

Active Ingredient	Suggested Reference From EURD list	PSUR submission Frequency	DLP	Submission date	Next DLP	Next submission date
Lubiprostone	Previously listed in the EURD list	1 year	8/29/2022	11/7/2022	8/29/2023	11/7/2023
Colestimide	Colesevelam	3 years	3/10/2021	6/8/2021		
Daclatasvir	Sofosbuvir	1 year	12/5/2022	2/13/2023		
Limaprost	Previously listed in the EURD list	13 years	1/1/2025	4/1/2025		
Mitiglinide	Previously listed in the EURD list	13 years	1/1/2025	4/1/2025		
Dalfampridine	Fampridine	3 years	1/21/2023	4/21/2023		
Omeprazole + Sodium bi-carbonate	Omeprazole	5 years	4/15/2022	7/14/2022		
Bupivacaine Hydrochloride + Fentanyl (injection)	Fentanyl (transdermal patches, solution for injection -nationally authorised product only)	3 years	4/30/2022	7/29/2022		
Edaravone	Japan only	1 year	12/12/2022	3/12/2023		
Loxoprofen	Ibuprofen	3 years	2/18/2023	5/19/2023		
Vilazodone	Trazodone	13 years	10/15/2025	1/13/2026		
Gentamicin + Miconazole + Mometasone	Mometasone	3 years	5/22/2023	8/20/2023		
Finerenone	Spirololactone	3 years	3/8/2024	6/6/2024		
Moxifloxacin HCL+ Dexamethasone (Ophthalmic)	Levofloxacin + Dexamethasone (ocular use)	1 year	6/12/2022	8/21/2022	6/12/2023	8/21/2023
Alcaftadine (Ophthalmic)	As the Innovator + FDA only	1 year	7/27/2022	10/5/2022	7/27/2023	10/5/2023

Carboxymethyl Cellulose + Glycerin (Ophthalmic)	Carmellose (eye preparation)	13 years	11/30/2025	2/28/2026		
Dexamethasone + Chlorpheniramine	Dexamethasone + Diphenhydramine hydrochloride	13 years	1/1/2025	4/1/2025		
Gatifloxacin sesquihydrate (Ophthalmic)	Ofloxacin (Topical use)	3 years	4/16/2024	7/15/2024		
Gemifloxacin	Levofloxacin (intravenous and oral use)	3 years	10/1/2023	12/30/2023		
Minodronic acid	Risedronate (Japan only)	1 year	5/1/2022	7/10/2022		
Rebamipide	Previously listed in the EURD list	13 years	1/1/2025	4/1/2025		
Guaifenesin + Oxememazine + Carbocisteine	Carbocisteine	13 years	9/14/2025	12/13/2025		
Butenafine	Terbinafine	5 years	9/30/2022	12/29/2022		
Retigabine	Previously listed in the EURD list	1 year	9/28/2021	12/7/2021	9/28/2023	12/7/2023
Ferrous sulphate + Folic acid + Riboflavine + Pyridoxine HCl + Zinc sulfate + Nicotinamide + Ascorbic acid +Thiamine	Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine	10 years	9/27/2027	12/26/2027		
Neomycin sulfate + Nystatin + Triamcinolone acetonide + Gramicidin	Neomycin sulfate + Nystatin + Triamcinolone acetonide	13 years	1/1/2025	4/1/2025		
Aluminium hydroxide gel + Magnesium hydroxide + Oxethazaine	Aluminium hydroxide gel + Dimeticone + Magnesium hydroxide	13 years	1/1/2025	4/1/2025		

