride	Japan only	1 year	30\04\2023	09\07\2023		09\07\2024	
Colestimide	Colesevelam	3 years	10/03/2024	08/06/2024		08\06\2027	
Molnupiravir	Newly authorized active ingredient	6 months	17\06\2023	26\08\2023	17\12\2023	25\02\2024	
Vitamin B1 + Vitamin B2 + Vitamin B6 + Nicotinamide + Dexpanthenol	Caffeine + Dexpanthenol+ Nicotinamide + Pyridoxine + Riboflavine + Thiamin	13 years	01\01\2025	01\04\2025		01\04\2038	
Vitamin B1 + Vitamin B2 + Vitamin B6 + Vitamin B12 + Nicotinamide + Calcium D- pantothenate + Ascorbic acid + Folic acid + Calcium phosphate + Ferrous sulphate + Potassium Iodide + Manganese sulphate + Potassium sulphate + Zinc sulphate	Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine	10 years	27\09\2027	26\12\2027		26\12\2037	
Guaifensine + Terpine + cineol + sodium benzoate	guaifenesin / herbal extracts	13 years	01\01\2025	01\04\2025		01\04\2038	
Cefdinir	Cefotaxime	3 years	18\12\2024	18\03\2025		17\03\2028	

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Sodium Chloride + Sodium Bicarbonate + Borax	Sodium Chloride	13 years	24\11\2025	22\02\2026		22\02\2039	
Benzoic acid + Salicylic acid (Topical)	Salicylic acid (Topical use)	13 years	25\04\2025	24\07\2025		24\07\2038	
Paracetamol + Pamabrom	Paracetamol + Orphenadrine citrate	13 years	01\01\2025	01\04\2025			
Chlorphenoxamine hydrochloride + Caffeine	Chlorphenoxamine hydrochloride	5 years	17\05\2023	15\08\2023		15\08\2028	
Phenylephrine Hydrochloride + Cyclopentolate Hydrochloride (Ophthalmic Solution)	Phenylephrine Hydrochloride (Ophthalmic)	5 years	01\01\2025	01\04\2025		01\04\2030	
Amoxicillin + Flucloxacillin	Amoxicillin	5 years	07\03\2022	05\06\2022		05\06\2027	
Vonoprazan	Japan only	1 year	23\08\2023	01\11\2023	23\08\2024	01\11\2024	
Doripenem	Meropenem	3 years	31\08\2024	29\11\2024		29\11\2027	PSUR frequency updated
Armodafinil	Modafinil	2 years	31\08\2023	09\11\2023		29\11\2025	PSUR frequency updated
Clidinium Bromide + Chlordiazepoxide	Acidinium Bromide	1 year	20\07\2023	28\09\2023	20\07\2024	28\09\2024	
Oxytetracycline hydrochloride + Polymyxin b	Hydrocortisone acetate + Oxytetracycline hydrochloride + Polymyxin b	13 years	01\01\2025	01\04\2025		01\04\2038	
Telmisartan + Amlodipine +	Olmesartan + Amlodipine +	5 years	24\04\2027	23\07\2027		23\07\2032	

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Hydrochlorothiazide	Hydrochlorothiazide						
Chlorzoxazone + Paracetamol	Chlorzoxazone	13 years	28\06\2025	26\09\2025		26\09\2038	
Silver sulfadiazine + Chlorhexidine Digluconate	Silver sulfadiazine	5 years	15\09\2025	14\12\2025		14\12\2030	
Dexpanthenol + Dexamethasone	Dexpanthenol + Hydrocortisone	13 years	01\01\2025	01\04\2025		01\04\2038	
Dextromethorphan + Chlorpheniramine	Dextromethorphan	5 years	01\11\2026	30\01\2027		30\01\2032	PSUR frequency and DLP were updated
Diloxanide + Metronidazole	Non reference	1 year	25\10\2023	03\01\2024	25\10\2024	03\01\2025	
Cyanocobalamin - Tannin complex in Aluminium monostearate	Cyanocobalamin	13 years	22\02\2025	23\05\2025		23\05\2038	
Magnesium hydroxide + Light Liquid Paraffin	Magnesium hydroxide	5 years	31\10\2026	29\01\2027		29\01\2032	
Nonoxynol-9	Non reference	1 year	01\05\2023	10\07\2023	01\05\2024	10\07\2024	
Revefenacin	Acridinium bromide	1 year	20\07\2023	28\09\2023	20\07\2024	28\09\2024	
Clofedanol	Pentoxifyverine	5 years	31\12\2023	30\03\2024		31\03\2029	
Paracetamol + Guaifenesin + Phenylephrine + Dextromethorphan	Dextromethorphan + Paracetamol + Phenylephrine	13 years	01\01\2025	01\04\2025		01\04\2038	
Chloramphenicol + Dexamethasone + Tetryzoline	Dexamethasone (Apart from centrally authorized products)	5 years	31\01\2026	01\05\2026		01\05\2031	

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Fluorometholone + Tetrahydrozoline	Fluorometholone	13 years	31\07\2025	29\10\2025		29\10\2038	
Difluprednate	Prednisolone	6 years	03/08/2023	01/11/2023		01\11\2029	PSUR frequency and DLP were updated
Sodium Chloride + Calcium Chloride + Potassium Chloride + Sodium acetate	succinylated gelatin, sodium chloride / sodium hydroxide / succinylated gelatin, calcium chloride / magnesium chloride / potassium chloride / sodium acetate / sodium chloride / succinylated gelatin, gelatin / sodium chloride / potassium chloride / magnesium chloride hexahydrate / sodium lactate	13 years	01\01\2025	01\04\2025		01\04\2038	
Sodium Chloride + Calcium Chloride + Potassium Chloride	calcium chloride dihydrate / magnesium chloride hexahydrate / malic acid / sodium acetate trihydrate / sodium chloride / potassium chloride, calcium chloride dihydrate /	13 years	01\01\2023	01\04\2023		31\03\2036	

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	sodium chloride / sodium lactate / potassium chloride, calcium chloride / sodium chloride / potassium chloride						
Sodium Chloride + Sodium Lactate + Calcium Chloride + Potassium Chloride	calcium chloride dihydrate / magnesium chloride hexahydrate / malic acid / sodium acetate trihydrate / sodium chloride / potassium chloride, calcium chloride dihydrate / sodium chloride / sodium lactate / potassium chloride, calcium chloride / sodium chloride / potassium chloride	13 years	01\01\2023	01\04\2023		31\03\2036	
Carvedilol + Hydrochlorothiazid e	Carvedilol	5 years	17\04\2027	16\07\2027		16\07\2032	
Hydroquinone +Tretinoin + Hydrocortisone (Topical)	Tretinoin (topical formulations)	5 years	31\08\2022	29\11\2022		29\11\2027	
Guaiaicol + Pholcodine	Non reference	1 year	29\05\2023	27\08\2023	29\05\2024	27\08\2024	
Ofloxacin + Dexamethasone	Levofloxacin + Dexamethasone (ocular use)	1 year	12\06\2023	21\08\2023	12\06\2024	21\08\2024	

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Tadalafil + finasteride	FDA only	1 year	31\08\2023	09\11\2023	31\08\2024	09\11\2024	
Terconazole	Terconazole from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Chlorzoxazone + Ketoprofen	ketoprofen (all formulations except topical)	5 years	23\01\2027	23\04\2027		22\04\2032	
Povidone Iodine+ Sucrose	Povidone iodinated	13 years	24\04\2025	23\07\2025		23\07\2038	
Acetylleucine	Acetylleucine from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Isotretinoin (Topical)	tretinoin (Topical formulations)	5 years	31\08\2022	29\11\2022		29\11\2027	
Mometasone furoate + Formoterol	Mometasone	3 years	22\05\2023	20\08\2023		20\08\2026	
Doxercalciferol	Doxercalciferol from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Paracetamol + Pseudoephedrine + Guaifenesin	Non reference	1 year	09\09\2023	18\11\2023	09\09\2024	18\11\2024	
Retapamulin	Retapamulin from removed entries in EURD list	3 years	11\04\2023	10\07\2023		10\07\2026	
Flibanserin	FDA only	1 year	09\09\2023	18\11\2023	09\09\2024	18\11\2024	
Ibuprofen + Methocarbamol	ibuprofen, ibuprofen lysine (not indicated in ductus arteriosus),	3 years	18\02\2023	19\05\2023		19\05\2026	