Glycerin + Carboxymethylcellulose + Sodium Hyaluronate	Glycerol	13 years	1/1/2025	4/1/2025		
Ascorbic acid + Zinc	Ascorbic acid	13 years	2/25/2025	5/26/2025		
Pipazethate	Non reference	1 year	5/1/2022	7/10/2022	5/1/2023	7/10/2023
Dexamethasone phosphate + Moxifloxacin	Moxifloxacin (Ophthalmic)	5 years	5/31/2026	8/29/2026		
Favipravir	Remdesivir	6 months	5/6/2022	7/15/2022	11/6/2022	1/15/2023
Artesunate + Sulfamethoxypyrazine + Pyrimethamine	Artesunate	6 months	6/22/2022	8/31/2022	12/22/2022	3/2/2023
Daclatasvir	Sofosbuvir	1 year	12/5/2022	2/13/2023		
Naphazoline HCL + Pheniramine maleate	Naphazoline	12 years	7/31/2024	10/29/2024		
Sulphamethoxazole + Trimethoprim + light Kaolin + Pectin	Sulphamethoxazole + Trimethoprim	8 years	3/31/2027	6/29/2027		
Aluminium hydroxide gel + Magnesium hydroxide + Simeticone	Aluminium oxide + Magnesium hydroxide + Simeticone	13 years	1/1/2025	4/1/2025		
Ethanolamine Oleic acid	Ethanolamine	13 years	1/1/2025	4/1/2025		
Metformin Hydrochloride + Repaglinide	Metformin	3 years	1/4/2024	6/30/2024		
Paracetamol + Pseudoephedrine + Diphenhydramine	Paracetamol + Pseudoephedrine + Chlorpheniramine	13 years	1/1/2025	4/1/2025		
Metoclopramide + Pyridoxine	Metoclopramide	3 years	11/17/2024	2/15/2025		

Levodopa + Entacapone	Carbidopa + Entacapone + levodopa	3 years	10/7/2024	1/15/2025		
Pemirolast	Japan only	1 year	4/30/2022	7/29/2022	4/30/2023	7/29/2023
Tolmetin sodium	Aceclofenac	3 years	3/31/2023	6/29/2023		
Sulfacetamide + Prednisolone	Prednisolone	13 years	7/13/2025	10/11/2025		
Eperisone	Tolperisone	3 years	6/1/2022	8/30/2022		
Phenylephrine Hydrochloride + Hypromellose (Ophthalmic Solution)	Phenylephrine (Ophthalmic formulations)	5 years	1/1/2025	4/1/2025		
Carbazochrome + Troxerutin	Carbazochrome	13 years	3/19/2025	6/17/2025		
Meclofenoxate	Japan only	1 year	4/30/2022	7/9/2022	4/30/2023	7/9/2023
Loratidine + Paracetamol + Pseudoephedrine	Paracetamol + Pseudoephedrine	5 years	6/28/2023	9/26/2023		
Ursodeoxycholic acid + Silymarin	Ursodeoxycholic acid, tauroursodeoxycholic acid	10 years	11/30/2026	2/28/2027		
Nitazoxanide	FDA only	1 year	7/29/2022	10/7/2022	7/29/2023	10/7/2023
Imeglimin Hydrochloride	Japan only	1 year	4/30/2022	7/9/2022	4/30/2023	7/9/2023
Molnupiravir	Newly authorized	6 months	6/18/2022	8/27/2022	12/17/2022	2/25/2023
Vitamin B1 + Vitamin B2 + Vitamin B6 + Nicotinamide + Dexpantenol	Caffeine + Dexpantenol+ Nicotinamide + Pyridoxine + Riboflavine + Thiamin	13 years	1/1/2025	4/1/2025		
Vitamin B1 + Vitamin B2 + Vitamin B6 + Vitamin B12 + Nicotinamide + Calcium D-pantothenate + Ascorbic acid + Folic acid +	Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine	10 years	9/27/2027	12/26/2027		

Calcium phosphate + Ferrous sulphate + Potassium Iodide + Manganese sulphate + Potassium sulphate + Zinc sulphate						
Guaifensine + Terpine + cineol + sodium benzoate	Guaifensine + herbal extract	13 years	1/1/2025	4/1/2025		
Cefdinir	Cefotaxime	3 years	12/18/2024	3/18/2025		
Sodium Chloride + Sodium Bicarbonate + Borax	Sodium Chloride	13 years	11/24/2025	2/22/2026		
Benzoic acid + Salicylic acid (Topical)	Salicylic acid (Topical use)	13 years	4/25/2025	7/24/2025		
Paracetamol + Pamabrom	Paracetamol + Orphenadrine citrate	13 years	1/1/2025	4/1/2025		
Chlorphenoxamine hydrochloride + Caffeine	Chlorphenoxamine hydrochloride	5 years	5/17/2023	8/15/2023		
Phenylephrine Hydrochloride + Cyclopentolate Hydrochloride (Ophthalmic Solution)	Phenylephrine Hydrochloride (Ophthalmic)	5 years	1/1/2025	4/1/2025		
Amoxicillin + Flucloxacillin	Amoxicillin	5 years	3/7/2022	6/5/2022		
Vonoprazan	Japan only	1 year	8/23/2022	11/1/2022	8/23/2023	11/1/2023
Doripenem	Meropenem	13 years	8/31/2034	11/29/2034		
Armodafinil	Modafinil	1 year	8/31/2021	11/9/2021	8/31/2023	11/9/2023
Clidinium Bromide + Chlordiazepoxide	Acridinium Bromide	1 year	7/20/2022	9/28/2022	7/20/2023	9/28/2023

Oxytetracycline hydrochloride + Polymyxin b	Hydrocortisone acetate + Oxytetracycline hydrochloride + Polymyxin b	13 years	1/1/2025	4/1/2025		
Telmisartan + Amlodipine + Hydrochlorothiazide	Olmesartan + Amlodipine + Hydrochlorothiazide	5 years	4/24/2022	7/23/2022		
Chlorzoxazone + Paracetamol	Chlorzoxazone	13 years	6/28/2025	9/26/2025		
Silver sulfadiazine + Chlorhexidine Digluconate	Silver sulfadiazine	5 years	9/15/2025	12/14/2025		
Dexpanthenol + Dexamethasone	Dexpanthenol + Hydrocortisone	13 years	1/1/2025	4/1/2025		
Dextromethorphan + Chlorpheniramine	Dextromethorphan	3 years	11/1/2024	1/30/2025		
Diloxanide + Metronidazole	Non reference	1 year	10/25/2022	1/3/2023		
Cyanocobalamin - Tannin complex in Aluminium monostearate	Cyanocobalamin	13 years	2/22/2025	5/23/2025		
Magnesium hydroxide + Light Liquid Paraffin	Magnesium hydroxide	5 years	10/31/2026	1/29/2027		
Nonoxynol-9	Non reference	1 year	5/1/2022	7/10/2022	5/1/2023	7/10/2023
Revefenacin	Acridinium bromide	1 year	7/20/2022	9/28/2022	7/20/2023	9/28/2023
Clofedanol	Pentoxyverine	5 years	12/31/2023	3/30/2024		
Paracetamol + Guaifenesin + Phenylephrine + Dextromethorphan	Dextromethorphan + Paracetamol + Phenylephrine	13 years	1/1/2025	4/1/2025		
Chloramphenicol + Dexamethasone + Tetryzoline	Dexamethasone (Apart from centrally authorized products)	5 years	1/31/2026	5/1/2026		

Fluorometholone + Tetrahydrozoline	Fluorometholone	13 years	7/31/2025	10/29/2025		
Difluprednate	Prednisolone	13 years	7/13/2025	10/11/2025		
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	1/1/2025	4/1/2025		
Sodium Chloride + 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	1/1/2023	4/1/2023		
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	1/1/2023	4/1/2023		