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	ibuprofen / caffeine						
Beta - Sitosterol	Phytosterol	13 years	01\01\2025	01\04\2025		01\04\2038	
Cefotetan Disodium	Second Generation Cephalosporins (cefprozil)	5 years	22\12\2022	22\03\2023		21\03\2028	
Acephylline piperazine	Pharmacovigilanc e committee decision	1 year	30\09\2023	09\12\2023	30\09\2024	09\12\2024	
Atenolol + Amiloride + Chlorthalidone	Atenolol + Chlorthalidone	5 years	09\09\2024	08\12\2024		08\12\2029	
Metaxalone	Metaxalone from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Amylocaine Hydrochloride + Benzocaine + Hamamelis Dry Extract (5% Tannines) + Zinc Oxide +Aesculus Dry Extract	Non reference	1 year	15\10\2023	24\12\2023	15\10\2024	24\12\2024	
Selenium + Manganese Sulphate monohydrate + Vit.E + Vit.C + Beta Carotene + Zinc Sulphate monohydrate + Cu Sulphate Monohydrate	Selenium	13 years	01\01\2025	01\04\2025		01\04\2038	
Vit.B1 + Vit.B2 + Vit.B6 + Folic acid + Calcium D Pantothenate +	ascorbic acid /biotin/cyanocob alamin/Folic acid/Nicotinamid	10 years	27\09\2027	26\12\2027		26\12\2037	

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Vit.C + Zinc Vit.B12 + Nicotinamide + Biotin + L-Carnitine	e/Pantothenic acid/ Pyridoxine hydrochloride/Ri boflavin/Thiamin e						
Acetylsalicylic acid + Magnesium carbonate + Aluminium glycinate	Japan only	2 years	01\02\2023	02\05\2023		02\05\2025	
Theophylline + Ambroxol + Guaiphenesin	Non reference	3 years	27\07\2026	25\10\2026		25\10\2029	
Tetrahydrozoline (Tetryzoline) + Zinc Sulphate	Tetryzoline	13 years	01\01\2025	01\04\2025		01\04\2038	
Terbutaline + Bromohexine HCL + Guaiphenesin + Menthol	Bromhexine	3 years	30\09\2023	29\12\2023		29\12\2026	
Bromhexine + Guaifenesin + Salbutamol	levosalbutamol, salbutamol	3 years	31\01\2023	01\05\2023		01\05\2026	
Tiemonium Methyl Sulphate	Pharmacovigilanc e committee decision	5 years	01\02\2023	02\05\2023		02\05\2028	
Magnesium oxide +Magnesium Gluconate	Magnesium oxide	13 years	30\06\2025	28\09\2025		28\09\2038	
Natural calcium carbonate from oyster shell eq.to calcium + Vitamin D3+ Sodium fluoride	Sodium fluoride	3 years	13\11\2022	11\02\2023		11\02\2026	
Lignocaine HCL + Clove oil + Geranium oil	lidocaine (topical use)	8 years	30\09\2028	29\12\2028		29\12\2036	

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L-Carnitine l-tartrate + Zinc gluconate	Carnitine	13 years	01\09\2025	30\11\2025		30\11\2038	
Biotin + Alpha lipoic acid	Biotin	7 years	01\01\2026	01\04\2026		01\04\2033	
Vitamin C + Vitamin B12 + L-lysine HCL + Ferrous glucine sulphate	Iron in any combination including one or more of the following: multivitamins /minerals / aminoacids / herbal extracts / lecithine (except for combinations with folic acid)	13 years	01\01\2025	01\04\2025		01\04\2038	
Keto analogues + Amino acids	Amino acid combinations (only combinations of pure amino acids or combination of amino acids with mineral compounds/electrolytes, i.v. application)	7 years	01\01\2026	01\04\2026		01\04\2033	
Magnesium carbonate + Citric acid	citric acid / magnesium / sodium, citric acid anhydrous / light magnesium oxide / sodium picosulfate	13 years	01\01\2025	01\04\2025		01\04\2038	
Codeine + Pseudoephedrine + Triprolidine	Pseudoephedrine + Triprolidine	3 years	31\12\2023	30\03\2024		31\03\2027	

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Brompheniramine maleate + Paracetamol + Pseudoephedrine Hydrochloride	Chlorpheniramine + Paracetamol + Pseudoephedrine	13 years	01/01/2025	01/04/2025		01\04\2038	
Glucose anhydrous + Sodium Chloride + Potassium chloride + Sodium Lactate	Glucose (apart from glucose1-phosphate) "all routes of administration", glucose in combination with calcium chloride and/or sodium chloride and/or magnesium chloride and/or sodium citrate and/or potassium chloride (intravenous or parenteral use)	10 years	02/09/2034	01/12/2034		01/12/2044	PSUR frequency and DLP were updated
Diosmin + Hesperidin + Ascorbic acid	Diosmin / hesperidin, ascorbic acid/ dry Ruscus extract titrated in sterolic heterosides/ Hesperidin methyl chalcone	13 years	01\01\2025	01\04\2025		01\04\2038	
Cefopeazone	Pharmacovigilance committee decision	3 years	11\01\2024	11\04\2024		11\04\2027	
Cefopeazone + Sulbactam	Pharmacovigilance committee decision	3 years	11\01\2024	11\04\2024		11\04\2027	

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Calcium Carbonate + Glycine + Dimethicone	Calcium carbonate/magnesium carbonate/simeticone	10 years	01\01\2029	01\04\2029		01\04\2039	
Heptaminol HCl	Heptaminol HCl from removed entries in EURD list	13 years	28\01\2025	28\04\2025		28\04\2038	
Hemicellulose + Papain + Pepsin + Diastase	Non-reference	3 years	05\05\2023	03\08\2023		03\08\2026	
fish oil + Borage seed oil + Flaxseed oil	Omega-3-acid ethyl esters	3 years	22\01\2023	22\04\2023		22\04\2026	
Besifloxacin (Ophthalmic)	Ofloxacin (topical use)	3 years	16\04\2024	15\07\2024		15\07\2027	
Sodium Chloride + Potassium Chloride + Sodium Lactate + Glucose Anhydrous solution for I.V Infusion	glucose (apart from glucose1-phosphate) "all routes of administration", glucose in combination with calcium chloride and/or sodium chloride and/or magnesium chloride and/or sodium citrate and/or potassium chloride (intravenous or parenteral use)"	10 years	02\09\2034	01\12\2034		01\12\2044	PSUR frequency and DLP were updated
Clobetasone + Tetrazyoline	Betamethasone / Tetrazyoline	5 years	30\09\2024	29\12\2024		29\12\2029	