Carvedilol + Hydrochlorothiazide	Carvedilol	5 years	4/17/2027	7/16/2027		
Hydroquinone +Tretinoin + Hydrocortisone	Tretinoin (topical formulations)	5 years	8/31/2022	11/29/2022		
Guaiacol + Pholcodine		1 year	5/29/2023	8/27/2023		
Ofloxacin + Dexamethasone	Levofloxacin + Dexamethasone (ocular use)	1 year	6/12/2022	8/21/2023		
Tadalafil + finasteride	FDA only	1 year	8/31/2023	11/9/2023		
Terconazole	Terconazole from removed entries in EURD list	13 years	1/1/2025	4/1/2025		
Chlorzoxazone + Ketoprofen	ketoprofen (all formulations except topical)	5 years	1/23/2027	4/23/2027		
Povidone Iodine+ Sucrose	Povidone Iodine	13 years	4/24/2025	7/23/2025		
Acetylleucine	Acetylleucine from removed entries in EURD list	13 years	1/1/2025	4/1/2025		
Isotretinoin (Topical)	tretinoin (Topical formulations)	5 years	8/31/2022	11/29/2022		
Mometasone furoate + Formoterol	Mometasone	3 years	5/22/2023	8/20/2023		
Doxercalciferol	Doxercalciferol from removed entries in EURD list	13 years	1/1/2025	4/1/2025		
Paracetamol + Pseudoephedrine + Guaifenesin	Non reference	1 year	9/9/2023	11/18/2023		
Retapamulin	Retapamulin from removed entries in EURD list	3 years	4/11/2023	7/10/2023		
Flibanserin	FDA only	1 year	9/9/2023	11/18/2023		
Ibuprofen + Methocarbamol	Ibuprofen	3 years	2/18/2023	5/19/2023		
Beta - Sitosterol	Phytosterol	13 years	1/1/2025	4/1/2025		

Cefotetan Disodium	Second Generation Cephalosporins (cefprozil)	5 years	12/22/2022	3/22/2023		
Acephylline piperazine	Pharmacovigilance committee decision	1 year	9/30/2022	12/9/2022	9/30/2023	12/9/2023
Atenolol + Amiloride + Chlorthalidone	Atenolol + Chlorthalidone	5 years	9/9/2024	12/8/2024		
Metaxalone	Metaxalone from removed entries in EURD list	13 years	1/1/2025	4/1/2025		
Amylocaine Hydrochloride + Benzocaine + Hamamelis Dry Extract (5% Tannines) + Zinc Oxide + Aesculus Dry Extract	Non reference	1 year	10/15/2023	12/24/2023		
Selenium + Manganese Sulphate monohydrate + Vit.E + Vit.C + Beta Carotene + Zinc Sulphate monohydrate + Cu Sulphate Monohydrate	Selenium	13 years	1/1/2025	4/1/2025		
Vit.B1 + Vit.B2 + Vit.B6 + Folic acid + Calcium D Pantothenate + Vit.C + Zinc Vit.B12 + Nicotinamide + Biotin + L-Carnitine	Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine	10 years	9/27/2027	12/26/2027		
Acetylsalicylic acid + Magnesium carbonate + Aluminium glycinate	Japan only	2 years	2/1/2023	5/2/2023		
Theophylline + Ambroxol + Guaiphenesin	Non reference	1 year	1/30/2023	4/1/2023		

Tetrahydrozoline (Tetryzoline) + Zinc Sulphate	Tetryzoline	13 years	1/1/2025	4/1/2025		
Terbutaline + Bromohexine HCL + Guaiphenesin + Menthol	Bromhexine	3 years	9/30/2023	12/29/2023		
Bromhexine + Guaifenesin + Salbutamol	Salbutamol	3 years	1/31/2023	5/1/2023		
Tiemonium Methyl Sulphate	Pharmacovigilance committee decision	5 years	2/1/2023	5/2/2023		
Magnesium oxide +Magnesium Gluconate	Magnesium oxide	13 years	6/30/2025	9/28/2025		
Natural calcium carbonate from oyster shell eq.to calcium + Vitamin D3+ Sodium fluoride	Sodium fluoride	3 years	11/13/2022	2/11/2023		
Lignocaine HCL + Clove oil + Geranium oil	lidocaine (topical use)	8 years	9/30/2028	12/29/2028		
L-Carnitine l-tartrate + Zinc gluconate	Carnitine	13 years	9/1/2025	11/30/2025		
Biotin + Alpha lipoic acid	Biotin	7 years	1/1/2026	4/1/2026		
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	1/1/2025	4/1/2025		
Keto analogues + Amino acids	Amino acid combinations (only combinations of pure amino acids or	7 years	1/1/2026	4/1/2026		