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Thiamine + Pyridoxine + Nicotinamide + Cyanocobalamine + Orotic acid + D panthenol + Folic acid	Cyanocobalamin / Pyridoxine / Thiamine	13 years	01\01\2025	04\01\2025		01\04\2038	
Ferrous fumarate	iron / oral preparations	13 years	01\01\2025	01\04\2025		01\04\2038	
Lesinurad	Lesinurad from removed entries in EURD list	2 years	21\12\2023	21\03\2024		21\03\2026	
Hydroxyprogesterone	medroxyprogesterone	13 years	20\08\2025	18\11\2025		18\11\2038	
Strontium Ranelate octahydrate	Strontium Ranelate from removed entries in EURD list	5 years	21\09\2023	20\12\2023		20\12\2028	
Hydrocortisone 17-butyrate	Hydrocortisone alone (except for products indicated in adrenal insufficiency in a modified release tablet formulation) from removed entries in EURD list	5 years	31\08\2024	29\11\2024		29\11\2029	
Soya Lecithin + Ascorbic acid + Thiamine + Riboflavin +Pyridoxine HCl) + Cyanocobalamine + Nicotinamide + Zn sulphate + Selenium yeast + DL alpha tocopheryl acetate	ascorbic acid/acid folic/alpha-tocopherol/biotin/cholecalciferol / cyanocobalamin/ nicotinamide/pantothenic acid/pyridoxine hydrochloride/	8 years	22\01\2029	22\04\2029			

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	retinol/riboflavin /thiamine						
Ascorbic acid + Thiamine + Riboflavin+ Pyridoxine + Cyanocobalamine + Nicotinamide Zn sulphate + Selenium + DL alpha tocopheryl acetate + Soya Lecithin + Silymarin	ascorbic acid/acid folic/alpha-tocopherol/biotin/cholecalciferol / cyanocobalamin/ nicotinamide/pantothenic acid/pyridoxine hydrochloride/ retinol/riboflavin /thiamine	8 years	22\01\2029	22\04\2029			
Iron(III) hydroxide polymaltose complex	iron / oral preparations	13 years	01\01\2025	01\04\2025		01\04\2038	
Vit B1 + Vit B2 + Vit B6 + Vit B12 + Vit C + Vit E + Folic acid + Ferrous Fumarate + Manganese + Copper + Calcium gluconate L-hydrate	iron in combination with folic acid and other substances	13 years	01\01\2025	01\04\2025		01\04\2038	
Ibuprofen + Chlorzoxazone	ibuprofen, ibuprofen lysine (not indicated in ductus arteriosus), ibuprofen / caffeine	3 years	18\02\2023	19\05\2023		19\05\2026	
Bacitracin zinc + Neomycin sulphate + Polymyxin b sulphate + Pramoxine hydrochloride	Bacitracin zinc / Neomycin sulphate / polymyxin b sulphate	13 years	31\01\2025	01\05\2025		01\05\2038	

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Nebivolol + Valsartan	Valsartan, hydrochlorothiazide / valsartan	2 years	30\04\2023	29\07\2023	30/04/2025	29/07/2025	
L-ornithine-L-aspartate	Ornithine	13 years	01\01\2025	01\04\2025		01\04\2038	
Crisaborole	Crisaborole from removed entries in EURD list	1 year	13\06\2023	22\08\2023	13\06\2024	22\08\2024	
Mosapride	Japan only	1 year	30\01\2023	01\04\2023	30\01\2024	01\04\2024	
Vitamin A (Palmitate) + Vitamin D3 (cholecalciferol) + Vitamin B1 (Thiamine HCl) + Vitamin B2 (Riboflavin) + Vitamin B6 (Pyridoxine HCl) + Vitamin C (Ascorbic Acid) + Vitamin E Acetate + Nicotinamide + Calcium Gluconate + Ferrous Gluconate + Vitamin B12 (cyanocobalamin) + Biotin + Calcium D-Pantothenate + Sodium Selenium + Flourine	thiamine / riboflavin / pyridoxine / ascorbic acid / nicotinamide / glucose, thiamine/riboflavin/pyridoxine/ascorbic acid / nicotinamide, ascorbic acid / biotin / cyanocobalamin / folic acid / nicotinamide / pantothenic acid / pyridoxine hydrochloride / riboflavin / thiamine, riboflavin / thiamine / calcium folinate / cyanocobalamin / nicotinamide, calcium pantothenate / nicotinamide / pyridoxine / riboflavin / thiamine	10 years	27/09/2027	26/12/2027		26/12/2037	DLP UPDATED on