	combination of amino acids with mineral compounds/electrolytes, i.v. application)					
Magnesium carbonate + Citric acid	Citric acid + magnesium + sodium, citric acid anhydrous + light magnesium oxide + sodium picosulfate	13 years	1/1/2025	4/1/2025		
Codeine + Pseudoephedrine + Triprolidine	Pseudoephedrine + Triprolidine	3 years	12/31/2023	3/30/2024		
Brompheniramine maleate + Paracetamol + Pseudoephedrine Hydrochloride	Chlorpheniramine maleate + Paracetamol + Pseudoephedrine Hydrochloride	13 years	2/28/2029	5/29/2029		
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)	13 years	3/22/2025	6/20/2025		
Diosmin + Hesperidin + Ascorbic acid	Diosmin / hesperidin, ascorbic acid/ dry Ruscus extract titrated in sterolic heterosides/ Hesperidin methyl chalcone	13 years	1/1/2025	4/1/2025		
Cefopeazone	Pharmacovigilance committee decision	3 years	1/11/2024	4/11/2024		
Cefopeazone + Sulbactam	Pharmacovigilance committee decision	3 years	1/11/2024	4/11/2024		
Calcium Carbonate + Glycine + Dimethicone	Calcium carbonate/magnesium carbonate/simeticone	3 years	1/1/2029	4/1/2029		
Heptaminol HCl	Heptaminol HCl from removed entries in EURD list	13 years	1/28/2025	4/28/2025		

Hemicellulose + Papain + Pepsin + Diastase	Non reference	3 years	5/5/2023	8/3/2023		
fish oil + Borage seed oil + Flaxseed oil	Omega-3-acid ethyl esters	3 years	1/22/2023	4/22/2023		
Besifloxacin (Ophthalmic)	Ofloxacin (topical use)	3 years	4/16/2024	7/15/2024		
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)"	13 years	3/22/2025	6/20/2025		
Clobetasone + Tetryzoline	Betamethasone & Tetryzoline	5 years	9/30/2024	12/29/2024		
Thiamine + Pyridoxine + Nicotinamide + Cyanocobalamin + Orotic acid + D panthenol + Folic acid	Cyanocobalamin / Pyridoxine / Thiamine	13 years	1/1/2025	1/4/2025		
Ferrous fumarate	iron / oral preparations	13 years	1/1/2025	4/1/2025		
Lesinurad	Lesinurad from removed entries in EURD list	2 years	12/21/2023	3/21/2024		
Hydroxyprogesterone	medroxyprogesterone	13 years	8/20/2025	11/18/2025		
Strontium Ranelate octahydrate	Strontium Ranelate from removed entries in EURD list	5 years	9/21/2023	12/20/2023		
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	8/31/2024	11/29/2024		

Tretinoin + Fluocinolone + Hydroquinone	tretinoin (oral formulations)	5 years	8/31/2023	11/29/2023		
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/ retinol/riboflavin/thiamine	8 years	1/22/2029	4/22/2029		
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	1/22/2029	4/22/2029		
Iron(III) hydroxide polymaltose complex	iron / oral preparations	13 years	1/1/2025	4/1/2025		
Vit B1 + Vit B2 + Vit B6 + Vit B12 + Vit C + Vit E + Folic acid + Ferrous Fumarate + Mangenes + Copper + Calcium gluconate L- hydrate	iron in combination with folic acid and other substances	13 years	1/1/2025	4/1/2025		
Ibuprofen + Chlorzoxazone	Ibuprofen	3 years	2/18/2023	5/19/2023		
Bacitracin zinc + Neomycin sulphate + Polymyxin b sulphate +	Bacitracin zinc/Neomycin sulphate/polymyxin b sulphate	13 years	1/31/2025	5/31/2025		

Pramoxine hydrochloride						
Nebivolol + Valsartan	Valsartan	2 years	4/30/2023	7/29/2023		
l-ornithine-l-aspartate	Ornithine	13 years	1/1/2025	4/1/2025		
Crisaborole	Crisaborole from removed entries in EURD list	1 year	6/13/2023	8/22/2023		
Mosapride	Japan only	1 year	1/30/2023	4/1/2023		
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	9/27/2029	12/26/2029		
Benproperine Phosphate	Non reference	1 year	12/13/2022	3/13/2023		

Color

Blue	Recently added active ingredients & active ingredient combinations
Red	Frequency & dates changed from previous list