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Benproperine Phosphate	Non reference	1 year	13\12\2022	13\03\2023	13\12\2023	13\03\2024	
Erdafitinib	Newly authorized & FDA only	6 months	07\03\2023	16\05\2023	07\09\2023	16\11\2023	
Cibenzoline	Cibenzoline from removed entries in EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Flubendazole	Flubendazole from removed entries in EURD list	5 years	04\02\2027	05\05\2027		05\05\2032	
Levomilnacipran	Milnacipran	3 years	30\04\2024	29\07\2024		29\07\2027	
Luliconazole	ketoconazole	13 years	31\05\2025	29\08\2025		29\08\2038	
Tetramethrin + Piperonyl butoxide	Permethrin	3 years	31\08\2023	29\11\2023		29\11\2026	
Ascorbic acid + DL-alpha tocopherol acetate + Milk thistle + Sodium Selenite Pentahydrate + Vitamin A palmitate + Zinc gluconate	alphatocopherol / ascorbic acid / biotin / calcium pantothenate / colexcalciferol / cyanocobalamin / magnesium / manganese / pyridoxine / riboflavin / thiamine / vitamin a / zinc	23 years	01\01\2035	01\04\2035		01\04\2058	
Fluphenazine + Nortriptyline	Nortriptyline	5 years	31\03\2023	29\06\2023		29\06\2028	
chlorphenamine + paracetamol + pseudoephedrine + Caffeine	chlorphenamine / paracetamol / pseudoephedrine	13 years	01\01\2025	01\04\2025		01\04\2038	
Star Flower Oil + DL- tocopherol acetate	a-tocopheril, a-tocopherol, vitamin E	13 years	01\01\2025	01\04\2025		01\04\2038	

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Evening Primrose Oil + DL- tocopherol acetate	a-tocopheril, a-tocopherol, vitamin E	13 years	01\01\2025	01\04\2025		01\04\2038	
Alginic acid + Calcium carbonate	alginic acid / aluminium oxide hydrated / sodium hydrogen carbonate, alginic acid / aluminium hydroxide / calcium carbonate / sodium carbonate	13 years	01\01\2025	01\04\2025		01\04\2038	
Alginic acid + Calcium carbonate + Sodium bicarbonate	alginic acid / aluminium oxide hydrated / sodium hydrogen carbonate, alginic acid / aluminium hydroxide / calcium carbonate / sodium carbonate	13 years	01\01\2025	01\04\2025		01\04\2038	
Sodium chloride + Potassium Chloride + Disodium hydrogen citrate + Glucose (oral administration)	Glucose (apart from glucose1-phosphate) "all routes of administration", glucose in combination with calcium chloride and/or sodium chloride and/or magnesium chloride and/or sodium citrate and/or	10 years	02/09/2034	01/12/2034		01\12\2044	PSUR frequency and DLP were updated

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	potassium chloride (intravenous or parenteral use)						
Aliskiren + Amlodipine	aliskiren, aliskiren / hydrochlorothiazide	3 years	30\09\2024	29\12\2024		29\12\2027	
Ursodeoxycholic acid + Chenodexoycholic acid	Non reference	1 year	09\10\2023	18\12\2023	09\10\2024	18\12\2024	
Castor oil	Sodium picosulfate	13 years	01\10\2025	30\12\2025		30\12\2038	
Sulpiride + Mebeverine	Amisulpride	3 years	30\03\2023	28\06\2023	20\01\2026	20\04\2026	DLP UPDATED
Nifedipine + Atenolol	atenolol / nifedipine from removed entries in EURD list	12 years	02\10\2034	31\12\2034			
Methocarbamol + Diclofenac	diclofenac (systemic formulations)	3 years	30\09\2024	29\12\2024		29\12\2027	
Amoxicillin + Dicloxacillin	Non reference	1 year	25\05\2023	03\08\2023	25\05\2024	03\08\2024	
Salbutamol + Guaifenesin	levosalbutamol, salbutamol	3 years	31\01\2023	01\05\2023		01\05\2026	
Desvenlafaxine	Venlafaxine	1 year	05\05\2023	14\07\2023	05\05\2024	14/07/2024	
Ceftibuten	Ceftibuten from removed entries in EURD list	5 years	02\07\2027	30\09\2027			
METHIONINE + L-LYSINE + ISOLEUCINE + PHENYLALANINE + HISTIDINE + L-leucine + L-threonine + L-	valine / histidine / isoleucine / leucine / lysine / methionine / phenylalanine / threonine /	10 years	01\08\2028	30\10\2028		30\10\2038	

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tryptophan + Tyrosine	tyrosine / tryptophan						
Miconazole + Mometasone	Mometasone	3 years	22\05\2023	20\08\2023		20\08\2026	
Simvastatin + Sitagliptin	sitagliptin, metformin hydrochloride / sitagliptin	3 years	03\08\2023	01\11\2023		01\11\2026	
erythromycin + Sulfafurazole	erythromycin (Systemic use)	3 years	11\03\2025	09\06\2025		09\06\2028	
Azithromycin + Dexamethasone	Non reference	6 months	30\04\2023	09\07\2023	30\10\2023	08\01\2024	
Erdafitinib	Newly authorized & FDA only	6 months	11\04\2023	20\06\2023	11\10\2023	20\12\2023	
solifenacin + Mirabegron	Non reference	1 year	30\06\2024	08\09\2024	30\06\2025	08\09\2025	
finafloxacin	Ofloxacin (Topical use)	3 years	16\04\2024	15\07\2024		15\07\2027	
ambroxol + doxycycline	ambroxol + doxycycline from removed entries in the EURD list	3 years	30\09\2025	29\12\2025		29\12\2028	
Bromhexine + Salbutamol	levosalbutamol, salbutamol	3 years	31\01\2023	01\05\2023		01\05\2026	
Salbutamol + Guaifenesin	Salbutamol + Guaifenesin from removed entries in the EURD list	3 years	31\01\2023	01\05\2023		01\05\2026	
aescin + Diethylsalicylate	diethylamine-salicylate / escin	13 years	01\01\2025	01\04\2025		01\04\2038	
Ezogabine	Retigabine from removed entries in EURD list	1 year	28\09\2023	07\12\2023	28\09\2024	07\12\2024	
N-acetylcystine	Acetylcysteine	5 years	13\09\2023	12\12\2023		12\12\2028	

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Betamethasone valerate + Neomycin Sulphate	betamethasone sodium phosphate / neomycin sulfate	9 years	01\01\2030	01\04\2030		01\04\2039	
Tobramycin + loteprednol etabonate	tobramycin (ophthalmic and otic use)	5 years	31\03\2026	29\06\2026		29\06\2031	
Pimavanserin	quetiapine	3 years	31\07\2023	29\10\2023		29\10\2026	
Sodium Chloride + Sodium Bicarbonate + Borax + L-menthol	Sodium Chloride	13 years	24\11\2025	22\02\2026		22\02\2039	
Calcium acetate + magnesium carbonate	Calcium Carbonate / magnesium carbonate from removed entries in the EURD list	13 years	01\01\2025	01\04\2025		01\04\2038	
Aluminium hydroxide + Magnesium hydroxide	Aluminium hydroxide gel / Dimeticone / Magnesium hydroxide	13 years	01\01\2025	01\04\2025		01\04\2038	
Guaifenesin + Paracetamol + Oxomemazine + Sodium benzoate	oxomemazine	13 years	11\03\2025	09\06\2025		09\06\2038	
Azintamide + Pancreatin + Hemicellulase	pancreatic enzymes, pancreatic extracts, pancreatin (except for the centrally authorised product)	13 years	16\10\2025	14\01\2026		14\01\2039	
Paracetamol + Dextromethorphan Hydrobromide +	dextromethorphan / paracetamol / phenylephrine	13 years	01\01\2025	01\04\2025		01\04\2038	

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Phenylephrine Hydrochloride Chlorpheniramine Maleate							
Bepotastine	epinastine	5 years	31/10/2027	29/01/2028		29\01\2033	
Caffeine + Ergotamine + Paracetamol + Metoclopramide	Paracetamol (Non IV formulations)	13 years	21\12\2025	21\03\2026		21\03\2039	
Allantoin + Onion extract + Heparin	Heparin	13 years	31\03\2025	29\06\2025		29\06\2038	
Silymarin + Acetylcysteine	Acetylcysteine	5 years	13\09\2023	12\12\2023		12\12\2028	
Chlorpheniramine maleate + Ibuprofen + Pseudoephedrine	Ibuprofen / Pseudoephedrine	1 year	18\07\2023	26\09\2023	18/07/2024	26/09/2024	
Paracetamol + Pamabrom + Pyrilamine	Paracetamol (Non IV formulations)	13 years	21\12\2025	21\03\2026		21\03\2039	
tretinoin + Fluocinolone + Hydroquinone + Euselex oil (Topical)	Tretinoin (topical formulations)	5 years	30\03\2027	28\06\2027		29\11\2032	
Benfotiamine + Pyridoxine + Cyanocobalamin	cyanocobalamin / pyridoxine / thiamine	13 years	01\01\2025	01\04\2025		01\04\2038	
thioctic acid + benfotiamine + Cyanocobalamin	thioctic acid	13 years	01\01\2025	01\04\2025		01\04\2038	
Salicylic acid + Urea	lactic acid / urea, urea	13 years	30\04\2025	29\07\2025		29\07\2038	
Guaiphenesin + Dextromethorphan + Pseudoephedrine + Chlorpheniramine	chlorpheniramine / dextromethorphan / paracetamol	13 years	16\12\2025	16\03\2026		16\03\2039	

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	/ pseudoephedrine						
Halfabar extract + methenamine	methenamine	13 years	02\08\2025	31\10\2025		31\10\2038	
D-Phenothrin	Permethrin	3 years	31\08\2023	29\11\2023		29\11\2026	
Suvorexant	Daridorexant	6 months	06/01/2023	17/03/2023	06\07\2023	14/09/2023	
Glycopyrronium bromide (indicated for chronic obstructive pulmonary disease)	glycopyrronium bromide (for centrally authorised product indicated for chronic obstructive pulmonary disease)	5 years	28\09\2027	27\12\2027		27\12\2032	
Oleoresin capsicum + Camphor + Menthol + Methyl salicylate + Oil of camphor	methyl salicylate, menthol / methyl salicylate, menthol / methyl salicylate / camphor, methyl salicylate/ camphor, methyl salicylate / menthol / camphor / tocopherol, methyl salicylate / camphor / menthol / turpentine (essence, oil), methyl salicylate / menthol / camphor / hydroxyethyl salicylate, methyl salicylate / menthol /	5 years	20\04\2027	19\07\2027		19\07\2032	

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	camphor / hydroxyethyl salicylate / benzyl nicotinate						
Thiamine + Pyridoxine + Riboflavin Calcium pantothenate +Tocopherol acetate Saccharomyces cerevisiae + L- cystine + Keratin + P-amino benzoic acid + D-biotin	calcium pantothenate / cystine / keratin / p-aminobenzoic acid / thiamine / yeast	13 years	01\01\2025	01\04\2025		01\04\2038	
Collagenase Clostridiopeptidase A	collagenase clostridium histolyticum (all indications except for treatment of Dupuytren's contracture and Peyronie's disease) (From removed entries in the EURD list)	3 years	31\12\2025	31\03\2026		31\03\2029	
Chlorpheniramine + Acetylcysteine	Acetylcysteine	5 years	13\09\2023	12\12\2023		12\12\2028	

Colour Refers to

Blue	Recently added active ingredients & active ingredient combinations
Yellow	PSUR Frequency and DLP updated
Orange	PSUR Frequency updated
Green	DLP UPDATED